Evaluation of factors affecting the exposure indicator of computed radiography and how it relates to radiation organ dose at a second level hospital in Zambia.

by

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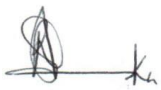
Declaration

I, Ricky Siasendeka, hereby declare that the contents of this thesis represent my own unaided work, and that the thesis has not previously been submitted for academic examination towards any qualification. Furthermore, the views expressed within this thesis are those of the author and do not represent the views of the Cape Peninsula University of Technology.

Signed:  **Date:** 10 February 2023

Dedications

To:

My lovely wife, Brenda, for her support, motivation and desire to see her husband advance in his studies.

She has been through sacrifices and times of loneliness brought about by her husband's busy schedules during the period of study.

My son Shoma, on whose time I was privileged to pursue this work. He had to put up with a non-participating father at times…

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LIST OF ABBREVIATIONS

AAPM	American Association of Physicists in Medicine
AEC	Automatic exposure control
AEG	Allgemeine Electric Gesellschaft
Al	Aluminium
ALARA	As low as reasonably achievable
AP	Antero-posterior
CD	Computer disc
CR	Computed Radiography
CSO	Central Statistical Office
CT	Computerised Tomography
DR	Digital Radiography
DVD	Digital video disc
ED	Effective dose
EI	Exposure Index
ESE	Entrance skin exposure
ESD	Entrance skin dose
FFD	Film Focus Distance
FSR	Film-Screen Radiography
FSD	Focal Spot to Skin Distance
Gy	Gray
HPCZ	Health Professions Council of Zambia
HRDC	Human Resource Development Committee
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
IEC	International Electro-Technical Commission
IP	Imaging plate
IQR	Inter quartile range
IR	Image receptor
JMP	John's Macintosh Project
kVp	Kilo-volts peak
LET	Linear energy transfer
mA	Milli-amperage
mAs	Milli-amperage per second
mGy	Milli-Gray
RS	Research Site
MRI	Magnetic Resonance Imaging
MREI	Manufacturer-recommended exposure index
MRR	Manufacturers recommended range
mSv	Milli-Sievert
NRC	National Research Council
OPD	Out-patient Department
PA	Postero-anterior
PACS	Picture Archiving and Communication System
PCXMC	Personal Computer program for X-ray Monte Carlo

PhD	Doctor of Philosophy
PSL	Photo stimulated luminescence
PSP	Photostimulable storage phosphor
RBE	Relative-Biological-Effectiveness
RIR	Relevant image region
RPA	Radiation Protection Authority
RSNA	Radiological Society of North America
S	Sensitivity number
SAMRC	South African Medical Research Council
SD	Standard deviation
SID	Source-to-image receptor distance
SNR	Signal to noise ratio
SPSS	Statistical Package for the Social Sciences
SSD	Source-skin distance
Sv	Sievert
TLD	Thermo luminescent dosimeters
UNSCEAR	United Nations Scientific Committee on the Effects of Atomic Radiation
UNZA	University of Zambia
UTH	University Teaching Hospital
WHO	World Health Organisation
WMA	World Medical Association

ABSTRACT

Introduction

The main purpose of conducting this research study was to evaluate if there was any significance in the difference between the Exposure Index (EI) of the postero-anterior (PA) chest, antero-posterior (AP) pelvis and lateral lumbar spine views obtained with a Computed Radiography (CR) system for patients referred for conventional diagnostic imaging and the manufacturer's standard/recommended EI. Secondly the factors affecting EI in the application of CR at a second level hospital in Zambia were also explored, and lastly, to understand the relationship that exists between EIs and radiation dose imparted to the patient.

Methods

A sample of 334 patients referred for conventional diagnostic imaging of the PA chest, AP pelvis, and that of the lateral lumbar spine views were enrolled in the study. These patients underwent an X-ray examination on a Fuji CR system. Radiographers were asked to record data for each patient. Data that was collected prospectively included exposure factors such as kilo-voltage peak (kVp) and milli-amperage per second (mAs). The other data collected included parameters such as source-skin distance (SSD), focal spot to skin distance (FSD), filtration, field size, anode angulation and exposure index. In addition, the patient's height as well as weight, the date and time of the radiographic examination were also recorded. The radiation quantity and the entrance skin exposure (ESE) of the PA chest, AP pelvis and the lateral lumbar spine, using exposure technique factors (mAs and kVp) was calculated using the Personal Computer Program for X-ray Monte Carlo (PCXMC). A total of 334 images were later on recorded (114 for PA chest, 107 AP pelvis and 113 lateral lumbar spine respectively) using the dose values alluded to above and recording the reciprocal EIs. The EI generated by the Fuji CR system is denoted as a sensitivity ("*S*") value.

The study of dose optimisation was associated with measuring the ESE [and changing it to entrance skin dose (ESD)] of a free-in-air to an anthropomorphic phantom model of the pelvis and lumbar spine, using the vendor's approved exposure factors (kVp and mAs) and dose values higher and lower than the vendor's values (reference dose) for each of the selected body parts. Later on, Fifty-four images (27 for each of the AP pelvis and lateral lumbar spine) were recorded using the dose values referred to above and recording the matching EIs.

Results

The results indicated that there was a notable difference in EI between examinations of the PA chest, pelvis and lateral lumbar examinations using a *p*-value which was < 0.05. There was a notable difference between the average EI generated by radiographers at the research site and the recommended EI value for the lateral lumbar spine.

The findings from the study also revealed that gender did not have a significant influence on EI – for all three views namely PA chest, AP pelvis and lateral lumbar spine. Similarly, time of examination did not have a significant influence on EI for all three examinations.

None of the following variables (kVp, mAs, height and weight) had a significant correlation with EI – in the lumbar spine area. None of the factors and co-variates (patient sex, age, time of examination, kVp, mAs, height and weight) had a significant influence on the EI. There was no notable relationship between effective dose and the EI in the lateral lumbar spine and PA chest examinations, however, there was a notable relationship between effective dose and the EI in the pelvis examinations.

Conclusion

The study revealed that radiation dose to the testicles and ovaries was higher when examining dose of the AP pelvis and lateral lumbar spine views compared to when examining the chest. As regards the uterus, dose was only higher when examining the pelvis compared to when examining the lumbar and chest. The lowest EI generated by the radiographer for the PA chest was 53 and the highest being 540 against the manufacturer approved EI range of 200 – 600. The lowest EI generated for the AP pelvis was 45 and the highest was 417 against the manufacturer recommended range of 200 – 400. For the lateral lumbar spine, the highest EI was 419 and the lowest was 35 against the manufacturer recommended range of 200 – 400. Generally, results of the study indicated that a significant difference existed between the average radiographer EI and the manufacturer approved EI value for the lateral lumbar spine and AP pelvis. Secondly, there was no notable relationship between effective dose and radiographer's EI in the lateral lumbar and PA chest examinations. However, a notable relationship existed between effective dose and EI in the pelvis examination.

CHAPTER 1

INTRODUCTION

THE NATURE AND SCOPE OF THE STUDY

1.1 Chapter Introduction

With the advancement in radiography technology, diagnostic imaging equipment has new ways of assessing exposure adequacy used by radiographers for conventional diagnostic examinations. One commonly used system is the Exposure Indicator (EI). The EI is a measure of the quantity of radiation exposure reaching the Image Receptor (IR). EI relies on milli-amperage per second (mAs), total irradiated area on the detector, and attenuation of the beam (Willis, 2002). EI is obtained from the mean detector entrance exposure which is in succession obtained from the mean pixel value of the image. A number of factors may influence the EI such as patient size, collimation, X-ray beam centring to the Computed Radiography (CR) imaging plate (IP), source-to-image receptor distance (SID) together with exposure technique factors such as kilo-volt peak (kVp) and mAs (Davidson & Sim, 2008; Willis, 2002). Despite the fact that EI is always obtained from the IR exposure, X-ray equipment manufacturers calculate the numeric value variously, leading to different ranges and definitions (Tompe & Sargar, 2023).

The sensitivity value (*S*) used by Fuji is based on the amount of amplification needed by the photomultiplier tube to alter the digital image. The *S* is inversely proportional to exposure. If the exposure increases, the Fuji *S* value decreases, as such the radiographer must have all the knowledge and understanding of the CR system they use (Agustin, 2013). Therefore, the EI serves to inform the radiographer as to the sufficiency of their exposure, similar to what film density did for conventional radiography. The absorption efficacy of the photo-stimulable phosphor material used in the CR cassettes decreases with increasing kVp (Khotle et al., 2009).

Studies have shown an association between exposure to low-dose, ionizing radiation and certain cancers and leukemia (National Research Council (NRC), 2006). Persons in danger of recurrent exposure to radiation, such as professionals in health care are regularly monitored and limited to effective doses of 100 milli-sievert (mSv) every five years (meaning 20 mSv per annum), with 50 mSv permitted per year (Wrixon, 2008). In contrast, exposure to radiation in patients who undergo medical imaging studies is not usually monitored, despite certain imaging procedures being repeated for some patients (International commission on radiation protection (ICRP) Publication 103, 2007; Wrixon, 2008).

Therefore, it is a requirement for radiographers to optimise protection of patients from radiation, according to the As Low As Reasonably Achievable (ALARA) principle developed by the ICRP. This principle require that images of patients be acquired with the lowest probable radiation dose without jeopardising diagnostic imaging quality (ICRP Publication 103, 2007).

The three principles on which radiation protection is based on are that of justification of exposure, using the lowest possible radiation dose at as low as reasonably attainable dose (optimisation) and dose limitation. The ICRP oversees the development of these fundamental principles. Justification refers to the concept of a radiation exposure performing more good than harm, optimisation is essential to ensure that the proper diagnostic image quality is achieved at a dose that is as low as reasonably achievable (Faulkner et al., 2005; Smans et al., 2010).

From 1959 when the ICRP began to advocate for the above-mentioned principles, the optimisation principle has been used in diagnostic radiology to advancement to the current technology. This imply that optimisation has been used in film-screen radiography (FSR), and now the evolution to CR and digital radiography (DR) enable new opportunities for optimisation research in radiology (ICRP, 2004; Matthews & Brennan, 2008; Mattsson, 2005; Smans et al., 2010).

As will be seen later in this thesis, the principle of optimisation was key to this study which among other objectives sought to investigate the relationship between the EI generated by radiographers and radiation dose. The resolve of this study was to explore the application of diagnostic medical imaging technologies that use X-rays to generate diagnostic images of patients. This was achieved by evaluating factors affecting EI in the application of a CR system at a second level hospital in Zambia (study site) and the association between EIs and dose to the patient. The research site chosen was ideal because it allowed a wide range of examinations including those that formed the focus of this study. Further, the researcher was an employee at this hospital and was very much acquainted with the hospital setting and operational requirements.

1.2 Background

Wilhelm Roentgen discovered X-rays on November 8, 1895 at Wurzburg University in Germany. In 1896 Roentgen produced an image of the hand of his wife (Knoll, 2010; Stabin, 2007). The use of radiographic imaging as a tool for diagnosis in medicine has been in existence for over one hundred years now since Roentgen discovered X-rays in 1895. This remarkable technical development progressed into Diagnostic Radiography, which at first used an X-ray sensitive film and later progressed into use of film-screen

image receptor where an X-ray sensitive film is placed in between two intensifying screens. Using this receptor to image a patient is referred to as FSR which has successfully been used as a diagnostic tool for over a century (Sprawls, 1995).

1.3 Shortcomings of film-screen Radiography

Imaging a patient using FSR, occurs where X-rays traverse through a patient and would fall on the intensifying screens which are then transformed into light which successively formed a latent image on the conventional film. Exposed radiographs that contain a latent image would be processed using chemicals to make the image visible (Serman, 2000).

Several problems have been observed with FSR. Poor image quality is one of the major problems of FSR if the correct radiation exposure has not been used. For example, if the radiation exposure selected is too high, the processed image of this overexposed film appears too dark making it a suboptimal image for diagnoses. On the other hand, if the radiation exposure made to the film is too low, the processed image is underexposed and appears too light compromising an adequate diagnosis. In both of these circumstances, the images produced lack the right image contrast and density and often have to be repeated in order to make a diagnosis. The patients would be exposed to high radiation doses due to the frequent exposures. Therefore, it is important for the radiographer to be very precise when selecting exposure factors for the anatomical part under investigation (Bushong, 2013; Seeram, 2011).

The other problem with FSR is that the archiving medium is usually by keeping the film in envelopes which are stored in a large room within the hospital radiology department. This method of film storage involves manual handling for archiving and retrieval of such images (Seeram, 2011). These hard copy images are at times difficult to retrieve if filed incorrectly in the wrong patient's imaging file or in the incorrect numerical or alphabetical order (Speelman, 2022[1]). Furthermore, since with FSR the latent image is made visible through chemical processing as mentioned at the beginning of this section, inadequate processing can result in fading of the radiograph over time (Serman, 2000). CR can address the challenges caused by FSR by means of its increased dynamic range and the ability to manipulate the image once it has been acquired (Seeram, 2011). The details about the latter will be described in the section that follows.

[1] Speelman, A, 2022. Personal communication. Storage of conventional diagnostic images. Cape Peninsula University of Technology, Cape Town South Africa.
Please note that according to the institution's referencing guidelines, personal communication is listed in text but not in the reference list.

1.4 Computed Radiography

Technological improvements in image acquisition techniques have undergone rapid changes over the past two decades through following the introduction of the first Fuji 101 (Fujifilm; Minato-Ku, Tokyo, Japan) CR system in 1983 (Warren-Forward et al., 2007). Over the years, radiography has gone through a digital/computed revolution and has experienced rapid growth in clinical use (Schaefer-Prokop et al., 2008). CR cassettes (containing the image plate) use photo-stimulated luminescence screens to capture the X-ray image, as a replacement for traditional X-ray film. The CR cassette goes into a reader to transform the data into a digital image (Fujifilm, 2006).

The core advantages of CR include having a broader dynamic range (latitude), its ability to manipulate radiographic contrast and brightness as part of post processing, several viewing possibilities, electronic transfer, storage alternatives and linear response of CR images (Bushberg, 2002). The broader exposure latitude possible with CR means that a wide range of radiation exposures (mainly mAs) can be used to produce a diagnostic image (Willis, 2002). The wide exposure latitude in CR is an important concept which needs to be fully understood and explored. Therefore, this study sought to determine the radiographer's ability to stay within the recommended exposure factor range when using a CR X-ray unit ensuring optimal image quality.

As explained before, CR has a wider exposure latitude than film-screen imaging. The consequence of this wide exposure latitude on image quality is one of the major advantages of CR imaging. In cases where the exposure used is too low or too high, the image quality is still suitable due to the ability to perform digital image processing on the CR system (Willis, 2002). There is low noise in an overexposed image making it seem very acceptable, but without signs of incident exposure level to the detector, this overexposure can go unnoticed with the resultant needless additional radiation dose to the patient (Seibert & Morin, 2011). Overexposures of 5–10 times the standard exposure may appear like a correctly exposed image, because of compensation made possible by the digital detector in DR. Absence of a feedback indicator and misunderstanding the purpose of the exposure indicator can result in unwanted patient dose, or ‘‘dose creep” referring to an unnoticed increase in exposure over time (Seibert & Morin, 2011). It is necessary to note that low doses take the effect of forming increased quantum noise. Compared to FSR, the dynamic range of CR is about 400-fold (Uffmann & Schaefer-Prokop, 2009). Wide dynamic range makes it a challenging and hard task for the viewer to distinguish between an underexpose and overexpose image (Berkhout et al., 2004).

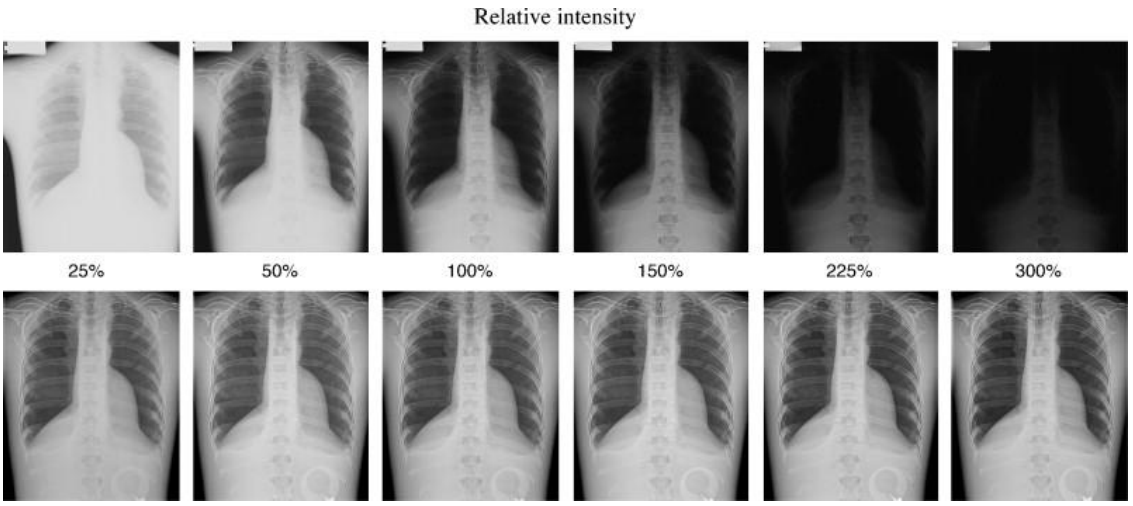


Fig 1.1: The result of differences in the levels of radiation doses on image quality (density) for FSR (top row) and DR images (bottom row) (Adopted from (Veldkamp et al., 2009).

1.5 Study Rationale

As indicated above, the EI provides feedback to the radiographer with regards to the adequacy of each exposure used for general diagnostic X-ray images. However, with manufacturer-specified EI's, confusion exists. The effective implementation of EI is hindered by this confusion. The new adopted standardised EI should inspire a good understanding and usage of the new EI (Brown et al., 1999). Some manufacturers also provide a system whereby increasing EI values point to increasing dose, while for other manufacturer systems, the opposite may be evident (Goske et al., 2011). This contradiction among vendors was seen as an obstacle to effective implementation of EI (Shepard et al., 2009) and for professionals who operated more than one vendor-specific system in their hospital confusion was evident over time. To counter the above mentioned variations, an internationally standardised EI has been established by the International Electro-Technical Commission (Standards, 2008), the American Association of Physicists in Medicine (AAPM) and diagnostic physicists in collaboration with DR system manufacturers (Seibert & Morin, 2011). This new standardised EI is intended to present a linear association between the detector exposure and the index value (Cohen et al., 2011).

The study described in this thesis took place within the research site (RS) which is a second level, referral hospital located in the southern region of Zambia and has a catchment area of 800, 000 people (CSO, 2015). The hospital has a radiology department with two X-ray units, one of which has fluoroscopy. There are also ultrasound and echocardiography/Doppler sections. The department has no Computerised Tomography (CT) and Magnetic Resonance Imaging (MRI) imaging modalities. The registers from the

radiology department indicate a high patient throughput with an average of 50 X-ray examinations performed in the department each day, most of which are postero-anterior (PA) chests. The patients that are attended to in the department are referred with an examination request form and the hospital file. There are 10 radiographers working in the Radiography department, with the two X-ray units each placed in separate rooms.

The hospital does not have a medical physicist for quality assurance and quality control and therefore depends on the one based at the University Teaching Hospital (UTH) located 200km away in the capital Lusaka. The research site upgraded its diagnostic imaging systems to CR in January 2016. It has a Fuji X-ray unit with a recommended *S* value (dose received equivalent) of 400 for general in-bucky examinations and 200 for out of bucky examinations.

The radiographers working at this department received a four-day orientation on the application of the CR X-ray unit at the point of installation. This transition meant that the radiographer can now generate a diagnostic image over a much wider range of entrance doses (under-exposure or overexposure) without any adverse effect on image quality. As mentioned already in this chapter, literature suggest that radiographers tend to use overexposure to avoid noisy images and that average exposures tend to increase over time if an appropriate exposure indicator is not given and checked routinely (Shepard et al., 2009).

Therefore, this transition provides an opportunity for research. A major and significant challenge in providing practical solutions in this respect is to optimise radiation protection of patients. This means *"keeping the radiation dose to its lowest while attaining the highest image quality for accurate diagnosis*" (Chhem, 2010). The ICRP (2007) recommendations also advocate for a minimum of two levels of optimisation. While one level entails optimisation related to the design and construction of X-ray imaging equipment, the other level relates to optimisation throughout daily operation. This study focused on the latter. Optimisation during daily procedures simply entails the effective use of several technical methods for image quality and dose optimisation.

A recent publication by Willis (2009) categorises these methods as:

i. Technological procedures of dose reduction
ii. Operational approaches for improving image quality
iii. Operational approaches for regulating dose to the patient
iv. Variations in imaging techniques to optimize image quality and dose.

1.6 Study Focus

The study sought to scrutinise the operational approaches for improving image quality and operational approaches for regulating patient radiation dose. The two significant factors that play the main role in dose and image quality optimisation associated to the aim of this study, in particular, are the exposure technique factors (kVp and mAs) that are used regularly on a daily basis, and which provide the radiographer with the exposure indicator for each examination. This is the only available feedback to the radiographer concerning the dose and image quality for every CR examination. This EI is therefore considered as the key to controlling exposure levels in CR (Willis, 2009).

1.7 Research Problem

The radiology department of the research site has a high flow of patients and has two sections; ultrasound with a daily average of 40 patients and diagnostic radiography with a daily average of 50 patients. With the introduction of DR technologies, radiographers' competency in selecting proper exposure factors and knowledge relating to the attenuation process has been questioned. This is owed to the 'erosion' of technical factors because of the capability of CR/DR in post processing (Allen et al., 2011). Two of the radiographers at the named hospital received a four-day post installation orientation while the other eight were newly recruited with no prior experience with the CR unit and were oriented by the two radiographers who were trained first. At the time of the study's conception, the researcher felt that the ability for post processing with the CR X-ray unit had potential for radiographers to fail to stay within the manufacturers' recommended EIs. Furthermore the researcher felt that this ability for post processing had potential for radiographers to fail to adhere to the ALARA principle as part of their radiographic techniques and radiation protection procedures which may result in under/over exposed images. While underexposed images have fewer X-ray photons that are absorbed by the IP and can be recognised by a noisy image appearance, overexposed images can simply go unnoticed, which can result in higher exposure which can cause possible harm to the patient (Berkhout et al., 2004). Although the EI does not directly relate to patient dose (high EI does not mean high dose), the importance of checking and evaluating the EI values used by radiographers at the said hospital cannot be underestimated.

Since the named hospital was among the first hospitals in Zambia to acquire a CR unit, data from this study would serve as a valuable baseline against which measurements at individual X-ray departments may be compared with in future and also as an opportunity of more reduction of patients' doses. As a way of providing refined evaluations of worldwide exposures, the United Nations Scientific Committee on the effects of Atomic

Radiation (UNSCEAR) (2000) has recommended more reviews of best practices worldwide (Radiation, 2000). The study described in this thesis involved a systematic compilation of EI data. Hence the radiographer's adherence or non-adherence to recommended EIs when using a CR X-ray unit stated in this work will as well be useful to both the named hospital and the public. Refer to Chapter 3 (Section 3.8.2) for a detail description of the methodology used for the EI compilation.

To the researcher's knowledge, no study was done between 2014 and 2018 to explore the optimisation of the mAs in the implementation of the standard EI by virtue of the dissimilarities in gender (sex) for the PA chest, antero-posterior (AP) pelvis and lateral lumbar spine when given similar radiation doses. Further, the researcher did not come across any research done in Zambia regarding radiographers' adherence to recommended EIs providing some originality of this study.

1.8 Research aim

This study aimed to evaluate factors affecting the radiographers' ability to stay within the recommended EI in the application of CR at a second level hospital in Zambia and the association between EIs and radiation organ dose to the patient in order to make recommendations for future radiographic practice and decision makers.

1.9 Research Question

For this study, the following research question was used: Do diagnostic radiographers at the research site in Zambia stay within the recommended EI for X-ray examinations of the adult PA chest, AP pelvis and lateral lumbar spine following the transition to CR and how it relates to radiation organ dose at a second level hospital?

1.10 Research Objectives

The objectives of this study were to:

- Establish whether there is a major difference between the EI for CR of the PA chest, AP pelvis and lateral lumbar spine of the study population and standard/recommended EI.
- Establish whether there is an association between specific factors (gender, weight, and technical factors like kVp, mAs, SID, FSD, filtration, field size and EI).
- Establish the relationship between EI and radiation dose in this study population.

1.11 Patient Organ Dose

One of the objectives of this study was to establish the relationship between EI and radiation dose in the study population. Several studies have reported different findings; for example, a relationship was noticed between radiation dose and EI (Butler et al., 2009). It is imperative to note that awareness of patient organ doses is necessary for providing an approximation of the radiation risk. The calculation for organ dose is explained in Chapter 2 (Section 2.16) of this thesis.

1.12 Risks associated with use of X-Rays

While it is known that X-rays provide important medical benefits by way of radiographic imaging, studies showed that X-rays could result in biological damage. This perception led to the discipline of Radiobiology, which is known as the study of the effects of radiation on biological systems (Mohan & Chopra, 2022). Additionally, various studies quoted in several reviews on radiation risks (Amis et al., 2007; Andriole et al., 2013; Brenner, 2006; Hall & Brenner, 2008; Martin et al., 2009) have categorised the biological effects of radiation into stochastic effects (i.e the possibility of the effect happening increases with increasing dose, and for which a threshold dose does not apply) and deterministic effects (i.e. the severity of the effect increases with increasing dose and for which there is a threshold dose) (Mohan & Chopra, 2022; Peck & Samei, 2010). The above effects are therefore potential risks patients may face when exposed to excessive doses when undergoing diagnostic X-ray examinations. This fact further supported the rationale for conducting this study i.e. to assess the level of adherence to the recommended EI by diagnostic radiographers at the research site. This study looked at the general radiation dose for three radiographic examinations in relation to the EI.

1.13 Radiation Protection

In order to address these effects of exposure to radiation when imaging patients, the ICRP established a comprehensive system of radiation protection approaches; which aim to reduce stochastic effects and to avoid deterministic effects. As explained before, this system of radiation protection is centred on the use of three principles of justification, optimisation, and dose limitation and serves as an outline for best practice in radiation protection throughout medical radiation exposure (Faulkner et al., 2005; ICRP Publication 103, 2007; Matthews & Brennan, 2008). Dose limits are associated with exposure levels lower the threshold dose for deterministic effects. By applying the threshold dose as a

starting point, dose limits are determined by allying the principles of justification and optimisation (Peck & Samei, 2010).

From the information above, it can be deduced that although justification refers to the idea of subjecting patients to radiation exposure only where the benefits outweigh the risks, it is necessary to ensure optimisation so as to meet the necessity of diagnostic image quality at a radiation dose that meets the ALARA principle (Faulkner et al., 2005; Smans et al., 2010). This principle of optimisation has been applied to diagnostic radiology in its advancement to current day technology. This means that optimization has been applied to FSR, and now the evolution to DR points to new prospects for optimisation research in diagnostic radiology (ICRP, 2004; Matthews & Brennan, 2008; Mattsson, 2005; Smans et al., 2010). The principle of optimisation is important to this study which seeks to determine the radiographer's ability to stay within the recommended EI when using a CR X-ray unit.

Studies have shown that during PA chest, and AP pelvis examinations, critical organs using effective dose as a measuring tool, are exposed to higher radiation, whereas Lumbar spine examinations are known to be related with higher Entrance Skin Dose (ESD) values when compared with all other X-ray examinations (Papadimitriou et al., 2001). The chest X-ray is the examination that is mostly performed at the hospital where the study was conducted taking up 40% of all the examinations, and the pelvis and lumbar spine examinations are also regularly performed.

1.14 Chapter summary

The study sought to explore the point of the relationship (or difference) between the EI for patients undergoing CR of a PA chest, AP pelvis and lateral lumbar spine and standard/recommended EI. To establish the relationship between EI and radiation dose in this study population. Secondly, the study sought to describe tendencies in the application of the CR X-ray unit by radiographers in adult patients with differences in gender and weight. In the second phase of this study, the researcher employed a quantitative research approach to look at the trends in a population of radiographers as regards to the standard selection of exposure factors when using the CR unit.

As can be seen, the two methods cited above are non-interventional (i.e. no control or manipulation of variables will occur as found experiments) and because the aim of this study was to explain the relationship between variables, a descriptive correlational approach was found to be appropriate for this study.

1.15 Thesis Structure and Overview

This thesis is structured into five chapters entitled ‘Introduction, which give an overview of the nature and scope of the study’ ‘Literature review,’ ‘Methodology,’ ‘Results,’ ‘Discussion and Conclusion’.

Chapter 2: This chapter reviews the literature from the time X-rays were discovered; use of film-screen imaging and its challenges; transition to CR and its challenges; radiation dose and dose measurement.

Chapter 3: This chapter describes the research design and methodology and procedures followed in this study. These include a statement of the purpose why the study was conducted; research viewpoint and design; study population, and sample used; research variables; research instruments employed; pilot studies; the data collection processes applied; and analysis of data.

Chapter 4: This chapter outlines the results of the study whose primary aim was to evaluate (i) factors affecting EI in the application of CR at a second level hospital in Zambia, (ii) the relationship between EIs and radiation dose to the patient. The results would reveal where there was adherence or non-adherence to the correct application of the recommended EI’s of the CR X-ray unit.

Chapter 5: This chapter explores the implications of the results presented in Chapter 4. The results are discussed in this chapter in the context of how they relate to the research objectives. The chapter further provides recommendations for future imaging practices and further research.

CHAPTER TWO

LITERATURE REVIEW

2.1 Chapter introduction

This study set out to establish whether there is a significant difference between the EI for CR of the PA chest, AP pelvis and lateral lumbar spine of the study population and standard/recommended EI. Other aspects explored included establishing whether there was an association between specific factors (gender, weight, and technical factors like kVp, mAs, SSD, FSD, filtration and field size) and EI as well as the relationship between EI and radiation dose in this study population. The Chapter brings out to the reader a review of the literature as it relates to the above stated objectives. Topics covered in this Chapter include a historical overview of the discovery of X-rays, image composition in FSR, CR, effects of exposure factors on image quality as well as dose creep associated with CR. Furthermore, this chapter also describes radiation protection, the need for understanding dose, the role of EI in dose management as well as radiographers' adherence to recommended EI's.

FSR imposed several challenges; one being an image of poor quality where the initial radiation exposure selected has not been correctly determined. As alluded to in Chapter 1, Section 1.3, if the radiation exposure to the film is too high, the film becomes overexposed and when processed, the image produced is too dark, and makes such an image inadequate for diagnosis. Similarly, if the radiation exposure to the film is too low, the resultant image produced is too light and does not give the observer enough detail for the compilation of a diagnosis (Veldkamp et al., 2009). The above shortcomings were addressed by introduction of CR and DR technologies (Speelman, 2022). The section that follows describes the discovery of X-rays and factors that led to the development of CR.

2.2 Medical X-Rays: Discovery and Application in Medicine

X-rays were discovered by Wilhelm Conrad Roentgen in 1895. Roentgen was born in 1845 and in 1865, he applied for admission to the Utrecht University even when he did not have the needed credentials vital for a normal student. Roentgen was informed about the possibility of him entering the Federal Polytechnic Institute in Zurich (which nowadays is known by the name ETH Zurich). He sat for the admission examination and enrolled for advanced studies in mechanical engineering after which in 1869, he graduated with a Doctor of Philosophy (PhD) from the University of Zurich (Linton, 2012). In 1895, he

discovered a new ray as he was working with rays from the cathode (electrons), and went on to investigate various properties that pertained to the new ray which he temporarily named "X-rays", using the mathematical description ("X") for a thing that is not known (Stoddart, 2022). Roentgen afterwards used this new ray and produced an X-ray picture of the hand of his wife (Haase et al., 1997). This knowledge resulted into the birth of a new tool to be applied in the field of medicine, and for this discovery, Roentgen was in 1901 awarded the first Nobel Prize in Physics (Linton, 2012).

This remarkable technical advancement developed into what is now known as medical radiography. Before the transition to modern technology, Medical Radiography used a film which was sensitive to X-rays and placed it in between two intensifying screens to form what is called a film-screen image receptor. Thomas Edison was the first to design intensifying screens for use with film as a joint recording medium. The use of this receptor when imaging a patient is referred to as FSR (Sprawls, 1995). For over 110 years now, radiography has proved to play a vital role in medical diagnosis and subsequent management of the patients.

Medical imaging is still centred upon the acknowledgement that different parts of the body attenuate a beam of X-rays in accordance with their density, generating an image which allows body structures to be identified and enable detection of abnormalities such as injury and disease conditions (Linton, 2012). When taking an image of the chest X-ray as an example, the calcium density found in the spine and in the ribs attenuates most of the X-rays, resulting into white areas appearing on a film. The radiographic densities of the stomach and liver appear grey. The stomach and liver attenuate fewer X-ray compared to bones which means it is easier to notice the difference between them. The density the fat found in muscles is lower than the density of water and appear a bit darker, but the difference can be observed by a trained eye (Geijer & Persliden, 2005).

2.3 Image composition in Film-Screen Radiography

From the time X-rays were discovered, FSR has been regarded to be the backbone of diagnostic radiology. The X-ray tube that is controlled by the X-ray generator is responsible for the production of X-rays. The X-ray tube houses an anode consisting of a target and a cathode which contains a filament. When a high current is made to flow and heat up the filament to a certain temperature, it makes electrons to heat up, in a process referred to as thermionic emission (Wolbarst, 2005). When an X-ray exposure is made, a high voltage is applied across the cathode and anode. This kVp causes the electrons to move at high speed to hit the target, therefore resulting in the production of X-rays (Molteni, 2020; Wolbarst, 2005).

The process in which electrons flow across the cathode and anode is referred to as the tube current which is expressed in milli-amperage (mA). Further, mAs is the product of mA and exposure time expressed in seconds (s). The energy of the high speed electrons that hit a target gets transformed into about 99% heat and only 1% X-rays (Wolbarst, 2005). This 1% or so of the radiation beam passes through the body part and strikes the intensifying screen to produce light as a result of the transformation of the X-ray energy into light and when this light reaches the film it creates a latent image (Ritenour, 1996). The film containing the latent image undergoes chemical processing to make the latent image visible and is then made ready for the reader to view and interpret (Serman, 2000).

The film image produced appears with varying amounts of blackening because different parts of the patient's anatomy absorb the quantities of radiation differently. This means that more blackening (overexposed image) comes in as a result of high exposure (more radiation) whereas less blackening (underexposed image) is cause by a low exposure (less radiation). An overexposed or underexposed image does not give enough diagnostic information. As a consequence of this narrow exposure latitude, the operator is expected to pay particular attention as regards the preciseness in the selection of exposure technique factors for the body part being examined (Seeram, 2011).

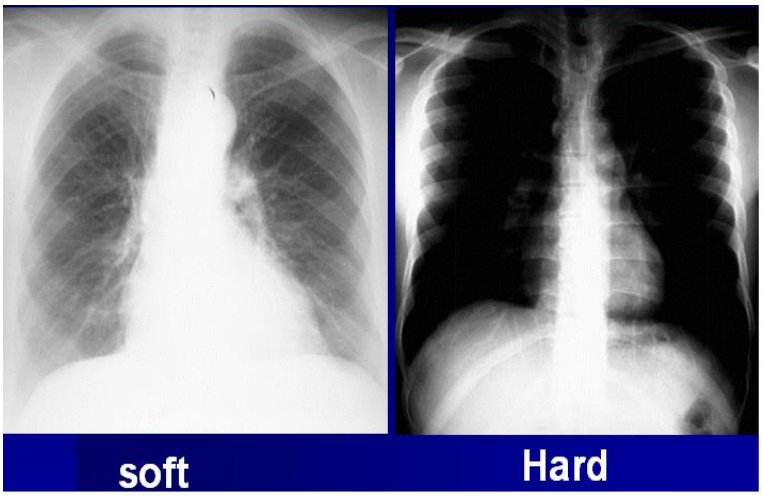


Figure 2.1: The visual image quality feedback in FSR as a result of low (soft) and high (hard) radiation exposures. (Veldkamp et al., 2009).

2.4 Transition from film-screen radiography to digital radiography

There are several problems imposed by FSR of which one is reduced quality of the image where the preciseness of the initial radiation exposure has not been properly determined. An image that does not add diagnostic information to clinical questions is known as a reject image (Kofler et al., 1999). In view of the above circumstances, the images produced fall short of the correct image density and contrast, and the implication is to have them repeated in order to produce the image quality that is required in coming up with a diagnosis. When radiographic images are repeated, the patient would be exposed to high radiation doses which has probable injurious effects when it irradiates human tissue (Bushberg, 2002).

There is currently more than one type of digital imaging systems being used which include CR, flat-panel DR, digital fluoroscopy and digital mammography. Of all these, CR has the highest dose requirements for any given image quality (Veldkamp et al., 2009). The title of this thesis looks at CR and as such this study only presents an overview of how the CR system operates.

2.5 Image acquisition in Computed Radiography

The CR cassettes captures the X-ray image using a photo-stimulated luminescence IP, in place of the X-ray film traditionally used by FSR. Image acquisition is the term that is used to refer to exposure of the IP by X-rays. It is during this stage that radiographers must be extra cautious with technical details that include using precise radiographic exposure factors (kVp, mAs) to avoid repeated exposure to the patient. As alluded to before, repetition of exposure is a concern because it exposes patients to unnecessary ionising radiation with a corresponding increase in radiation dose (Rastegar et al., 2019; Zewdu et al., 2017).

The IP is processed within a CR reader by means of a laser beam in order to render visible the latent image. This is the process which is referred to as photo-stimulated excitation (Fujifilm, 2006). There is systematic scanning of the IP as it passes through the CR reader. The photo stimulated luminescence (PSL) produced by the IP is picked up by a special device which collects light and sends it to a photomultiplier tube where an electric signal is produced. The signal produced by the photomultiplier tube is afterwards digitised and thereafter sent to a digital computer where it is processed to create a CR image and the image created is shown on the computer monitor [in a grey scale]. Finally, using a high intensity light, the IP is erased in order to get rid of any residual energy that could have remained following the scanning of the IP by the laser beam. Once this is done, the

erased IP is now ready to be used again (Culbertson et al., 2011; Fujifilm, 2006; Seibert, 2004).

2.6 Advantages of Computed Radiography

The key benefits of CR include a wider dynamic range (latitude), the provision for post processing (alteration of radiographic contrast and brightness) along with several options for viewing. Thirdly, the ability for electronic transfer of images means that images can easily and quickly be disseminated digitally regardless of geographical location which makes it possible for a wider number of potential reading/reporting radiologists to have access to the images. Furthermore, the electronic transfer of images excludes the need to transfer images between departments enabling potentially faster interpretation turn-around times. Fourthly, are the wider storage options for images, and all of them take up considerably reduced storage space and are often much less expensive than what is necessary for FSR. These options include storage on a Picture Archiving and Communication System (PACS) server, mini-PACS server, computer disc (CD), digital video disc (DVD) and off-site storage. The broad exposure latitude of CR implies that a radiographer can use a much greater range of radiation exposures (mainly mAs) to generate a diagnostic image. The problems encountered with FSR have been solved by digital radiography (Bushberg, 2002; Seibert & Morin, 2011; Shepard et al., 2009). The wide exposure latitude is significant within the context of this study which seeks to determine the radiographer's ability to stay within the recommended EI range when using the CR unit while ensuring optimal image quality.

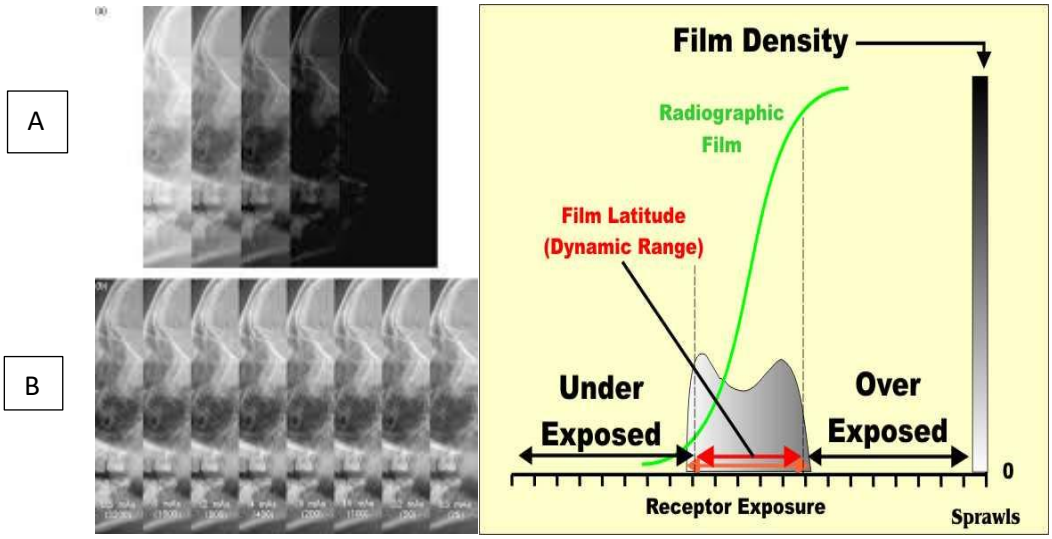


Figure 2.2: Difference in dynamic range between FSR (A) which is narrow, and DR (B) which is wider (Sprawls, 1995).

2.7 Effects of mAs and KVp on the image

The strength of an X-ray beam emerging from an X-ray tube is measured in mA, and is what is referred to as the X-ray quantity, also generally called the radiation exposure (Bushong, 2013). The mAs is a product of mA and time expressed in seconds. The number of X-ray photons in the X-ray beam is an expression of the X-ray quantity and gets affected by several factors which include mAs, kVp, filtration, and distance; where the effect of filtration is the absorption of long wave-length X-ray photons with low penetrating power while distance affects the intensity of radiation and exposure time directly. This review (and the broader study to some extent) will only outline the relationship between mAs and kVp.

The amount of X-rays or the radiation exposure from the tube is directly proportional to the mAs denoting that when the mAs gets doubled, the exposure reaching the patient also gets doubled. On the contrary, the exposure affected in a different way by the kVp, where if the kVp gets doubled, the exposure increase by a factor of four (Huda & Gkanatsios, 1997). Excessive or inadequate radiation exposure reaching the digital IR, due to the mAs or kVp, should be revealed in the generated exposure indicator value. The exposure errors from kVp and mAs should be revealed in the generated exposure indicator value; however, the possibility to adjust contrast during computer processing can sustain image brightness. It is assumed that the mAs-dose relationship is to a larger extent understood better compared to the kVp-dose association (Bushong, 2013).

There are three principal factors that determine image quality, namely contrast, resolution, and noise. The radiographer has direct control of these three image quality characteristics through correct selection of the kVp and mAs used during the imaging process. These factors have an influence also on the exposure received by the patient as alluded to before (Van Metter & Yorkston, 2001).

Where possible, a higher kilovoltage and a lower mAs should be applied in order to reduce exposure to the patient. When the kilovoltage is increased, less mAs is required in order to maintain the preferred exposure to the IR and reduce the radiation dose to the patient. For example, changing from 75 to 86 kVp when imaging a pelvis results in a 15% increase and would need half the mAs required for the original 75 kVp. A higher kVp increases the beam penetration, enabling lower radiation to achieve a desired exposure to the IR (Huda and Gkanatsios, 1997).

2.8 Risks associated with medical X-rays

Projection radiography involves use of ionising radiation and though beneficial to patient management, its use comes with the risk of radiation dose to patients. Diagnostic imaging, which includes conventional projection radiography, is considered by researchers to carry what may be considered small, but real risks (Verdun et al., 2008). One of the principles of justification for a radiological procedure is that the application of any specified X-ray examination to an individual patient is justified where that particular application is considered to do more good, than harm to an individual patient (ICRP Publication 103, 2007). This is discussed in detail under Section 2.11 of this chapter.

Diagnostic radiology is considered the single most leading source of ionising radiation which is man-made and contributes about 14% of total universal exposure from man-made and natural sources (Moore et al., 2009). There have been serious concerns raised about health risks in this regard. Other documented direct evidence of radiation risks from X-rays is derived from epidemiological studies of high levels of cancer in the human population that gets exposed (Hall & Brenner, 2008). Although general radiography generates low doses well below 10 milli-Grays (mGy), it is believed that stochastic effects happen even at low doses. And hence the ICRP considers it scientifically realistic to assume that the occurrence of induced cancer or hereditary effect increases in proportion to increased absorbed dose (Brennan et al., 2007).

Current expert consensus suggest that when there is increased dose without a threshold, it is anticipated that there will be the risk of radiation-induced cancer and hereditary disease (López et al., 2018). This means that each exposure of the patient to the X-radiation counts, and the consequences accumulate. There is thus a need for radiographers to be conscientious about this fact when choosing exposure factors when conducting X-ray examinations on patients.

2.9 Risks associated with medical X-rays on selected conventional diagnostic radiographic examinations

Studies have shown that during PA chest, and AP pelvis examinations, critical organs are exposed to radiation, whereas examinations of the Lumbar spine are highly associated with higher ESD values when compared with all other types of X-ray examination (Papadimitriou et al., 2001).

This exposure to ionising radiation can be considerably different by virtue of the differences in body morphology (body build) amongst the different genders (sex). Various

studies have shown that there are a number of major illnesses that are influenced by gender. It is also true that gender influences potential risks that could come as a result of exposure to X-rays or ionizing radiation emitted by radioactive materials or accelerators. For example when compared to male breasts, the female breasts have been found to be very sensitive to ionizing radiation (ICRP Publication 103, 2007).

The difference exists between age groups as well in terms of radiation dose limits. When children, adolescents and adults are given the same radiation doses, the risks are bigger for children and adolescents compared to those for adults in that children grow very fast, and their cells are very sensitive to radiation (Khotle et al., 2009). Since it is well known that the effects of radiation take long even years to advance, the time for the manifestation of any potential effects from ionizing radiation in children is prolonged by their youthful years. However, the radiation dose levels needed to acquire radiographs of adults are much higher than those of children. Therefore, there is need to see to it that the risk related to a diagnostic X-ray examination for a child should not be more than that of an adult. As adults advance in age, exposure to radiation becomes less of a concern because of the reduced sensitivity of their body tissues to the effects of radiation (Brenner, 2006).

As stated in the introduction section of this chapter, the idea of effects from radiation led to the study of the *"effects that radiation has on biological systems"* the discipline generally referred to as radiobiology, (Martin et al., 2009). The biological effects or risks that arise from exposure to ionizing radiation are explained in the recent literature (Amis et al., 2007; Brenner, 2006; Fazel et al., 2009; Hall & Brenner, 2008; Peck & Samei, 2010; Verdun et al., 2008). For dose limitation purposes, the diverse radiation effects have in recent decades been separated by the ICRP into either stochastic effects (with no threshold) or tissue reactions (formerly termed non-stochastic or deterministic effects, which have a threshold) (ICRP Publication 103, 2007). Deterministic effects occur only when a threshold of exposure (i.e. a specific dose) has been exceeded. The severity of these deterministic effects increases with dose and can cause damage which may result in skin burns or hair loss; the higher doses can cause internal organ failure. Stochastic effects have no threshold and happen by chance, as such, the probability that exposure to radiation will result into a stochastic effect depends on dose. However, there is no relationship between dose and the severity of stochastic damage. Recommendations on dose limits have been made with this framework, in which effective dose limits target to keep stochastic effects below undesirable levels and equivalent dose limits target to prevent tissue reactions (Hamada & Fujimichi, 2014).

Radiation protection aims at constantly inhibiting the deterministic effects caused by radiation and lessening the risk of stochastic effects to a level that is reasonably achievable. The dose limits are set in order to ensure that deterministic effects are ruled out. Radiation protection is discussed in detail in Section 2.11 below.

2.10 Dose creep associated with computed radiography in medical X-rays

The higher radiation dose received by the patient is a major challenge imposed by higher than usual exposures caused by unwanted 'dose creep'. Dose creep happens when a wider range of radiographic exposure factors can be used that are accurate for a wider range of patient sizes, compared to projection radiography where the range is much narrower. Using a higher than normal radiographic exposure, still result in an acceptable radiographic image with CR systems. The trend of dose creep is considered to reduce where radiographers are provided with previous EI values for the same x-ray examination (Warren-Forward et al., 2007).

The wider exposure latitude with CR may bring about dose creep or dose drift; these terms are used to explain the unintended overexposure to the patient, following the introduction of digital imaging technologies (Cohen et al., 2011; Gibson and Davidson, 2012). This increase is determined, at least partly by a need to reduce quantum mottle since radiologists usually show concern about underexposed images as opposed to overexposed images, except where saturation occurs (Shepard et al., 2009). The notion of overexposure is what literature supports in order to avoid noisy images and suggests that the average exposures have a trend to creep up over time where there is no provision and routine monitoring of a clear exposure indicator (Andriole et al., 2013).

CR technologies have been said to have the ability to reduce radiation dose to the patient (Schaefer-Prokop et al., 2008), however, inadvertent overexposure is likely owing to the large dynamic range of CR, (Moore et al., 2009) since image quality is more likely to be affected by underexposure rather than overexposure (Aichinger et al., 2012)

2.11 Radiation protection and resource allocation

As mentioned in the introduction section, in order to address the effects of exposure to radiation when imaging patients, the ICRP established a wide-range system of radiation protection measures; the aims are to reduce stochastic effects and to avoid deterministic effects (Wrixon, 2008). The three principles on which radiation protection in radiography is based are those of justification, optimisation, and dose limitation. Matthews and

colleagues described these as a process *"to articulate a framework for best practice in radiation protection during medical radiation exposure"* (Matthews & Brennan, 2008). Dose limits imply that exposure levels should be used that are below the threshold dose for deterministic effects. Literature indicates that when taking the threshold dose as a starting point, dose limits can be determined using the principles of justification and optimisation (Peck & Samei, 2010).

Through the principle of justification it is guaranteed that more good than harm is considered whenever making a decision that alters the radiation exposure to the patient. Further, it is necessary to apply the principle of justification at different levels/scales and over varying timeframes. Taking the preparation for or response to an emergency exposure situation as an example, justification should consider whether the general protection strategy will or not will do more good than harm, bearing in mind the balance of risks and benefits (Wrixon, 2008).

From the information above, it can be deduced that whereas justification refers to the idea of subjecting patients to radiation exposure only where the benefits outweigh the risks, optimisation is essential in as far as meeting the requirement of achieving diagnostic image quality at a radiation dose that is ALARA (Faulkner et al., 2005; Smans et al., 2010). The principle of optimisation is planned for use to those conditions for which the execution of protection approaches has been warranted i.e. at all levels and for all timeframes. Optimisation of the protection strategy sees to it that the likelihood of acquiring exposures, the numbers of people exposed and the extent of their individual doses should be kept as low as reasonably achievable, bearing in mind societal and economic factors (Wrixon, 2008).

This principle of optimisation has been used in diagnostic radiology in its advancement to present day technology. This means that optimization has been applied to FSR, and now the transition to DR lead to new opportunities for optimisation research in diagnostic radiology (ICRP, 2004; Matthews & Brennan, 2008; Mattsson, 2005; Smans et al., 2010). The principle of optimisation is important to this study which seeks to determine the radiographer's ability to use exposures that are within the recommended EI when using a CR X-ray unit.

The purposes of the recommended system of dose limitation are to ensure that no exposure is unjustified in relation to its benefits, that all necessary exposure is kept as low as reasonably achievable (the ALARA principle), and that the doses received do not exceed the specified limits. The reference level can be considered as a pointer of the level of exposure regarded acceptable, given the prevailing situations. Reference levels are

values to advise decisions on protection strategies in prevailing and emergency exposure situations (ICRP, 2004). Reference levels are tools that support the practical execution of the optimisation principle beginning with identification of exposures that need attention which is more specific and then by going through the exposure scenario to further increase protection. Reference levels can be specified in measurable quantities (such as ambient dose rates, maximum permissible levels in foodstuffs) to enable their application in specific situations (Wrixon, 2008).

2.12 Understanding Dose

Radiation dose can be defined as a measure of the quantity of energy per unit mass which is absorbed in tissues from an X-ray beam and is expressed in joules (unit of energy) per kilogram (unit of mass) (ICRP Publication 103, 2007). The unit of measure for radiation dose is the Gy, which is equivalent to one joule/kilogram. The ICRP (2007) stated that; *''the quantities, equivalent dose and effective dose, with their unit being Sievert (Sv), should not be used in the quantification of radiation doses or in determining the need for any treatment in situations where tissue reactions are caused''*. Overall, in such circumstances, doses should be given in terms of absorbed dose in Gy whereas if high linear energy transfer (LET) radiations (e.g. neutrons or alpha particles) are involved, a relative biological effectiveness (RBE)-weighted dose, (Gy), may be used.

It is acknowledged that literature quotes several radiation doses in Sv or mSv because this unit has been used before by various professionals and are familiar with it. There is also the fact that the use of a threshold model for the specific endpoints of cataract and circulatory disease is still unclear. For low-linear energy transfer radiation, the actual mathematical value in either unit is the same (Hamada & Fujimichi, 2014).

A study done in the United States on effective dose, calculated population based amounts of effective doses for the study population generally and for each age-based and sex-based group categorised according to the following dose levels: low (≤3 mSv per year, the background level of radiation from natural sources; moderate (>3 to 20 mSv per year, the upper yearly maximum for occupational exposure for at-risk workers, averaged over 5 years); high (>20 to 50 mSv per year, the upper yearly maximum for occupational exposure for at-risk workers in any given year) and very high (>50 mSv per year) (Brenner et al., 2003; Fazel et al., 2009; ICRP Publication 103, 2007).

The results from the above-mentioned study showed that the mean effective dose was 2.4±6.0 mSv per person annually, and the median effective dose was 0.1 mSv per person annually (interquartile range, 0.0 to 1.7; 95th percentile, 12.3) (Fazel et al., 2009). As mentioned already in the paragraph above, the fraction of subjects going through these procedures and their mean doses differed in relation to age, sex, and health care market. To put this in much clearer terms, the natural background radiation from radioactive materials in the earth and cosmic rays from space during the period of 1 year produce about 0.003 Gy or 3 mGy. The skin dose distributed from a correctly exposed chest radiograph to an average size man is about 0.15 mGy (Seibert & Morin, 2011). For radiographs, the dose of 1 Gy is equal to a dose equivalent of 1 Sv. For the chest radiograph however, an entrance skin dose of 0.15 mGy for example, delivers an effective dose of about 0.04mSv; 1mSv for the lumbar spine and 1mSv for the pelvis. The highest skin dose is useful for assessment of probable deterministic effects caused by ionizing radiation (e.g., radiation burn, hair loss and other acute effects) at very high radiation dose, whereas the effective dose estimate is helpful for stochastic effects such as cancer induction probability. Both measures are useful when stating dose estimates to the patient, (Seibert & Morin, 2011).

2.13 Acceptable level of patient dose

Radiation dose that a patient is subjected to is an essential consequence of obtaining the X-ray images used to describe the anatomical and patho-physiological processes and come up with a diagnosis. Since X-rays are hazardous and have a related risk, it is essential to guarantee that there should be more benefits in making a correct diagnosis than the risks associated with being exposed to ionizing radiation (Brenner, 2006; Bushong, 2013; Seibert & Morin, 2011). Fortunately, the risks associated with being exposed to ionizing radiation in amounts usually applied when undertaking specified medical imaging procedures are relatively low and similar to other risks that are considered acceptable for daily life. Therefore, optimisation of the radiographic study in terms of achieving the required image quality at the lowest probable radiation dose should always be considered in order to make the most of the benefit-to-risk ratio. It should be noted that this is only but the minimum radiation dose and not essentially the lowest dose possible that results in image quality adequacy to allow an experienced radiologist to come up with a confident diagnosis. So long the investigation is suitable, the benefit to an individual patient (to confirm or eliminate disease or trauma) will far offset the related risk (Seibert & Morin, 2011).

2.14 Exposure Indicator

CR allows for post processing to manipulate the brightness of an image, and as such, information regarding the exposure made to the IR is vital. With FSR, over- and underexposure are reasonably easy to notice from the image relative radiographic density. It may be difficult for the human observer to critique exposure by merely evaluating an image visually due to the ability by CR to compensate for under- and overexposure by up to 100% and 500%, respectively. Therefore, CR systems are designed to derive at an indication of exposure for each image in an effort to offer feedback to the radiographer (Kowalczyk & Comer, 2009). The EI can be defined as a measure of the digital detector's reaction to radiation in the relevant image region (RIR) of an image acquired by means of DR (Seibert & Morin, 2011).

It is not obvious to notice exposure errors by simply looking at the digital image since the digital data are standardised to produce images with density or brightness which is adequate for a diagnosis. Most manufacturers of digital IRs recommend a range for the exposure index centred on the radiographic procedure. If the exposure indicator value does not fall within this range, image quality or exposure to the patient or both could be compromised (Standards, 2008). This is as presented in the Table 2.1 below.

Table 2.1: Clinical ranges of Exposure Indices for the Fuji CR unit: (Fuji, 2011)

Examination	**Average Exposure Index**	**Coefficient of variation**	**Target Range**
PA Chest	515	41%	200 – 600
Lumbar Spine/AP Pelvis	168	45%	100 – 400

As mentioned before each manufacturer of DR/CR units recommend their own ‘‘exposure indicator’’, with an algorithm for its calculation; for example, Kodak terms this as EI while Fuji terms it *S* value (ICRP, 2004). This exposure indicator is expressed as the EI (Shepard et al., 2009).

EI is the measure of the quantity of exposure received by the image receptor (Uffmann & Schaefer-Prokop, 2009). EI is dependent on mAs, total area irradiated on the detector, and beam attenuation (Seibert & Morin, 2011). The use of a low kilovoltage (kVp) and a high current (mAs) exposure will produce a higher dose to the patient when compared to high kVp, low mAs exposures. It has been commented that the trend in digital imaging is

to use higher exposures than what is required because the digital system is capable of correcting image quality following poor exposures (Shepard et al., 2009). Overexposure presents more complications in that the latent image on the CR may still remain if not completely erased and when high kV is applied at the next exposure it introduces additional scatter and hence digital noise into the new image produced. A lot of newly qualified radiographers will have had little experience of using a film-based system in obtaining images and may not be familiar with the effect on patient dose when applying an incorrect exposure factor. Also, the effect of varying exposure factors on changes in contrast and density are also less obvious owing to the ability of digital post processing that takes place (Shepard et al., 2009). In a digital imaging system, the suitable imaging protocol must be carefully chosen for the correct anatomical region being radiographed. This is to ensure that the exposure index value does not falls outside the acceptable range. Thus, without understanding of the X-ray acquisition techniques and habitus of the patient, it is not probable to directly calculate the patient dose from the exposure index value. Although EI is always derived from the IR exposure, the numeric value is calculated differently by equipment manufacturers, resulting in different ranges and definitions (Hamada & Fujimichi, 2014).

Fuji uses *S* that is associated to the amount of amplification needed by the photo-stimulator to alter the digital image. The *S*-value is inversely proportional to exposure. The Fuji *S* value decreases if the exposure increases, as such the radiographer requires to have direct knowledge and training of the CR system they are using (Agustin, 2013).

Since DR devices are capable of correcting for under- and overexposure conditions, the EI, therefore, offers the radiographer with feedback as to the sufficiency of each exposure, and an idea of whether a correct radiographic technique was used, in the way that film density did with conventional radiography. This is particularly significant in the effort to optimize radiographic studies and acquisition techniques, especially for children, in whom radiation sensitivity is reasonably high.

2.15 Challenges with Exposure Indicator and its standardisation

Confusion exists regarding EIs due to individual manufacturers' specific EIs. This existing confusion hinders the effective implementation of EI. The standardised new EI which has been adopted is expected to encourage more understanding and usage of the new EI (Brown et al., 1999). A system is offered by some manufacturers whereby raising the EI values indicates increasing dose, while for other manufacturers' systems, the opposite is apparent (Goske et al., 2011). This irregularity among vendors was regarded as the one

preventing the effective implementation of EI (Shepard et al., 2009), and misunderstanding was apparent between professionals who worked with more than one manufacturer specific system. An International standardised EI has been established by the IEC, the AAPM and internationally popular diagnostic physicists working together with manufacturers of DR systems in an effort to counter the variations mentioned above (Seibert & Morin, 2011). This new standardised EI is intended to show a linear association between the detector exposure and the index value (Cohen et al., 2011).

The *S*-number for Fuji is as a result of the following association, using an ordinary resolution IP and under regular processing procedures. The EI is known as the *S* value and is inversely proportional to the exposure on the image plate; therefore a low exposure will produce a high *S*-number, and a high exposure will produce a low *S*-number (Carter & Veale, 2018). The *S*-number can be assumed as being equal to the speed of the IP and by reducing the exposure, the speed of the IP gets increased (hence the *S*-number is large, say *S*=1000) and the resultant image will be noisy. Further, by increasing the exposure, the speed gets decreased (low *S*-number, say *S*=50, and the resultant image is adequate, but the dose to the patient is much higher (Goldman et al., 2005; Seibert, 2004). The *S*-number discussed in this paragraph can be expressed by the following formula:

$$S = \frac{200}{\text{Exposure to the IP (MRR)}}$$

(Carter and Veale, 2018)

2.16 Measurement of radiation dose

The knowledge of patient organ doses is at all times important for providing an approximation of the radiation risk. Direct experimental patient dose measurements are difficult to be done and in phantom measurement is hard and time-consuming work. Therefore, it has been proposed that the solution is to adopt the Monte Carlo formula to provide an approximation of organ doses in patients undergoing X-ray examinations (Ahmed et al., 2017). The Personal Computer program for Monte Carlo (PCXMC) is a computational program that lets organ absorbed dose to be evaluated with the purpose of providing information for reducing dose and improving the X-ray radiographic techniques (Tapiovaara et al., 1997).

There have been realistic agreements of the PCXMC 2.0 calculations with comparisons to measurements with phantom models. Smans and colleagues (2010) compared

PCXMC 2.0 to calculated doses in two premature baby voxel phantoms with weights of 590g and 1910g showing PCXMC 2.0's applicability to the small body sizes of neonates. However, there were variances in measurements which were described by the differences in phantom model simulation and positioning in the X-ray field. Smans and colleagues (2010) used two different Monte Carlo simulations to relate the different models, the voxel phantom simulation scheme and PCXMC 2.0, with the notion that the voxel phantom simulation was more precise. Further studies have also revealed differences with use of voxel phantoms (Smans et al., 2010). The PCXMC was used to calculate patient dose and is explained in chapter 3 of this thesis.

2.17 Medical X-Rays in Zambia

In Zambia, almost all public hospitals both in rural and urban areas are equipped with some form of X-ray unit. Conventional radiography involves basic plain FSR X-ray examinations. Radiography in Zambia has not escaped the technological advancement. The country has been going through a shift from conventional radiography to CR/DR.

This transition means that the radiographer can now generate a diagnostic image over a much wider range of entrance doses (under-exposure or overexposure) without any adverse effect on image quality. As mentioned already in this chapter, literature suggests that the concept of overexposure is often used to avoid noisy images and suggests that average exposures have a tendency to increase over time if a clear EI is not provided and monitored routinely (Shepard et al., 2009).

2.18 Radiographers' adherence to recommended Exposure Indices

Peters and Brennan conducted a study to check whether radiographers were operating within the ranges of the manufacturer-recommended EI (MREI) for routine chest, abdomen and pelvis X-ray examinations under diverse situations and to look at factors affecting the EI. Their results indicated that majority of the examinations that were looked at demonstrated EI values that were not within the MREI ranges, with median EI values documented for female patient radiographs being significantly higher than those for male patients and was the same for all manufacturers (Peters & Brennan, 2002).

Seeram (2012) conducted a study to examine the radiation dose-image quality optimisation of a Fuji CR Imaging System; and to assess the radiographers' knowledge components of CR, confidence and attitudes when applying the CR system in clinical practice. This dose optimisation study involved taking measurements of the entrance skin exposure (ESE) and translating it to ESD free-in-air to an anthropomorphic phantom model of the pelvis and lumbar spine. This was done by means of the manufacturers' recommended exposure settings (kVp and mAs) and dose values above and below the

values for the manufacturer (reference dose) for the three examinations described. The phantom dosimeter results of Seeram's study revealed a strong positive linear association between dose and mAs; mAs and inverse EI; dose and inverse EI for both the AP pelvis and AP lumbar spine.

Another study conducted by Warren-Forward and colleagues investigated (i) whether the images produced by radiographers had exposure indices that fell within the manufacturers' recommended range (MRR); (ii) the phenomenon of exposure creep, and (iii) the association between EIs and radiation dose (Warren-Forward et al., 2007). The results showed that 38% of lateral lumbar spine examinations at one hospital and 38% of PA chest examinations at another were produced with EIs below 1700; below the MRR of 1700 to 1900.

2.19 Chapter summary

Chapter 2 presented an analysis of the literature on a number of principles and technical concepts significant to the objectives of this study. Firstly, literature reviewed revealed that since its discovery, X-rays have been applied broadly in medicine using the FSR system. This imaging system comprised of a number of limitations, including the narrow dynamic range (exposure latitude).

Secondly, the technology involved in CR was reviewed. The key element emphasised was the wide latitude possible with CR systems which allows for the use of a wide differences of exposure technique factors. EIs have devised by Manufacturers which provide radiographers with feedback concerning dose reaching the detector.

Thirdly, the review looked at the risks related to radiation exposure. These are referred to as bio effects and consist of stochastic and deterministic effects. The fourth major aspect of this literature review addressed elements that precisely relate to exposure technique methods in CR imaging. Two factors were reviewed: kVp and mAs since they impact the exposure to the patient as described earlier. Further, the literature reviewed revealed that the Monte Carlo calculation software was adopted to provide an estimate of organ doses in patients undergoing conventional X-ray examinations.

Finally, the literature review concluded with referring to studies which evaluated the use of the CR system in practice, precisely in terms of confidence and knowledge in use of the system. The next chapter will present in detail, the research methods used in this study as well as the underpinning ethical principles.

CHAPTER 3

METHODOLOGY

3.1 Chapter Introduction

This chapter describes the research methodology and procedures used for the data collection for the study. The following topics will be covered in this chapter namely: research objectives, the pilot test of data collection forms, research design, sample and sampling methods, informed consent and research variables explored. Furthermore, the chapter will cover research instruments, data analysis, ethical considerations and end with the chapter summary.

The study used two steps that were designed to address the objectives of this study. The first step involved a prospective collection of data related to exposure indices, exposure factors and other factors affecting the EI for the adult PA chest, AP pelvis and lateral lumbar spine examinations. Three hundred and thirty-four images acquired on patients referred for diagnostic imaging, were recorded at the research site (n=114 of the PA Chest; n=107 of the AP pelvis and n=113 of the lateral lumbar spine). The radiographer selected mAs and kVp values to produce the EI (referred to henceforth as test EIs), as well as obtaining the EI recommended by the manufacturer (referred to henceforth as reference EIs) were also recorded.

The second step involved the use of PCXMC Monte Carlo calculation software to calculate the radiation dose to the patients undergoing the above stated three radiographic examinations. The exposure factors (mAs and kVp) and associated test and reference EIs were recorded and correlated with the associated ESDs. The findings of the latter will be discussed in Chapter 4 of this thesis.

3.2 Aim and Research Objectives

This study aimed at evaluating factors affecting EI in the application of CR at a second level hospital in Zambia and the association between EIs and radiation dose to the patient. The research objectives were as follows: whether there was a significant difference between the EI for CR of the PA chest, AP pelvis and lateral lumbar spine in an adult population and the standard/recommended EI. Secondly, the study sought to establish whether there was an association between specific patient and technical factors (gender, weight, and technical factors like kVp, mAs, SSD, FSD) and EI. Thirdly, whether an association existed between EI and radiation dose in this study population.

3.3 Research Design

This study employed a quantitative, descriptive approach to conduct this scholarly inquiry. A quantitative approach was used to express a large number of information in numerical form whereas the descriptive approach was used to describe non-numerical details about the study (Hicks, 2009). A non-experimental cross-sectional design was used to relate variables and to describe EI accuracies in a population of individual radiographers in the application of the CR X-ray unit. A non-experimental design was used because the study did not subject participants to any form of experiments or treatment, to determine if there were any differences in the outcome which could be attributed to the intervention they received. An experimental design involves alteration of one of the variables to see what difference it makes to the other variable (Hicks, 2009). The cross-sectional approach in this study used a correlational research process at one point in time to measure the degree of association (or relation) between two or more variables which included dependent variables such as the ESD, EI, by radiographers using the CR unit, the independent variables; technique and exposure factors (mAs and kVp) using statistical procedures of association and correlational analysis.

3.4 Pilot Testing of data collection forms

The data collection form used in this study was designed by the researcher with the aim of establishing how individual radiographers used parameters of the CR imaging system under study and is explained in detail under section 3.8.2 of this chapter. This data collection form was not adopted from any other source and is the work of the researcher. A pilot test was done to establish whether the data collection form was user-friendly, included all relevant information and whether this form was clearly understood by participating diagnostic radiographers in order to correctly capture the required variables. The radiographers tested the data collection form on nine patients: three for each examination (PA chest, AP pelvis and lateral lumbar spine). No problems were encountered so the original form designed as per Appendix 1 was used for the main study. Data from the pilot study did not form part of the main data set.

3.5 Sample size and sampling methods

Participants who assisted with the data collection included diagnostic radiographers working at the research site; both male and female and ranged in ages from 25 to 40 years old. The population of these diagnostic radiographers were registered with the

Radiation Protection Authority (RPA) and with the Health Professions Council of Zambia (HPCZ). All radiographers (n = 10) (excluding student radiographers) at the study research site were asked to participate voluntarily. The radiographers were experienced in performing the X-ray examinations of the PA chest, lateral lumbar spine and AP pelvis. These radiographers were requested to complete the data entry forms of patients routinely referred for imaging studies onto the data collection form tested during the pilot. The data collection process is described in detail under section 3.6 of this chapter. Collection of the said data was done in line with the required ethical considerations which are discussed under Section 3.11 of this chapter.

Patients referred for imaging studies were selected using convenient/incidental sampling of consecutive patients. Incidental sampling was used because the study employed a non-probability method of collecting data which involved selecting the most easily accessible people from the population (Hicks, 2009). No specific patient was assigned to a specific radiographer. Patient data was collected between January 2020 and May 2020 between 08:00 to 18:00 and after hours from 18:00 to 08:00. Data were collected for 335 adult patients (≥ 18 years), of both sexes who were referred for PA chest, AP pelvis and the lateral lumbar spine X-ray examinations.

The PA chest, the AP pelvis and lateral lumbar spine X-ray examinations were preferred because they are the examinations that are requested for frequently at the research site. Specifically, these areas of the body contain some of the radiation sensitive organs, for example reproductive organs (ovaries) are located in the primary X-ray beam during pelvic examinations, while the lateral lumbar spine requires a higher exposure and has a higher dose compared to the other two examinations, and the testes are very near to the primary beam in the lumbar spine examination. The study population of patients considered only adult patients (aged 18 years and above) whose data variations in exposure factors were not expected to be as much compared to children. For the sample size, the researcher was guided by the statistician during the data collection process to establish when sufficient data was collected for statistical significance purposes. A sample size of n=335 X-ray examinations of the three body regions indicated above was considered adequate for this study.

3.6 Informed Consent

Radiographers were requested to take part in the study using a participant information sheet (Appendix 2) and afterwards made to sign the informed consent form (Appendix 3)

since they were directly involved in data collection. Before signing the informed consent form, the researcher asked radiographers to read and understand the contents of the informed consent form. As for the patients, a letter requesting them to participate in the study was provided to them (Appendix 4). The radiographer explained the procedure to the patient before they were requested to sign the consent form stating the nature of the examination and the data which would be collected from their file (Appendix 5).

3.7 Research Variables

Taking into consideration the research objectives of this thesis outlined in Chapter 1 of this study, a number of independent and dependent variables were noted. While the dependent variables were the ESD, EI, radiographers' correct use of CR unit, the independent variables included technique and exposure factors (mAs and kVp). Exposure factors were considered to be independent variables in that when altered, it would affect the dependent variable like EI and ESD. These variables were described in Chapter 1, section 1.1 and were used for calculating dose.

3.8 Research Instruments

3.8.1 Computed Radiography Unit

The department had two X-ray rooms that were fully registered with, and monitored by the RPA, Ministry of Health, of Zambia. The CR unit used in this study was installed at the hospital in February 2016 and was a Fuji X-ray unit; Model-E7242X (2015). This unit is connected to a computer scanner (FCR Prima T2; Model-CR-IR 392 (2014), Japan, with an acceptable '*S*' value in the range of 200 to 400.

The X-ray room used in this study is one of the restricted rooms in the hospital radiology department, requiring RPA certification. The X-ray room and X-ray unit were subject to radiation safety checks by the RPA, a department in the Ministry of Technology. The room is labelled as Room 2 and consisted of a Fuji under Bucky Diagnost installed in 2016.

The specifications for a number of characteristics of the X-ray unit which include the X-ray generator, X-ray tube, kVp and mAs ranges, collimator as well as the scatter radiation grid used with the relevant X-ray table are listed in Table 3.1 below:

Table 3.1: Specifications of the CR unit used in this study.

Characteristics	Specifications
X-Ray Generator	High Voltage – FujiFilm GXR-40
kVp Range	40–125 kVp
mAs Range	0.5 to 800 mAs
AEC – X-Ray Table	AEG
X-Ray Tube	Toshiba Rotanode
Focal Spot Sizes Small	Small = 0.6 mm Large = 1.5 mm
Anode Target Angle	14°
Filtration	Permanent Filtration = 0.9 mm Al/75kV (Additional 0.4 mm – 1.5 mm)
Collimation	Yes, beam dimensions in inches or cm
Grid in X-Ray Table	Yes
Focal Distance of Tube to Table	40 to 178 cm range

AEC = Automatic Exposure Control
AEG = Allgemeine Electric Gesellschaft
AI = Aluminium

The figure 3.1 below shows the components of the x-ray unit used for the data collection.

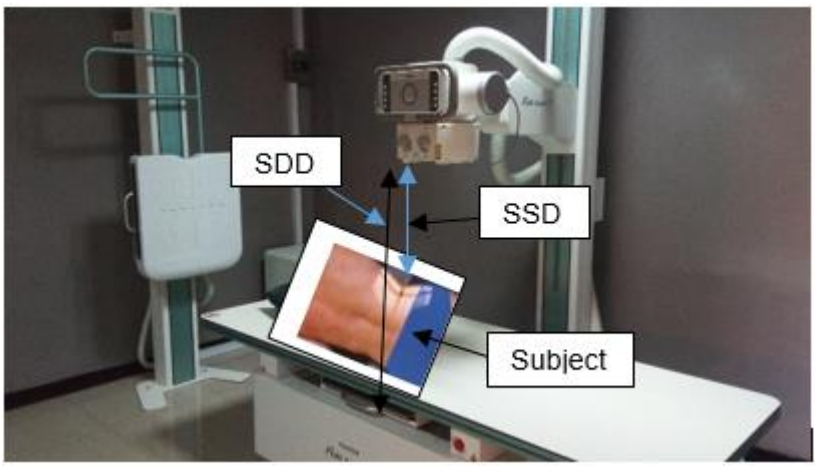


Fig 3.1: Diagrammatic illustration for imaging of the Lateral Lumbar Spine.

The components of the x-ray unit used in this study is as shown in figure 3.2 below:

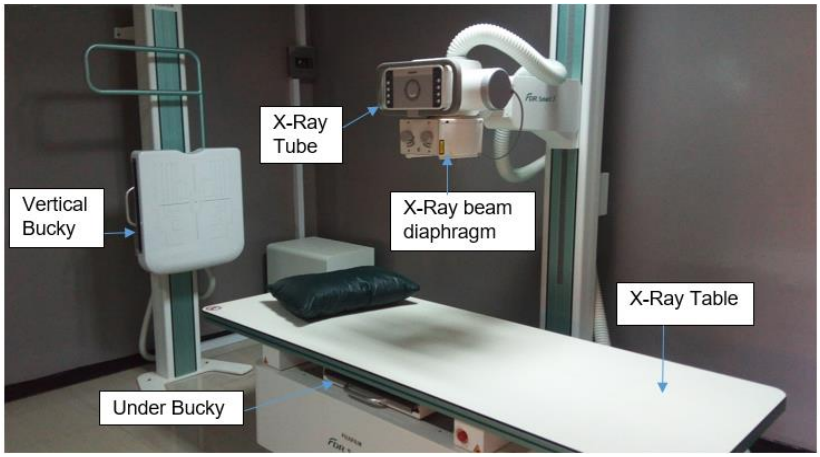


Fig 3.2: Image of the Fuji X-Ray unit

The image processing equipment was a Fuji CR system. The three major components of this system are demonstrated in Figure 3.3. These are the CR imaging plate enveloped in a CR cassette; the laser scanning and plate erasure components (commonly referred to as the CR scanner/processor) as well as the image review computer workstation.

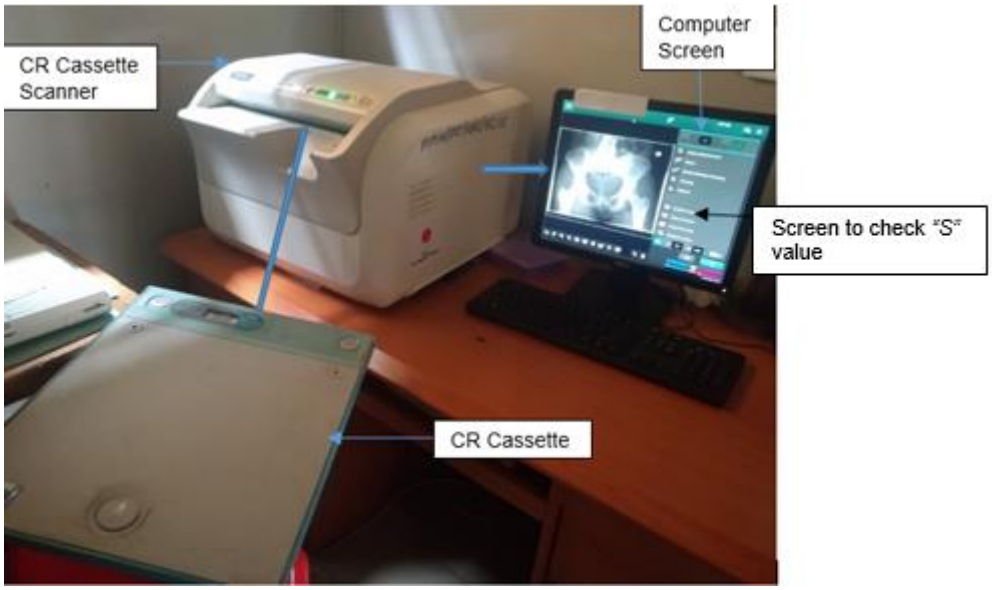


Fig 3.3: Image acquisition system and screen to check the ***'S'*** value **(EI)**

3.8.2 Data collection methods

In order to record the required data for the PA chest, AP pelvis and lateral lumbar spine, radiographers had to complete a data collection form (Appendix 1) used during the pilot test. This data collection form was designed by the researcher to establish how individual radiographers used parameters of the CR imaging system under study. Completion of the

data collection form involved entering of data under each column by hand and determining optimum exposure factors and associated EI generated by radiographers.

The data collection form was completed by all the participating radiographers where each was assigned a separate form to complete. The completed forms were collected immediately by the researcher and kept securely in the researcher's office within the radiology department. The data collection form consisted of 15 variables organised around the following headings:

i. Patient details included study number, age and gender.
ii. Part to be examined which included PA chest, AP Pelvis and lateral lumbar spine.
iii. kVp recorded the voltage used for each specific examination.
iv. mAs recorded the 'current' used for each specific examination.
v. FSD (cm) recorded the distance between the X-ray tube focus and the subject.
vi. SDD (cm) recorded the distance between the source (focus) and the IP.
vii. Field size (cm) recorded the field on the patient which was being exposed to radiation.
viii. Anode angle which recorded the angle the target surface of the anode sits at in relation to the vertical. The X-ray unit used in this study had an anode angle of 14º.
ix. Filtration: This entails recording the filtration applied for each examination. The X-ray unit used for this study had a permanent filtration of 0.9Al/75.
x. Date of examination recorded whether it was Monday - Friday, weekend or on a public holiday.
xi. Time of examination recorded whether the time of the examination fell within normal working hours (Monday-Friday 8am – 4pm) or outside working hours (Monday-Friday 4pm – 8am, weekend and public holiday).
xii. Height (cm): The height of the patient was recorded.
xiii. Weight (kg): The weight of the patient was recorded.
xiv. Type of exposure: There was an option of Auto/Manual. The unit used for this study had manual type of exposure.
xv. EI: This involved recording the EI generated by the unit for each image processed in this study. This was important since this study explored the optimisation of the EI as a dose-management strategy.

3.8.3 Use of PCMXC Monte Carlo software

Patient dose assessment was done by comparing the radiographer generated EIs for the PA chest, AP pelvis and lateral lumbar spine to those of the manufacturer. To achieve

this, and with the help of the statistician, the Monte Carlo formula was used to calculate effective radiation dose for each examination/patient. The kVp, mAs, FSD, SID, Field size, anode angle, filtration, EI, height and weight for each of the PA chest, AP pelvis and lateral lumbar spine examinations done, were computed using the Monte Carlo software. The Monte Carlo computation generated the effective dose. The use of the Monte Carlo software is explained in Chapter 2 Section 2.16.

The data collected included information regarding the examination performed, exposure factors, the exposure index; the date and time when the radiographic exposures were taken which were used to classify the radiographs into two: those taken 'in hours' and 'out of hours'. The factors mentioned in this paragraph were measured in order to establish whether gender, time and/or day when the examination was performed had any influence on the way radiographers select exposure factors and subsequently on EI values. The patients' weight and height were copied from the patients' medical records folder as recorded by the referring department.

3.9 Data Analysis

Data was analysed with the help of a statistician using the Monte Carlo software. Nonparametric tests such as correlation between effective dose and EI for the PA chest, AP pelvis and the lateral lumbar were used as a way of establishing whether there was a substantial difference between the EI for CR of the PA chest, pelvis and lateral lumbar spine examination and the EI recommended manufacturers. Tables and graphs were used to display data. Secondly, the nonparametric independent-Samples Mann-Whitney U Test was used to test difference in categories across sex and time for CR of the PA chest, pelvis and Lateral Lumbar spine. Nonparametric correlations were done for each examination to test the influence of the continuous variables (kVp, mAs, height and weight) on the radiographers' generated EIs. Tables and graphs were used to present the findings which are described in Chapter 4 of this thesis. Thirdly, nonparametric correlations were used to analyse the relationship between EI and radiation dose. Nonparametric correlations were used due to the fact that the EI was not normally distributed. Tables and G-Graphs were used. These results are described in detail in Chapter 4.

3.10 Ethical considerations.

Ethics is defined as the study or science of moral values or ethical principles which consist of beneficence, justice and autonomy as outlined by the South African Medical

Research Council (Anderson, 2001; SAMRC, 2004). An extract from the Helsinki Declaration of, 2013 states that ‘‘every precaution must be taken by researchers to safeguard the privacy of research subjects and the confidentiality of their personal data and to lessen the effect of the study on their physical, mental and social integrity’’ (World Medical Association {WMA}) (Granerud, 2013). In order to achieve this, the researcher maintained anonymity of the patients, hospital and participating radiographers throughout the study. The radiographers' names were not recorded on the data collection form, and the completed forms were not stored separately for each radiographer but were all put in the same secured cabinet in order to maintain confidentiality. When extracting patient information from the CR unit workstation computer, the name of the patient was not recorded for the purpose of this study. Patient's hospital numbers were recorded but these were only used as a cross-reference for the data collected. The informed consent form used in this study had a statement concerning the participation of individuals in the study assuring them that confidentiality will be strictly maintained. The completed forms were kept in a lockable cabinet in the office where only the researcher had access to the data. The publications that will derive from this study would also not reveal the name of the research site nor participants.

All the measures outlined in the preceding paragraph were done taking into consideration the following Helsinki principles of ethics as acknowledged by the SAMRC (SAMRC, 2004):

Autonomy (respect for the person - a notion of human dignity). This calls for the patient to have autonomy of thought, intention, and action when coming up with decisions regarding health care procedures (Granerud, 2013). Therefore, for this study, the decision-making process was free of coercion and participants were free to withdraw their participation at any stage of the study without any penalties on their part. It was important for the patient to understand all the risks and benefits of the procedure and the likelihood of success in order for him/her to make a fully informed decision. The researcher sought to explain the procedure to the patient and that the examination would take longer than usual. Upon acceptance, the patient was required to sign a consent form as stated above. This step assisted in ensuring that the patients' rights to a fully informed decision were not infringed upon as per the Helsinki declaration, principle of autonomy (Granerud, 2013).

Beneficence (benefit to the research participant). This requires that the procedure be provided with the intent of doing good for the patient involved (Granerud, 2013). The

principle of beneficence therefore demands that health care workers improve and maintain skills and knowledge, frequently update training, consider individual situations of all the patients, and strive for net benefit. The researcher conducted this study during normal routine daily activities of the radiology department. No patients were recruited outside the daily referrals to the department (radiographers did not book any patients specifically for this study). As such the principle of not exposing patients to unnecessary radiation or research procedures was applied, and therefore maintaining the safety of the patient throughout the examination; this is in line with the Helsinki principle of risks, burdens and benefits (Granerud, 2013).

Non-maleficence (absence of harm to the research participant). This aspect requires that a procedure does not injure the patient involved or others in society (Granerud, 2013); to achieve this, the study was conducted in a safe and certified X-ray room as indicated under Section 3.8.1 of this chapter, and all procedures were conducted by qualified diagnostic radiographers. The researcher took all necessary steps aimed at protecting the radiographers' integrity by maintaining their anonymity.

The radiographers were required to have an up-to-date practicing license and a thermo luminescent device (TLD). Radiographers also signed a consent form as stated above with assurance that they could pull out from the study at any given time. In order to ensure that radiographers were not overworked, a flexible arrangement was made in completing the data collection form. Only the researcher had access to patients' data which was kept in a lockable and secure place located in the office.

3.11 Ethics approval and site permission

Permission for a go ahead to conduct this study was sought from the research site's Human Resource Development Committee (HRDC) (Appendix 6). Research Site permission was obtained from the hospital (Appendix 7) and Research Ethics Committee of the Faculty of Health and Wellness Sciences at the Cape Peninsula University of Technology (CPUT) (Appendix 8). The ethical permission provided by the CPUT sufficed for the study as the hospital's site permission could not be considered as having received ethical approval.

3.12 Chapter Summary

This chapter presented information about the study design; subjects and population included, research variables; the pilot study conducted, data collection and analysis as well as the ethical considerations upheld during the study. Participants included in this

study were all diagnostic radiographers (n = 10) employed at the study site. Patients were also included in this study and each of these participants completed an 'Informed Consent' form to indicate acceptance to be part of the study which is an ethical requirement as explained under Section 3.10 of this chapter.

Data was collected of consecutive adult (≥ 18 years) male and female patients who were referred for a PA chest, AP pelvis and the lateral lumbar spine examinations. The following factors were recorded for each examination; patient sex/gender, examination time, patient age, exposure factors (kVp & mAs), height (cm) and weight (kg). The Monte Carlo (PCXMC) computer software program was used to calculate radiation dose to specific organs for an X-ray examination of all patients enrolled. Ethical considerations upheld during this study included autonomy, beneficence and non-maleficence. The next Chapter describes the results of the study as they pertain to the research objectives.

CHAPTER 4

RESULTS

4.1 Chapter Introduction

This chapter presents the findings as related to the three objectives of the study which were to: establish whether there was a notable difference between the EI for CR of the PA chest, AP pelvis and Lateral Lumbar spine of the study population and manufacturer's recommended EI, whether there was an association between specific factors (gender, weight, and technical factors like kVp, mAs, SSD, FSD, filtration and field size) and EI and establish whether an the association existed between EI and radiation dose in this study population. This chapter will also present the findings from the PCXMC Monte Carlo calculations to calculate radiation dose to the patients who underwent X-ray examinations of the three examinations stated before. The following topics are described in this Chapter: General image data characteristics, comparison of EI for the different radiographic views, comparison of EI for CR versus recommended EI, gender association with EI, correlation of kVp, mAs, height and weight with EI and association between EI and radiation dose.

4.2 General image data characteristics

A total of 335 patients were included in the study as can be noted in Table 4.1. Data for all 335 radiographic images were analysed. The data analysed was segmented into three anatomical regions: chest, pelvis and lateral lumbar spine. More female patients were referred for imaging during the study period for the chest and pelvis views. The distribution by gender was tested for normality using the Shapiro-Wilk test with a p-value set at 0.05 as the level of significance. The Shapiro–Wilk test is a test of normality in frequentist statistics; it tests the null hypothesis that a sample came from a normally distributed population (Macintosh, 2004). Therefore if the statistical value calculated was less than the chosen alpha level, then the null hypothesis can be rejected and there is proof that the data tested were statistically significant. The results from the Shapiro-Wilk test showed a notable difference existed between the sample statistic of the EI generated by radiographers and the manufacturer's recommended EI. On the other hand, if the *p* value is greater than the selected alpha level, then the null hypothesis (that the data came from a normally distributed population) cannot be rejected (e.g., for an alpha level of 0.05, a data set with a *p* value of less than 0.05 rejects the null hypothesis that the data are from a normally distributed population) (Macintosh, 2004).

Table 4.1: Data distribution of age by gender

Examination View	Distribution			
	Female patients		Male patients	
	n (%)	Median Age (IQR)	n (%)	Median Age (IQR)
Chest	65 (57%)	25 (20-46)	49 (43%)	40 (26-49)
Lateral lumbar spine	51 (46.36%)	43 (31-65)	63 (57.27%)	47 (24-81)
Pelvis	60 (56%)	35 (29-54.5)	47 (43.9%)	47 (30-62)

Data of the PA chest, AP pelvis and the lateral lumbar spine that was not normally distributed was reported using median and associated interquartile range, whilst the normally distributed data was reported using the mean and standard deviation. Data distribution of median kVp and mAs by radiographic views is as shown in Table 4.2.

Table 4.2: Data distribution of median kVp and mAs by radiographic view

Radiographic views	**Median kVp (IQR)**	**Median mAs (IQR)**
Chest	81 (80-83)	10 (8-12.8)
Lateral lumbar spine	80 (70-90)	64 (64-65)
Pelvis	75 (73-80)	42 (40-44)

4.3 Comparison of EI for the different radiographic views

The first objective in the study compared the EI generated for each examination in comparison with the vendor's recommended EI. The interest in this statistical calculation was not to compare the EI of the three examinations but to compare/correlate the EI for each examination to the vendor's recommended EI values in order to check adherence to the recommended EI values. As can be noted in Table 4.3 below, the recommended EI is different for the chest compared to the lateral lumbar spine and pelvis views. The average generated EI is also different for the chest compared to the lateral lumbar spine and pelvis views. The table also shows that some radiographer generated EIs fell outside the manufacturer's recommended EIs.

Table 4.3: Clinical ranges of radiographer and manufacturer's Exposure Indices

Examination	Average EI	Coefficient of variation	Recommended EI	Radiographers' EI
PA Chest	515	41%	200 – 600	35 – 555
Pelvis	168	45%	100 – 400	43 – 439
Lateral Lumbar Spine	168	45%	100 – 400	35 – 419

To test whether there was a major difference between the actual EI for CR of PA chest, AP pelvis and lateral lumbar radiographic views, the non-parametric independent Samples Kruskal-Wallis Test was used. A Kruskal-Wallis test can be used whenever there is need to determine whether or not the difference between the medians of three or more independent groups is statistically notable (Zach, 2019). The assumptions for this test were that the distribution of EI is the same across categories of the radiographic views obtained with the level of significance (p) set at 0.05. The findings show that the results were statistically significant for this calculation between the three areas examined because of p being less than 0.001 ($p<0.001$). The statistic for the chest was higher than that of the lateral lumbar spine and AP pelvis whereas there was no significant difference between the lateral lumbar spine and AP pelvis. The box and whisker plot illustrated in Figure 4.1 shows the distribution of the EI for the three radiographic views, indicating the mean, median and range as demonstrated in table 4.4:

Table 4.4: Distribution of EI indicating Mean, Median and Range

Chest	Pelvis	Lateral lumbar spine
Mean = 311.56 (SD 131)	Mean = 196 (SD 97.3)	Mean = 202.5 (SD 94)
Median = 293.5 (53-540)	Median = 167 (52-395)	Median = 185 (59-382)
Radiographer's range = 35-836	Radiographer's Range = 43-439	Radiographer's Range = 35-419

SD = standard deviation

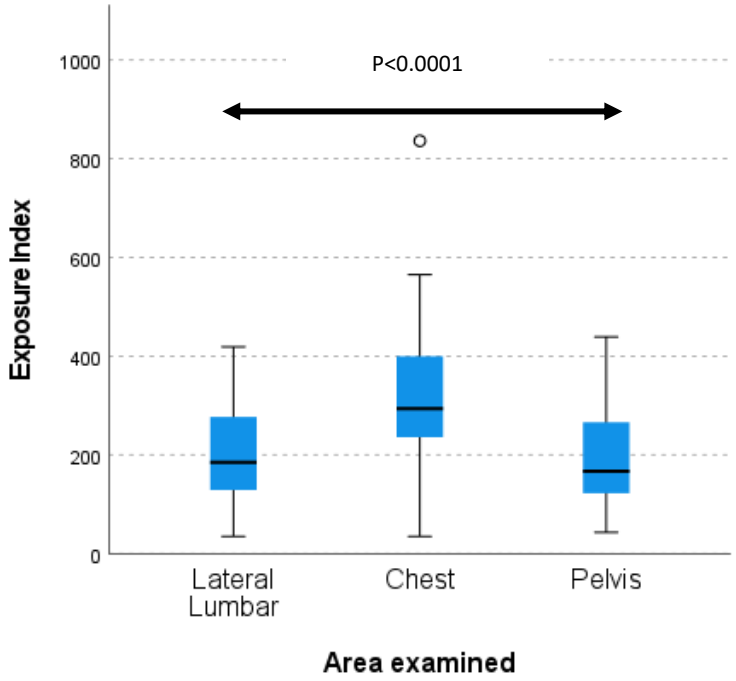


Figure 4.1: Distribution of the EI for the three radiographic views EIs across the different areas examined

The three categories of the radiographic views were compared in pairs. The purpose of comparing each option in pairs (twos) was done in order to simplify the decision-making process on the difference in EIs. Each row tests the null hypothesis that the Sample 1 and Sample 2 distributions were normally distributed. Asymptotic significances (2-sided tests) are displayed. The significance level was 0.05. Significant values have been adjusted by the Bonferroni correction for multiple tests. When the above mentioned pairwise comparison of the regions was done, a notable difference in the distribution of the EI was noted between the pelvis and lateral lumbar spine as illustrated in table 4.5 below:

Table 4.5: Pairwise comparisons of area examined

Sample 1-Sample 2	Test Statistic	Std. Error	Std. Test Statistic	Sig.	Adj. Sig.[a]
Pelvis-lateral lumbar	7.630	13.035	.585	.558	1.000
Pelvis-chest	90.950	13.035	6.977	.000	.000
lateral lumbar-chest	-83.320	12.827	-6.496	.000	.000

4.4 Comparison of EI for CR versus recommended EI

Another statistical calculation performed was to compare/correlate the EI for each examination to the manufacturer recommended EI values to check adherence to the recommended EI values. Firstly, the EI values were tested for normality using both Kolmogorov-Smirnova and Shapiro-Wilk tests. In statistics, the Kolmogorov–Smirnov test is a nonparametric test of the equality of continuous or discontinuous, one-dimensional probability distributions that can be used to compare a sample with a reference probability distribution (one-sample Kolmogorov–Smirnov test) or to compare two samples (two-sample Kolmogorov–Smirnov test) (Dimitrova et al., 2020). The Shapiro–Wilk test is a test of normality in frequentist statistics; it is explained in detail in section 4.1 of this chapter. The table below shows that a notable difference existed between radiographers' EIs and the manufacturer's recommended EI.

Table 4.6: Kolmogorov-Smirnov and Shapiro-Wilk tests comparing EI for each examination to the recommended EI values

	Area examined	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
		Statistic	df	Sig.	Statistic	df	Sig.
Exposure Index	Lateral lumbar spine	.088	114	.031	.956	114	.001
	Chest	.105	114	.004	.968	114	.007
	Pelvis	.145	107	.000	.930	107	.000

a. Lilliefors Significance Correction

4.4.1 Lateral lumbar spine

For the lateral lumbar spine, a one sample Student T-Test was done to compare the average EI with the manufacturer's recommended EIs as shown in table 4.7 below. A one sample test of means compares the mean of a sample to a pre-specified value and tests for a deviation from that value (Macintosh, 2004)**.**

Table 4.7: One-Sample T-test Statistic of the lateral lumbar spine

	N	Mean	Std. Deviation	Std. Error Mean	Coefficient of variation
Exposure Index	114	202.53	94.039	8.808	46.4%

The one sample static for the lateral lumbar spine showed that a significant difference existed between the sample statistic and the manufacturer's recommended EI of 168 as demonstrated in tables 4.7 above and 4.8 below.

Table 4.8: One-Sample Student T-Test of the lateral lumbar spine with Test value of 168

	Test Value = 168					
	t	df	*p*-value. (2-tailed)	Mean Difference	95% Confidence Interval of the Difference Lower	Upper
Exposure Index	3.920	113	<0.001	34.526	17.08	51.98

4.4.2 PA Chest

A One sample Student T-Test of the Chest was done to compare the average radiographers' EI with the EI recommended by the manufacturers. The one sample statics for chest is summarised in table 4.9 below:

Table 4.9: One-Sample T-Test Statistic of the chest

	N	Mean	Std. Deviation	Std. Error Mean	Coefficient of Variation
Exposure Index	114	311.56	131.411	12.308	42.18%

The One sample Student T-test using 515 (manufacturer's average EI) as a test value showed that a significant difference existed between the sample statistic and the recommended EI of 114 as demonstrated in the table below.

Table 4.10: One-Sample Student T-Test of the chest with Test Value of 515

	t	df	*p*-value. (2-tailed)	Mean Difference	95% Confidence Interval of the Difference Lower	Upper
Exposure Index	-16.529	113	.000	-203.439	-227.82	-179.05

4.4.3 AP Pelvis

The One sample Student T-Test of the pelvis with actual value of 168 One-Sample Statistics was done as shown in the table below.

Table 4.11: One-Sample Student T-Test of the AP pelvis

	N	Mean	Std. Deviation	Std. Error Mean	Coefficient of Variation
Exposure Index	107	196.16	97.254	9.402	49.58

The actual One sample Student T-Test using the 168 (manufacturer's average EI) value showed that a significant difference existed between the sample statistic (p=0.003) and the recommended EI of 107 as demonstrated in table 4.12 below:

Table 4.12: One-Sample Student T-Test of the AP pelvis with Test Value of 168

	t	df	*p*-value. (2-tailed)	Mean Difference	95% Confidence Interval of the Difference	
					Lower	Upper
Exposure Index	2.995	106	.003	28.159	9.52	46.80

The second objective was to establish whether there was an association between specific factors (age, gender, technical factors like kVp and mAs, radiographic views, normal working hours/after hours) and EI. For each of the regions each specific factor was analysed in relation to the manufacturer's recommended EIs for association.

4.5 Gender association with EI

4.5.1 Lateral lumbar spine - An Independent-Samples Mann-Whitney U Test was performed with significance set at 0.05. A Mann-Whitney U test is used to compare the variances between two independent samples when the sample distributions are not normally distributed, and the sample sizes are small (n <30) (Zach, 2019). It was found that gender did not have a significant influence on the MREI – in the lateral lumbar spine p=0.667). Figure 4.2 below shows the distribution comparison between the female and males.

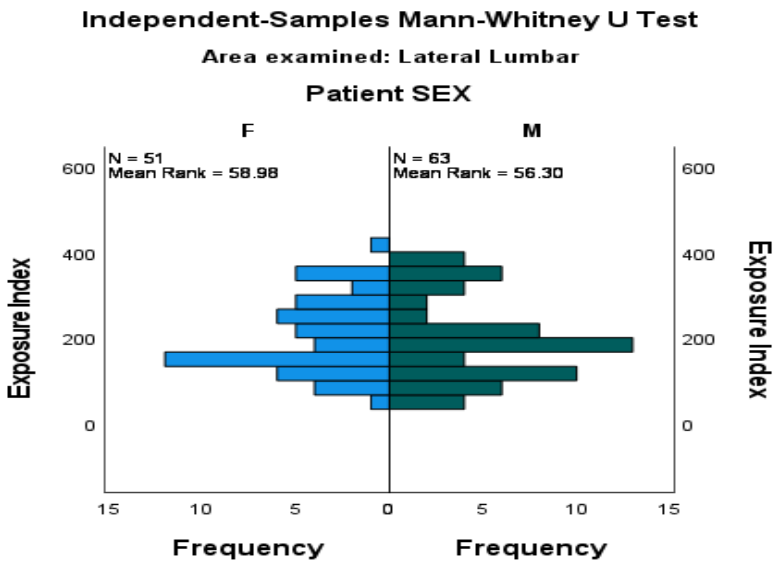


Figure 4.2: Frequency distribution comparison of EI for female versus male for the lateral lumbar spine

4.5.2 PA Chest - An Independent-Samples Mann-Whitney U Test was performed with significance set at 0.05. Gender did not have a significant influence on the MREI – in the chest area; *p*=0.952). The graph below shows the distribution comparison between the females and males.

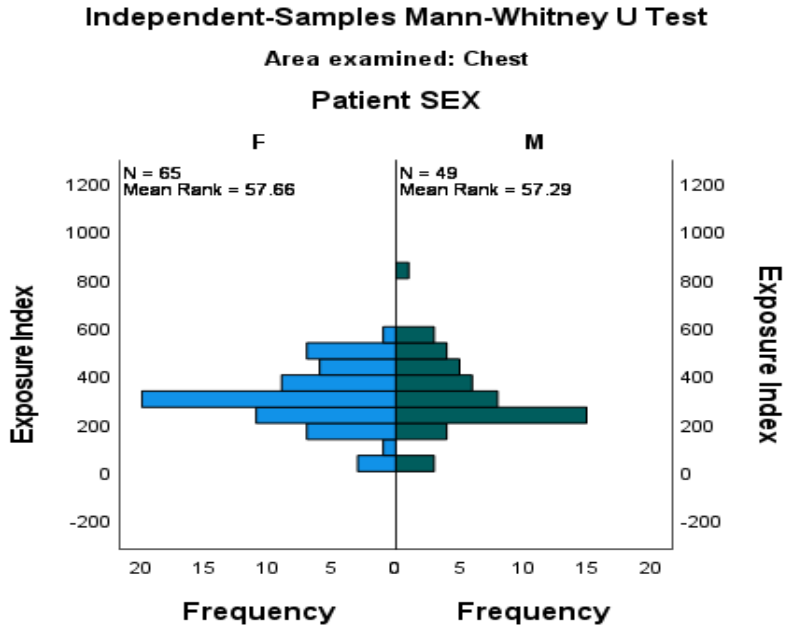


Figure 4.3 Distribution comparison of EI for the chest between females and males

4.5.3 AP Pelvis - An Independent-Samples Mann-Whitney U Test was performed with significance set at 0.05. Gender did not have a significant influence on the manufacturer's recommended EI – in the pelvis area; *p*=0.917). The graph below shows the distribution comparison between the female and males.

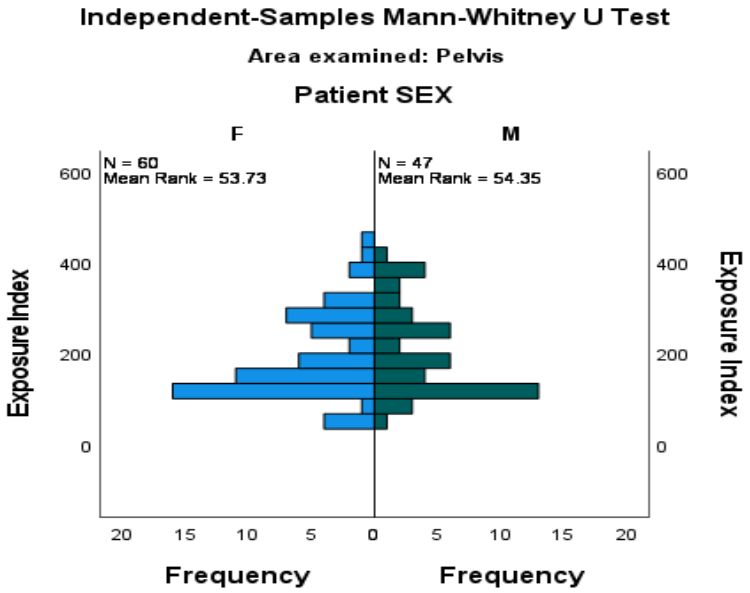


Figure 4.4 Distribution comparison of EI for the pelvis between the female and males

4.6 Correlation of kVp, mAs, height and weight with EI

4.6.1 Lateral lumbar spine

Table 4.13 below shows the outcome of a correlation analysis between the radiographers' generated EI and the manufacturers recommended EI for the lateral lumbar spine examination. The EI was correlated to the continuous variables (kVp, mAs, height, and weight) and it must be noted that the distribution was not normally distributed. The table demonstrates the correlation coefficient and *p* value of the lumbar spine for each exposure parameter. As highlighted, none of the *p*-values were less than < 0.05 – so none of these variables had a significant correlation with manufacturer's recommended EI – in the lateral lumbar Spine. See table 4.13 below.

Table 4.13: Correlations of the kVp, mAs, height and weight with EI for lateral lumbar Spine

			Exposure Index
Spearman's rho	kVp	Correlation Coefficient	.041
		p-value (2-tailed)	0.665
		N	114
	mAs	Correlation Coefficient	-.056
		p-value (2-tailed)	0.557
		N	114
	HEIGHT (CM)	Correlation Coefficient	-.115
		p-value (2-tailed)	0.225
		N	114
	WEIGHT (KG)	Correlation Coefficient	-.004
		p-value (2-tailed)	.970
		N	112

*.Correlation is significant at the 0.05 level (2-tailed).

a. Area examined = Lateral lumbar spine

4.6.2 PA Chest

Table 4.14 below shows the outcome of a correlation analysis between the radiographers' generated EI and the manufacturers recommended EI for the PA chest examination. The EI was correlated to the continuous variables (kVp, mAs, height, and weight) and it must be noted that the distribution was not normally distributed. The table demonstrates the correlation coefficient and *p* value of the PA chest for each exposure parameter. As highlighted, none of the *p*-values were less than < 0.05 – so none of these variables had a significant correlation with manufacturer's recommended EI – in the PA chest examination. See table 4.14 below.

Table 4.14: Correlations of kVp, mAs, height and weight with EI for the Chest

			Exposure Index
Spearman's rho	kVp	Correlation Coefficient	-.143
		p-value (2-tailed)	.128
		N	114
	mAs	Correlation Coefficient	.122
		p-value (2-tailed)	.197
		N	114
	height (cm)	Correlation Coefficient	-.090
		p-value (2-tailed)	.342
		N	114
	weight (kg)	Correlation Coefficient	.166
		p-value (2-tailed)	.082
		N	111

4.6.3 AP Pelvis

Table 4.15 below shows the outcome of a correlation analysis between the radiographers' generated EI and the manufacturers recommended EI for the pelvis examination. The EI was correlated to the continuous variables (kVp, mAs, height, and weight) and it must be noted that the distribution was not normally distributed. The table demonstrates the correlation coefficient and *p* value of the lumbar spine for each exposure parameter. As highlighted, none of the *p*-values were less than < 0.05 – so none of these variables had a significant correlation with manufacturer's recommended EI – in the pelvis examination. See table 4.15 below.

Table 4.15: Correlations kVp, mAs, Height and Weight with EI for the Pelvis

			Exposure Index
Spearman's rho	kVp	Correlation Coefficient	.049
		p-value (2-tailed)	.615
		N	107
	mAs	Correlation Coefficient	.136
		p-value (2-tailed)	.163
		N	107
	Height (CM)	Correlation Coefficient	.053
		p-value (2-tailed)	.588
		N	107
	Weight (KG)	Correlation Coefficient	.061
		p-value (2-tailed)	.539
		N	104

4.7 Association between EI and radiation dose

The third objective was based on the use of PCXMC Monte Carlo calculation software to estimate radiation dose to the patients undergoing the three X-ray examinations. This software was used to calculate patient doses using a batch of data files (Patient sex/gender + examination time + patient age + kVp + mAs + height {cm} + weight {kg}). The software renamed the data file and called it PCXMC 2.0 rotation once for each of the data files processed. Renaming and deleting of files in the folder was done without having the user to hamper with such operations. This automatic calculation was invoked by saving a file named 'Autocalc.dfR' in the folder 'PCXMC\MCRUNS'. When PCXMC 2.0 was started, the program checked whether a file of this name existed in this folder. Once the file was found, the program would start the Monte Carlo simulation detailed in the Autocalc.dfR file and then calculate the patient's organ doses. The calculated dose was used to show how well the participants' effective doses compared to the recommended ones; then the result was checked to see if there was a pattern with high doses for uterus, ovaries and testicles (reproductive organs) for each of the three examinations. The exposure factors (mAs and kVp) and related EIs for both reference and test were recorded

and correlated with the associated ESDs. The objective was to establish the association between EI and radiation dose in this study population. Finally, a correlation between EI and effective dose was made to check whether non-adherence to the recommended EI had a positive relation with an increase in radiation dose. Table 4.16 shows the adult effective radiation doses for diagnostic radiology procedures and the recommended dose (Mettler et al., 2008).

Table 4.16: Adult effective radiation doses for diagnostic radiology procedures

AREA EXAMINED	AVERAGE DOSE	RECOMMENDED DOSE
Lateral lumbar spine	1.15 mSv	0.5 – 1.8 mSv
PA chest	0.02 mSv	0.007 – 0.050 mSv
Pelvis	0.6 mSv	0.2 – 1.2 mSv

The objective also sought to establish whether the high doses were potentially imparted to the uterus, ovaries and testicles (reproductive organs) for each examination. A secondary objective was to establish whether non-adherence to recommended EI had any association to the increase in radiation dose.

4.7.1 Correlation for the lateral lumbar spine EI and radiation dose

Table 4.17 shows the outcome of a Spearman's rho correlation analysis between the radiographers' EI and effective dose (ED) obtained as per the ICRP 103 for the lateral lumbar spine examination. The results showed no significant association between the radiographer's EI and ED. This is as displayed in Table 4.17 below.

Table 4.17: Correlation between effective dose and EI for lateral lumbar spine view

Correlations

			Effective Dose ICRP103	Exposure Index
Spearman's rho	EFFECTIVE DOSE ICRP103	Correlation Coefficient	1.000	.051
		Sig. (2-tailed)	.	.591
		N	114	114
	Exposure Index	Correlation Coefficient	.051	1.000
		Sig. (2-tailed)	.591	.
		N	114	114

4.7.2 Correlation for the PA chest view

Table 4.18 shows the outcome of a Spearman's rho correlation analysis between the radiographers' EI and ED obtained as per the ICRP 103 for the PA chest examination. The results showed no significant association between the radiographer's EI and ED. This is as displayed in Table 4.18 below.

Table 4.18: Correlation between effective dose and EI for PA Chest view

Correlations[a]

			Effective Dose ICRP103	Exposure Index
Spearman's rho	Effective dose ICRP103	Correlation Coefficient	1.000	-.127
		Sig. (2-tailed)	.	.178
		N	114	114
	Exposure Index	Correlation Coefficient	-.127	1.000
		Sig. (2-tailed)	.178	.
		N	114	114

4.7.3 Correlations between effective dose and EI for the AP pelvis

Table 4.19 shows the outcome of a Spearman's rho correlation analysis between the radiographers' EI and ED obtained as per the ICRP 103 for the AP pelvis examination. The results showed that correlation was significant at the 0.05 level (2-tailed) which indicates that there was a significant association between the radiographers' EI and ED for the AP pelvis (p-value < 0.05). The results are tabulated in Table 4.19 below.

Table 4.19: Correlation between effective dose and EI for the pelvis view

Correlations[a]

			Effective Dose ICRP103	Exposure Index
Spearman's rho	Effective dose ICRP103	Correlation Coefficient	1.000	.236*
		Sig. (2-tailed)	.	.015
		N	107	107
	Exposure Index	Correlation Coefficient	.236*	1.000
		Sig. (2-tailed)	.015	.
		N	107	107

Table 4.20 below shows the mean and standard deviation of the ED for 114 examinations of the lumbar spine.

Table 4.20: One-Sample Statistic for the lumbar spine

	N	Mean	Std. Deviation	Std. Error Mean
Effective dose ICRP103	114	.18943951	.081244375	.007609233

Table 4.21 below shows the outcome of a one sample statistic T-Test for the lumbar spine where the average ED from the sample was 0.189 mSv (as shown in Table 4.20 above), whilst the recommended ED range by ICRP is between 0.5 – 1.8 mSv (average of 1.15 mSv). The table summarises the comparison between the obtained average ED and the recommended ED for lateral lumbar spine. The results showed a significant difference between ED and the recommended ED of 1.15mSv for the lumbar spine view as shown in Table 4.21 below.

Table 4.21 One-Sample T-Test for the lateral lumbar spine

	Test Value = 1.15					
	t	df	P-value. (2-tailed)	Mean Difference	95% Confidence Interval of the Difference Lower	Upper
Effective dose ICRP103	-172.233	113	.000	-1.310560491	-1.32563575	-1.29548523

Table 4.22 below shows the mean and standard deviation of the ED for 114 examinations of the PA chests.

Table 4.22: One-Sample T- Test Statistic for the chest

	N	Mean	Std. Deviation	Std. Error Mean
Effective dose ICRP103	114	.01945425	.006739894	.000631249

Table 4.23 below shows the outcome of a one sample statistic T-Test for the PA chest where the average ED from the sample was 0.019 mSv (as shown in Table 4.22 above), whilst the recommended ED range by ICRP is between 0.007 – 0.050 mSv (average of 0.02 mSv). The table summarises the comparison between the obtained average ED and the recommended ED for the chest examination. The results showed no notable difference between the ED and the recommended ED of 0.02mSv for the PA chest as shown in Table 4.23 below.

Table 4.23: One-Sample T-Test for the PA chest

	Test Value = 0.02					
	t	df	p-value. (2-tailed)	Mean Difference	95% Confidence Interval of the Difference Lower	Upper
Effective dose ICRP103	-.865	113	.389	-.000545754	-.00179637	.00070486

Table 4.24 below shows the mean and standard deviation of the ED for 107 examinations of the pelvis.

Table 4.24: One-Sample T-Test Statistic for the AP pelvis

	N	Mean	Std. Deviation	Std. Error Mean
EFFECTIVE DOSE ICRP103	107	.42317408	.140956663	.013626795

Table 4.25 below shows the outcome of a one sample statistic T-Test for the pelvis where the average ED from the sample was 0.423 mSv (as shown in Table 4.24 above), whilst the recommended ED range by ICRP is between 0.2 – 1.2 mSv (average of 0.6 mSv). The table summarises the comparison between the obtained average ED and the recommended ED for the chest examination. The results showed a significant difference between ED and the manufacturer's recommended ED of 0.6mSv for the pelvis view as shown in Table 4.25 below.

Table 4.25: One-Sample T-Test for the AP pelvis

	Test value = 0.6					
	t	df	*p*-value. (2-tailed)	Mean Difference	95% Confidence Interval of the Difference Lower	Upper
Effective dose ICRP103	-2.976	106	.000	-.176825916	-.20384236	-.14980947

The scatter diagram graph pairs of numerical data, between the effective dose and one variable (e.g., uterus, ovaries, and testicles) on each axis, to look for a relationship between them was also computed. This graph was used to correlate effective dose to the area being examined.

Figure 4.5 below shows the scatter plot of ED to the uterus when examining the pelvis. The graph used plots with the line of best fit to show this relationship. The results showed that scatter radiation was more to the uterus when examining the pelvis which indicates

a positive correlation between the pelvis examination and ED to the uterus. The scatter plot of the uterus for the pelvis examination is illustrated in figure 4.5 below.

Figure 4.5: Scatter Plot of radiation dose to the uterus for the pelvis view.

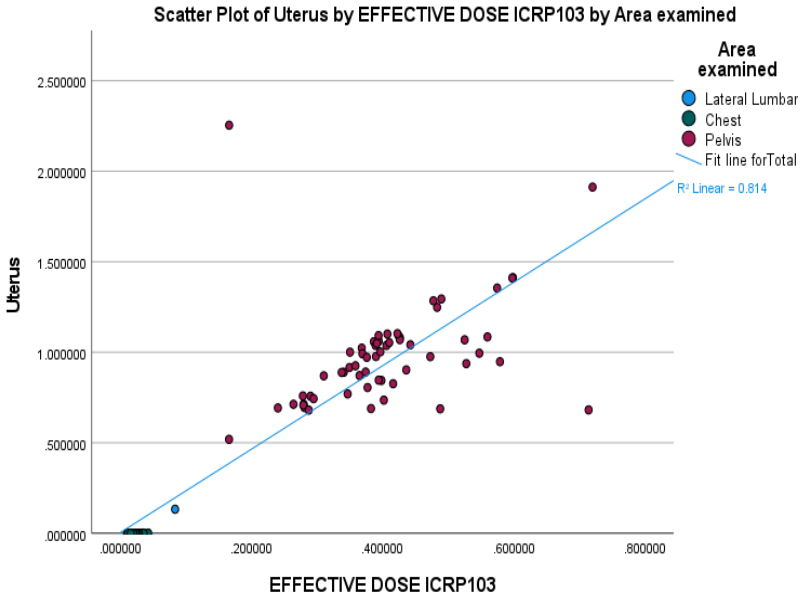


Figure 4.6 shows the scatter plot of ED to the ovaries when examining the lumbar spine. The graph used plots with the line of best fit to show this relationship. The results showed that scatter radiation was more to the ovaries when examining the lateral lumbar spine which indicates a positive correlation between the lateral lumbar spine examination and ED to the ovaries. The scatter plot of the ovaries for the lateral lumbar spine examination is illustrated in figure 4.5 below.

Figure 4.6: Scatter Plot of radiation dose to the ovaries for the lateral lumbar spine view.

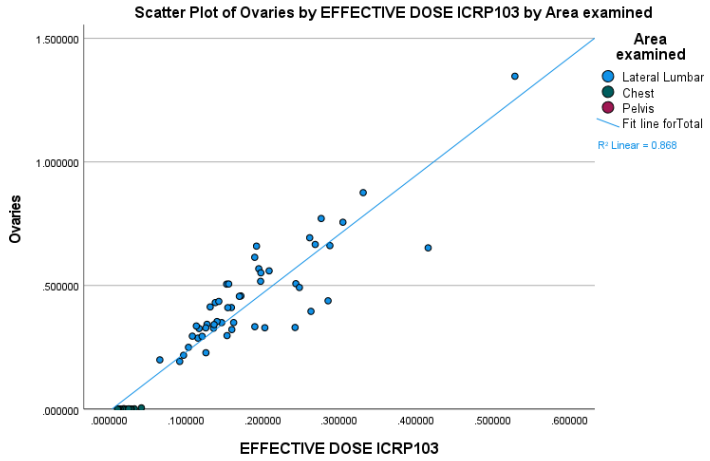
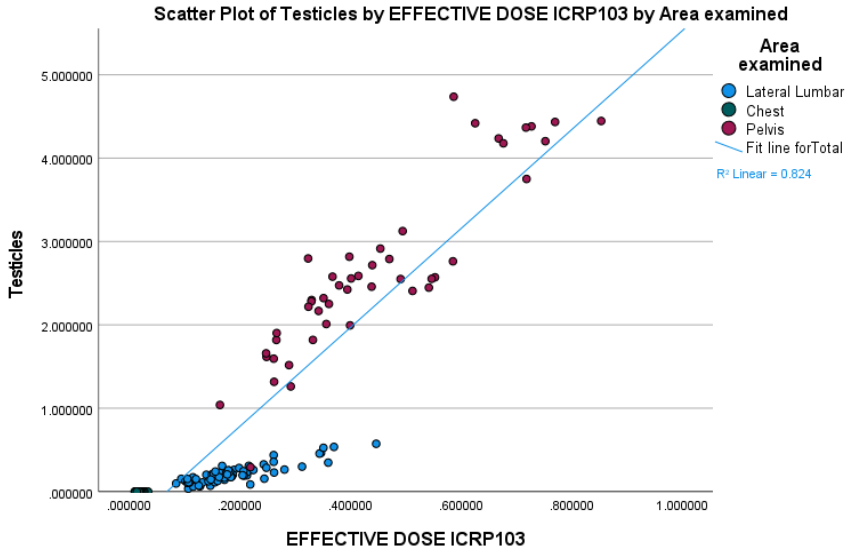


Figure 4.7 shows the scatter plot for the pelvis and lateral lumbar spine examinations with reference to ED to the testis. The blue dots illustrate the relationship of ED to the testis from the lateral lumbar examination whilst the red dots show for the pelvic examinations. The two distributions indicate a variation in the dose contribution to the testis by the two examinations, with the pelvic examinations showing greater dose to the testis compared to the lateral lumbar examination. This is illustrated in Figure 4.7 below.

Figure 4.7: Scatter Plot of effective dose to the testicles for the AP pelvis and lateral lumbar Spine views.



4.8 Chapter summary

This section presents a summary of the results of this study. The results revealed that there was a significant difference between the mean EI of the radiographers and the MREI value for the lateral lumbar spine and AP pelvis examinations. Gender had no significant influence on radiographer's EI – for the PA chest, lateral lumbar spine and AP pelvis. It was also noted that examination time did not have a significant influence on EI of the PA chest, lateral lumbar spine and pelvis examination. None of kVp, mAs, height and weight had a significant correlation with radiographer's EI – for the lateral lumbar spine, AP pelvis and PA chest examination. It was also found that none of the factors and co-variates namely patient sex, age, time of examination, kVp, mAs, height and weight had a significant influence on the radiographer's EI.

Only one factor among the dependent variables had a significant influence on scatter radiation to the reproductive organs, and that was patient's gender. There was no notable relationship between effective dose and radiographer's EI in the lateral lumbar spine and PA chest examinations. However, there was a significant relationship between effective dose and EI in the pelvis examination.

Results from the Monte Carlo calculation showed that the effective dose using ICRP 103 of the uterus was more when examining the AP pelvis view; the effective dose of the ovaries was high when examining the lateral lumbar spine view; while effective dose of testicles was high when examining the pelvis and lateral lumbar spine views. The next Chapter interprets the findings and provide some recommendations.

CHAPTER 5

DISCUSSION

5.1 Chapter introduction

This chapter explores the implications of the results presented in chapter 4. The results are discussed in the context of how they relate to the objectives of this study and how they complement each other in meeting the main aim of the study and the conclusions reached. This study explored some significant areas shown to be problematic regarding the transition from FSR to DR. To address these concerns, three objectives were formulated which were firstly to establish whether there was a significant difference between the EI for CR of the PA chest, AP pelvis and the lateral lumbar spine in an adult population and the standard/recommended EI. Secondly, the study sought to establish whether there was an association between specific factors (gender, weight, and technical factors like kVp, mAs, SSD, FSD, filtration and field size) and EI. Thirdly, whether an association existed between EI and effective dose in this study population. These objectives were investigated by means of the guiding principles of quantitative non-interventional research methods as extensively described in Chapter 3. Other aspects described in this chapter include an overview of the study, the implications for further research, and the implications for clinical practice. In addition, several recommendations will be made based on limitations drawn from this research study.

The need for conducting this study arose from problems introduced by the use of CR systems when examining the human body. The transition from FSR to DR posed a challenge for radiographers as many had to become familiar with new concepts and had to discard the old ways of doing things. One fundamental problem posed by CR is that of exposure creep which results in increased radiation doses to patients (Gibson and Davidson, 2012). A second major challenge posed by CR is the wide dynamic range of the digital imaging system as described in Section 2.10 of Chapter 2 of this thesis. Exposure creep implies unintentionally exposing patients to higher doses of radiation, whereas wide dynamic range implies that radiographers can still acquire an acceptable diagnostic radiograph with an unnecessary high radiation dose and vice versa.

5.2 Overview of the study

In this study, it was important to ensure that CR parameters used by radiographers remained within the recommended ranges that do not cause unnecessary radiation exposure to the study population. The CR unit used had regular quality control checks to

keep it in good working condition so as to ensure that the equipment did not cause any unwarranted influence on the study results. Any deviation from the recommended parameters ought to result from exposure caused by radiographers in their use of the CR unit and not from poor equipment performance. Additionally, good equipment performance ensures that imaging results were relevant and accurate in relation to the radiation dose. Secondly, the data collection tool in Appendix 1 needed to be tested to ensure acceptable capture of the required data for the study. A pilot test was therefore conducted to address the reliability of the CR unit and the data collection tool.

The study consisted of two steps to address the three objectives of this study. Step one involved collecting specific data of the patient undergoing examinations of the PA chest, AP pelvis and lateral lumbar spine views using the data collection tool in Appendix 1 which included gender, weight, and technical factors like kVp, mAs, SSD, FSD, filtration and field size. Step two involved comparing the EI generated by the radiographer to the manufacturer recommended EI and assessing the association between EI and radiation dose. The purpose of collecting this data was to correlate the specific factors and related EIs with the ESD and to establish an optimized EI for the main purpose of dose management. The PCXMC Monte Carlo calculation software was used to estimate effective dose to the patients undergoing X-ray examinations. The calculated dose was used to show how well the participants' effective doses compared to the recommended ones; then the result was checked to see if there was a pattern with high doses to the uterus, ovaries and testicles (reproductive organs) for each examination.

5.3 Importance of Exposure Index

The first objective of this study was aimed at establishing whether there was a significant difference between the EI for CR of the PA chest, AP pelvis and the lateral lumbar spine in an adult population and manufacturer's standard/recommended EI. The data on recommended EIs provides the basis for optimisation of dose to enable the users of the CR unit to work within the manufacturers' recommended EIs as a way of fulfilling the ALARA principle. In other words, how to use as low as reasonably achievable dose in CR units without compromising image quality. It is well known that any reduction made in dose to the patient would also minimise the risk of both stochastic and deterministic effects (Stabin, 2010) as described in Section 2.12 of Chapter 2. In this study, the radiation dose to the patient was recorded using the Monte Carlo calculation as described in Section 5.2 above. The ESD provides a dependable approximation of the risk of

deterministic effects (ICRP, 2004). This study measured the ESD free-in-air to the PA chest, AP pelvis and lateral lumbar spine examinations.

5.4 Exposure Index and radiation dose

The results from this study revealed that gender had a significant influence on scatter to the reproductive organs during X-ray examination of the AP pelvis and lateral lumbar spine as presented in figures 4.5, 4.6 and 4.7 in the previous Chapter. This finding compared well with study conducted by Geinjer and Perslidan, (2005) as high doses (e.g. 4.7mGy) were recorded to the gonads which when examining the pelvis. This therefore requires accurate application of exposure factors (mAs and kVp) when examining the pelvis and lateral lumbar spine of each gender. If the dose to the gonads is minimised, it is realistic to take it that the risks of genetic effects (stochastic effects) will also be minimised (Stabin, 2007). This is an essential goal of ensuring radiation protection of patients in diagnostic imaging and was an important aspect of this study.

5.5 Radiographer acquired EI versus manufacturer recommended EI

The first objective in this study compared the EI generated for each examination in comparison with the vendor's recommended EI. As explained in Section 4.2 of Chapter 4, the interest in this statistical calculation was not to compare the EI of the PA chest, AP pelvis and lateral lumbar spine examinations but to compare/correlate the EI for each examination to the vendor's recommended EI values in order to check radiographers' adherence to the manufacturers' recommended EI values. The results from this study revealed that there was a notable difference between the average EIs generated by radiographers and the manufacturers' recommended EI value for the lateral lumbar spine and AP pelvis (lateral lumbar spine $p<0.000$; Chest $p<0.001$; Pelvis $p<0.003$). A similar study was conducted by Brennan and colleagues (2007) on whether radiographers were meeting MREI ranges for routine chest, abdomen and pelvis X-ray examinations under an assortment of conditions and to examine aspects affecting the EI. The results from the study by Brennan, and colleagues showed that most examinations revealed EI values that were not within the MREI ranges, with notably higher median EI values recorded for the female patients' radiographs than those for male patients for all manufacturers (Stabin, 2007). The findings by Brennan, and colleagues correlate with this study which also revealed high EI values when examining the female pelvis as shown in figures 4.5 and 4.6 in Chapter 4.

Another study was conducted by Warren-Forward and colleagues (2006) to assess EIs in computed radiography for the PA chest and the lateral lumbar spine at two hospitals. Two of the objectives for their retrospective study were to establish whether radiographers were producing images with EIs that were within the MREI and the relationship between EIs and radiation dose. Their results showed that 30% of lateral lumbar spine examinations at hospital B and 38% of PA chest examinations at one hospital were produced with EIs below 1700. In their phantom study, when using a varied tube potential (70-125 kVp) and maintaining a constant EI of 1550, ESD was reduced by 56%. These results indicate that there was a potential to reduce the MREI and optimise patient dose. There was also evidence to suggest that EI was not a reliable indicator of patient dose (Themes, 2016). The study by Warren and colleagues (2006) correlates with this study that there is potential to reduce MREI and optimise patient dose since some EIs recorded from this study were below the MREI.

5.6 Association between specific factors and EI

The second objective of this study sought to establish whether there was an association between specific factors (gender, weight, and technical factors like kVp, mAs, SSD, FSD,) and EI. The results showed that gender height and weight had no significant influence on radiographers' EI. The results also revealed that time when the examination was taken had no significant influence on radiographers' EI. Furthermore, none of technical factors like kVp, mAs, SSD, FSD, had a significant influence on radiographers' EI. As for scatter radiation, only gender among the dependent variables had a significant influence on scatter radiation to the reproductive organs. Similar studies indicated below have discussed possible causes of EI variations, with these being based on working hours and patient gender differences. Their findings do not correlate with this study's findings. For example, a study conducted by Mothiram and colleagues (2013) reported that EI variations between examinations taken within hours and out of hours can occur, with higher EIs being recorded in the latter situation (Mothiram et al., 2013). This is similar with the findings by Peters et al who linked higher EIs on working hours to staffing levels and levels of staff experience (Peters & Brennan, 2002). The two studies described above further attributed the findings to radiographers' reluctance to have to repeat an exposure during these busy shifts. Whilst the above studies showed variations on time when the examination was taken, this study revealed that time when the examination was taken had no significant influence on radiographers' EI. Another study conducted by Lanca and colleagues (2013) revealed a variation in EI values between genders with women often obtaining higher values compared to their male counterparts (Mothiram et al., 2013).

5.7 Association between effective dose and EI

The third objective was to establish whether an association existed between EI and effective dose in this study population. The Monte Carlo software in this study was based on measuring the ESD free-in-air for the PA chest, AP pelvis and lateral lumbar spine respectively. Data of the EI was collected for each body part in the field of examination. Radiographers generated EIs which ranged from 53 – 540 for the PA chest, 45 – 417 for AP pelvis and 35 – 419 for the lateral lumbar spine. Scatter plots of the dose as a function of exposure factors (kVp and mAs) for the PA chest, AP pelvis and lateral lumbar spine showed the association between exposure factors and dose to the different body parts. Higher exposure factors to the pelvis and lateral lumbar spine resulted in higher effective dose to the reproductive organs. Effective dose to specific body parts changed with each examination as shown in Figures 4.5; 4.6 and 4.7. For example, in the AP pelvis, effective dose was higher to the prostate than to the ovaries and uterus; exposure to the pelvis at 82kVp and 66mAs resulted in a dose of 4.24mGy for the prostate and 1.91mGy for the uterus (Chapter 4, Figure 4.7). For the lateral lumbar spine the same relationship holds true; at 90kVp and 80mAs, the highest dose was to the ovaries at 4.12mGy. The dose measurements for the PA chest, AP pelvis and lateral lumbar spine, showed a strong positive linear association between effective dose, exposure factors and the part being examined (Chapter 4, Figures 4.5; 4.6 and 4.7). Several authors have published on the topic of dose and EI and others have found that no relationship exists between patient radiation dose and EI as described by Fauber et al., (2011). On the other hand, Butler et al, (2009) in their study established optimum EIs for the antero-posterior (AP) projections of a pelvis and knee on a Carestream Health (Kodak) CR system and compared the generated EIs with manufacturers' recommended EI values from a patient dose and image quality perspective. The study used human cadavers to produce images of clinically relevant standards and found that there was a correlation between ESD and EI. More studies were conducted, and interestingly, Silva and Yoshimura (2014) found that EI could be used as a dose estimator but that the relationship between EI and dose was dependent upon the projection-(Silva & Yoshimura, 2014). Furthermore, Cohen et al., (2011)found that the standardised EI and DI were excellent tools for monitoring the consistency of patient exposures in a study that was undertaken on neonatal portable chest radiographs (Cohen et al., 2011). However, Butler et al., (2009) indicated that EIs can be unreliable with CR but entirely consistent in DR. The findings by Butler et al., (2009) that there was a correlation between ESD and EI correlate with the findings of this study.

5.8 Summary of the Results

The results of the study showed that there was a notable difference between the mean EI of the radiographers and the recommended EI value for the AP pelvis and lateral lumbar spine. There was no significant relationship between effective dose and radiographers' mean EI in the lateral lumbar spine and PA chest examinations. However, there was a significant association between effective dose and EI in the pelvis examination. The optimised EI values (as close to the recommended EI as possible) for the pelvis and the lumbar spine obtained in this study were more in close approximation with those described by Seibert (2004). For example, Chest $p<0.001$ (Chapter 4, Table 4.23); Pelvis $p<0.003$ (Chapter 4, Table 4.26); Lateral lumbar spine $p<0.000$ (Chapter 4, Table 4.20). Gender had no significant influence on EI – in the examinations of the PA chest, AP pelvis and lateral lumbar spine. It was also noted that time the examination took place, did not have a significant influence on EI – in the examinations of the PA Chest, lateral lumbar spine and Pelvis.

None of the variables kVp, mAs, height and weight, had a significant correlation with EI between the three views – in the PA chest, AP pelvis and lateral lumbar spine. It was also found that none of the factors and co-variates such as patient sex, age, time of examination, kVp, mAs, height and weight had a significant influence on the EI. The overall EI generated from all the variables above was also not significant. Only one factor among the dependent variables had a significant influence on scatter to the reproductive organs, and that was the patient's gender.

There was no notable relationship between effective dose and EI in PA chest and the lateral lumbar spine examinations. The correlation between EI and dose for lateral lumbar spine was $p=0.000$. However, there was a significant relationship between effective dose and EI in the pelvis examination ($p = 0.015$); this is an indication of non-adherence by some radiographers to the recommended EIs since it has a relationship with effective dose because it reflects higher exposure factors (kVp and mAs).

Results from the Monte Carlo calculation showed that effective dose (using ICRP 103) of the uterus was more when examining the pelvis view; effective dose (using ICRP 103) of the ovaries was high when examining the lateral lumbar spine view; while the Effective Dose (using ICRP 103) of the testicles was high when examining the AP pelvis and the lateral lumbar spine views. The ESD provides a dependable estimate of the risk of

deterministic effects (ICRP, 2000); however, the dose-bio effect relationship fell outside the scope of this study.

The study showed that the effective dose (using ICRP 103) of testicles and ovaries was higher when examining the AP pelvis and lateral lumbar spine. As for the uterus, the effective dose (using ICRP 103) was only higher when examining the pelvis. For the lateral lumbar spine, the lowest actual EI was 35 and the highest was 419 against the manufacturer recommended EI range of 200 – 400. Although the study shows that some radiographers at the named hospital failed at times to stay within the manufacturer's recommended EI values for the AP pelvis and lateral lumbar spine, there was no indication as regards which radiographer generated the EIs that were not within the recommended range due to anonymity of the data collection process. Due to this anonymity, it would be difficult to conduct targeted mentorship on the correct use of the CR unit since it would not be known as to which radiographer was producing EIs that were outside the recommended ones. It is assumed that non-adherence to the MREI's was influenced highly by the post processing image contrast manipulation options made possible by the CR unit. However, the head of department may use these findings to offer in-service training to all radiographers. Dose optimisation and use of a reasonably new digital imaging technology now almost common in clinical practice were, essential features of this thesis. Dose optimisation at all times require ongoing scientific investigations, as science and technology continue to advance. Based on the results of this study the section that follows looks at the study's recommendations.

5.9 Recommendations

The study confirmed the notion that radiographers at times failed to adhere to the MREI's when using the CR X-ray unit, and this posed a risk to the patients. The risk posed was in the form of either deterministic effects which increased with dose and could cause damage which would result in skin burns or hair loss; higher doses could result in internal organ failure; or stochastic effects with no threshold and could happen coincidentally, so the probability that radiation exposure would cause a stochastic effect depended on dose. Critical radiosensitive organs when examining the chest include breasts and the foetus in the case of pregnant women; for the pelvis and lumbar regions, critical organs include ovaries, testis and the foetus for pregnant women. There is a need to incorporate detailed orientation on the CR unit for all radiographers to develop more accurate ways on the use of the equipment and therefore heighten the protection of patients. There is also a

necessity to extend such a study to other facilities which are using the CR X-ray unit in Zambia to assess the correct use of the CR unit on a wider basis. Additionally, decision makers who look at the enrolment, distribution and assigning of radiographers ought to communicate to the vendors to take into consideration the training needs of radiographers in the use of CR units. Further, future studies may include an assessment of radiographers' knowledge and competences on the CR unit to gain an understanding of the nature of training that would be required. That will help in developing more precise standard operating procedures which could fine tune training to a particular sub-set of radiographers and at the same time provide useful information for improving the use of CR X-ray units. It can be assumed that the current Zambian diagnostic imaging system transitioning from FSR to CR X-ray units may not be offering adequate protection to patients because of the non-adherence by radiographers to the MREI. These problems can be addressed by dedicated post installation training, continuous professional development and refresher courses for diagnostic radiographers at the research site. There is a need to reorganise the guidelines to integrate post installation training. It should be noted that due to the sample selected for this study not being representative of the larger population of diagnostic radiographers employed in the country where the study was conducted, these findings are only contextual to the research site.

Various factors such as exposure factors selection and radiographic technique may have caused high radiation dose to patients. These causative factors need to be identified. As the study has shown that poor combination of exposure factors (kVp and mAs) can cause profound effect on effective dose to the patient, exceptions ought to be made if the high exposure occurs as a result of faulty equipment. Post installation training on the correct use of equipment needs to be incorporated into the institutional guidelines to ensure the correct use of that CR X-ray system to reduce potential risks to patient's health and safety.

Further studies should emphasise on whether radiology departments use MREI values and exposure technique factors (mAs and kVp) recommendations, and whether such departments create their own EI values and exposure technique factors. Finally, future studies should include a factor to ascertain the stability of the EI as a valuable feedback tool. At the moment, there is a wide range of EIs and detector exposures (Table 2.1) used by different vendors of digital radiography imaging systems (Chapter 2; Section 2.15) and this brings about confusion among radiographers regarding the meaning of EI values of the different CR units (Brown et al., 1999).

5.10 Study Limitations

Generalisation of the results of this study is subject to limitations identified as follows:

1. The radiographers received a four-day post CR installation training which may not have been adequate to grasp the correct application of the CR unit when performing X-ray examinations. The results of this study could have been influenced by this fact.
2. The study involved only one hospital making generalisation of the results to the larger population of diagnostic radiographers not possible.
3. Data collection was limited to ten radiographers working at the research site. This was the maximum number of radiographers that could be gotten for this study. A larger sample of radiographers might result in a different research outcome.
4. The sample size of radiographers may not have been large but considering that participation in this study was purely on a voluntary basis, the sample size was close to the maximum number of participants at the research site.

5.11 Conclusion

This study provides useful insights regarding radiographers' adherence to recommended EIs when applying the CR unit and dose optimisation of the Fuji CR imaging system when examining the PA chest, AP pelvis and the lateral lumbar spine views. Care must be taken when selecting exposure factors for any conventional diagnostic examination to make sure that the dose to the patient is not outside acceptable limits. When examining the mentioned views, the study showed that there was a notable difference between the average EI and the manufacturers' recommended EI value for the AP pelvis and lateral lumbar spine but not for the PA chest. Other variables, factors and co-variates (e.g. sex, age and time) had no significant influence on EI. It is vital to understand the association between EI values in order to be able to deduce the potential dose to the patient. Furthermore, results from the Monte Carlo calculation showed that higher effective dose to the testicles was evident when examining the pelvis. It would be useful to audit the EI values generated by radiographers for a range of radiographic examinations in order to determine whether the exposures are optimum for dose and image quality as this could be useful at ensuring good work practices with the CR unit and subsequently reducing radiation dose to the patient.

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APPENDIX 1

DATA COLLECTION FORM

PATIENT DETAILS			PART EXAMINED (Tick)			kVp	mAs	FSD	SDD	Field size	DAY/TIME OF EXAM		EI	Height	Weight
STUDY NO.	AGE	SEX	Lateral Lumbar	Chest	Pelvis						Normal hours	After hours			

kVp: kilo Voltage peak
mAs: mili Amperage second
FSD: Focal Spot-to-Skin Distance
SDD: Source-Skin Distance
EI: Exposure Index

APPENDIX 2

RADIOGRAPHERS' PARTICIPATION LETTER

Dear Radiographer,

RE: REQUEST TO PARTICIPATE IN A STUDY

You are being requested to take part in a research study on the Evaluation of factors affecting Exposure Index (EI) in the application of Computed Radiography (CR) at a second level hospital in Zambia. Particularly, the study has the following objectives:

- Establish whether there is a significant difference between the EI for CR of PA chest, AP pelvis and lateral lumbar spine of the study population and standard/recommended EI.
- Establish whether there is an association between specific factors (gender, weight, and technical factors like kVp, mAs, SSD, FSD, filtration and field size) and EI.
- Establish the association between EI and radiation dose in this study population.

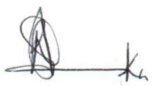
This research study will require that you enter data regarding kV, mAs, gender, age, and time the examination was conducted on patients referred for the PA chest, AP pelvis and lateral lumbar spine views, on the form that will be provided by the researcher. The completed forms will be stored in a lockable cabinet in the office of the head of radiology unit where access is restricted to only the researcher and the supervisors. There are no foreseen risks or discomforts associated to this research.

A number of steps will be taken to guard your anonymity and identity. While you will be required to enter data on a form, there will be no mention of your name or that of the research site on the forms, nor when publishing the results of this study. All information will be destroyed after an agreed period of time.

Your participation in this research is absolutely voluntary. As such, you may refuse to participate in this study at any stage for any reason. There are no rewards for participating. The results from this study will be accessible in writing in journals read by health institutions and professionals, to help them enhance their understanding of the experience of using a CR X-ray unit. The results may also be presented in person to health professional bodies and administrators. However, at no time, will your name be used or any identifying information exposed. If you wish to obtain a copy of the results from this study, you may get in touch the researcher at the contact details given below.

If you need any information regarding this study, or would like to speak to the researcher, feel free to do so. If you have any other questions concerning your rights as a participant in this research, you may also contact the secretary of the Faculty of Health and Wellness Sciences' Research Ethics Committee at Cape Peninsula University of Technology Ms N. Seth at sethn@cput.ac.za.

Yours faithfully



Ricky Siasendeka
Researcher

CPUT Supervisor: Dr. Aladdin Speelman
E-mail: speelmana@cput.ac.za Phone+27 21 959-658

APPENDIX 3

INFORMED CONSENT FORM FOR RADIOGRAPHERS

I have taken time to read the above information concerning this research study on the Evaluation of factors affecting Exposure Index (EI) in the application of Computed Radiography (CR) at a second level hospital in Zambia and agree to be a participant in the study.

The resolve and type of the study have been described to me in detail and I understand that there are no direct risks to me. I have been assured of confidentiality and safety during the period of this study. I therefore authorise the researcher to proceed with the use of the information obtained from me in this study.

(Printed Name) _____

(Signature) _____

(Date) _____

Researcher's contact details: Name: Ricky Siasendeka (Mr)

Telephone: +260 979 049853
Email: siasendekar@yahoo.com

Supervisor's contact details: Name: Dr Aladdin Speelman

Telephone: +27 21 959-6538

Email: speelmana@cput.ac.za

APPENDIX 4

PATIENT PARTICIPATION LETTER

Dear Patient:

REQUEST TO PARTICIPATE IN A STUDY

You are being requested to take part in a research study on the Evaluation of factors affecting Exposure Index (EI) in the application of Computed Radiography (CR) at a second level hospital in Zambia. The study aims to see if radiographers are using the new X-ray unit properly when X-raying patients. The information needed for the study includes your age, sex, height, weight, and other information from the X-ray machine. There are no foreseen risks or discomforts associated to this research.

Your participation in this research is absolutely voluntary. As such, you may pull out from the study at any stage for any reason. Your identity and personal information will be kept confidential. There will be no mention of your name anywhere when publishing the results of the study.

The results from this study will be published and will therefore be available to professionals and the public. The results may also be presented in person to health professional bodies and administrators. However, at no time, will your name be revealed, or any identifying information revealed. If you wish to obtain a copy of the results from this study, you may get in touch with the researcher at the contact details given below.

If you need any information regarding this study, or would like to speak to the researcher, feel free to do so. If you have any other questions concerning your rights as a participant in this research study, contact the secretary of the Faculty of Health and Wellness Sciences' Research Ethics Committee at Cape Peninsula University of Technology Ms. N. Seth at sethn@caput.ac.za.

Yours faithfully

Ricky Siasendeka
Researcher

CPUT Supervisor: Dr. Aladdin Speelman
E-mail: speelmana@cput.ac.za Phone+27 21 959-658

APPENDIX 5

INFORMED CONSENT FORM FOR PATIENTS

PATIENT DECLARATION

I have taken time to read (or have been read to) the above information concerning this research study on the 'Evaluation of factors affecting Exposure Index of Computed Radiography at a second level hospital in Zambia' and agree to be a participant in the study.

The resolve and type of the study have been described to me in detail and I understand that there are no direct risks to me. I therefore authorise the researcher to proceed with the use of the information obtained from me in this study.

I AGREE TO PARTICIPATE

(Printed Name) _____

(Signature) _____

(Date) _____

Researcher's contact details: Name: Ricky Siasendeka (Mr)

Telephone: +260 979 049853
Email: siasendekar@yahoo.com

Supervisor's contact details: Name: Dr Aladdin Speelman

Telephone: +27 21 959-6538
E-mail: speelmana@cput.ac.za

APPENDIX 6:

REQUEST FOR SITE PERMISSION

The Medical Superintendent

Research site

Dear Sir

RE: REQUEST TO CONDUCT A RESEARCH STUDY

The above subject matter refers.

I am enrolled for Master's degree in Radiography at the Cape Peninsula University of Technology, South Africa. I wish to undertake a study entitled ''Evaluation of factors affecting the Exposure Index (EI) of Computed Radiography (CR) at a second level hospital in Zambia''. Particularly, the study has the following objectives:

- Establish whether there is a significant difference between the EI for CR of PA chest, AP pelvis and lateral lumbar spine of the study population and standard/recommended EI.
- Establish whether there is an association between specific factors (gender, weight, and technical factors like kVp, mAs, SSD, FSD, filtration and field size) and EI.
- Establish the association between EI and radiation dose in this study population.

This study may provide data on whether discrepancy/adherence exist in exposure factors when using a CR X-ray unit. Further, findings may assist hospitals that will plan to acquire CR X-ray units to have adequate knowledge regarding the proper use of the unit. The researcher intends to conduct this study during normal routine daily activities of the radiology department. No extra consumables will be required since no patients will be recruited outside the daily list of patients referred for imaging within the department. The principle of not exposing patients to unnecessary radiation will also apply, and therefore maintaining the safety of the patient throughout the examination.

The collection of data will be done in a manner that will not disrupt the normal operations of the departments as both the researcher and other radiographers will be expected to adhere to the normal working schedule for the department. Anonymity and confidentiality for both, the radiographer, the patient and research site will be maintained throughout the study. The radiographers' name will not appear on the data collection forms and the name of the hospital will only appear in the thesis for submission to CPUT but not for publication. Completed forms will be stored in a lockable cabinet found in the office for the head of radiology department. It is intended that 335 patients will be recruited in this study.

The study report will only be disseminated to stakeholders for the sole purpose of information and planning of the services on the use and management of X-radiation. I therefore wish to seek your approval to conduct the study at the mentioned hospital. The researcher will seek to describe the process to the patient and that the examination may take longer than usual. Upon acceptance, the patient will be required to sign a consent form attached. This will assist in seeing to it that the patients' rights to a fully informed decision are not infringed upon. I trust this application will enjoy your favourable consideration.

Ethical approval to conduct this study will also be sought form the Research Ethics Committee within the Faculty of Health and Wellness Sciences at the Cape Peninsula University of Technology.

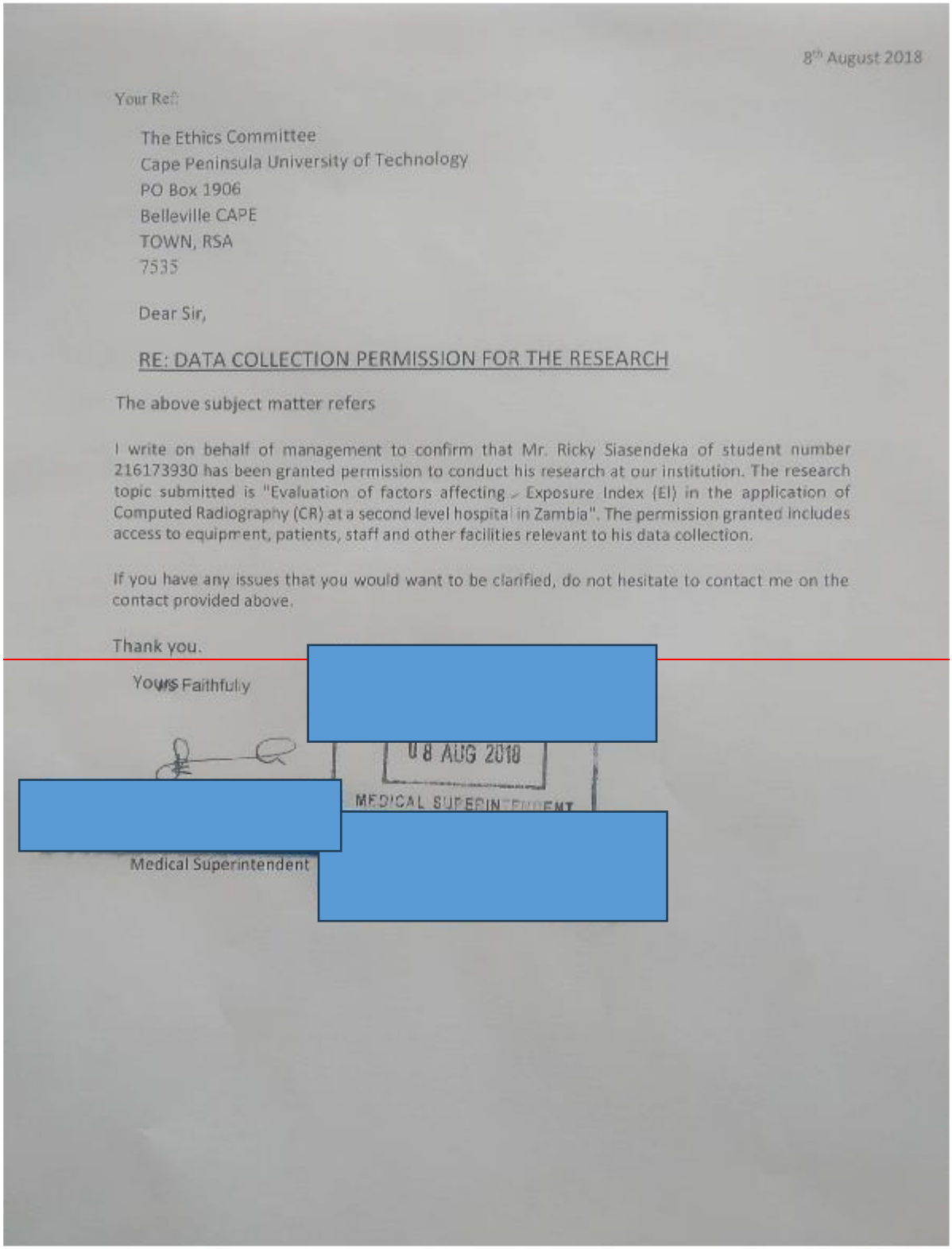
Yours faithfully

Ricky Siasendeka
Researcher

CPUT Supervisor: Dr. Aladdin Speelman
E-mail: speelmana@cput.ac.za Phone+27 21 959-658

APPENDIX 7

Site permission: Research site



8th August 2018

Your Ref:

The Ethics Committee
Cape Peninsula University of Technology
PO Box 1906
Belleville CAPE
TOWN, RSA
7535

Dear Sir,

RE: DATA COLLECTION PERMISSION FOR THE RESEARCH

The above subject matter refers

I write on behalf of management to confirm that Mr. Ricky Siasendeka of student number 216173930 has been granted permission to conduct his research at our institution. The research topic submitted is "Evaluation of factors affecting Exposure Index (EI) in the application of Computed Radiography (CR) at a second level hospital in Zambia". The permission granted includes access to equipment, patients, staff and other facilities relevant to his data collection.

If you have any issues that you would want to be clarified, do not hesitate to contact me on the contact provided above.

Thank you.

Yours Faithfully

[redacted]

08 AUG 2018

MEDICAL SUPERINTENDENT

[redacted]

Medical Superintendent

[redacted]

CamScanner

APPENDIX 8

ETHICS CLEARANCE CERTIFICATE

Cape Peninsula University of Technology

HEALTH AND WELLNESS SCIENCES RESEARCH ETHICS COMMITTEE (HW-REC)
Registration Number NHREC: REC- 230408-014

P.O. Box 1906 □ Bellville 7535 South Africa
Symphony Road Bellville 7535
Tel: +27 21 959 6917
Email: simonsy@cput.ac.za

4 November 2019

REC Approval Reference No:
CPUT/HW-REC 2019/H120

Dear Mr Ricky Siasendeka

Re: APPLICATION TO THE HW-REC FOR ETHICS CLEARANCE

Approval was granted by the Health and Wellness Sciences-REC to Mr Ricky Siasendeka for ethical clearance on 4 November 2019. This approval is for research activities related to student research in the Department of Science in Radiography at this Institution.

TITLE: **Evaluation of factors affecting Exposure Index (EI) of Computed Radiography (CR) at a second level hospital in Zambia**

Supervisor: Ms F Isaacs and Prof K Jooste

Comment:

Approval will not extend beyond 5 November 2020. An extension should be applied for 6 weeks before this expiry date should data collection and use/analysis of data, information and/or samples for this study continue beyond this date.

The investigator(s) should understand the ethical conditions under which they are authorized to carry out this study and they should be compliant to these conditions. It is required that the investigator(s) complete an **annual progress report** that should be submitted to the HWS-REC in December of that particular year, for the HWS-REC to be kept informed of the progress and of any problems you may have encountered.

Kind Regards

Dr. Navindhra Naidoo
Chairperson – Research Ethics Committee
Faculty of Health and Wellness Sciences