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Determination of effective dose and entrance skin dose from dose area product values for barium studies in adult patients at a large tertiary hospital in the Western Cape

by

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DECLARATION

I, Nazlea Behardien Peters, declare that the contents of this dissertation/thesis represent my own unaided work, and that the dissertation/thesis has not previously been submitted for academic examination towards any qualification. Furthermore, it represents my own opinions and not necessarily those of the Cape Peninsula University of Technology.

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23 August 2017

Date

ABSTRACT

Background and objectives

The issue of patient doses received during fluoroscopy procedures, raised concerns for the researcher, as there may have been probable past skin injuries or deterministic injuries that may not have been documented. Amongst the radiology staff, there was very little understanding of what the actual dose area product (DAP) value means in real terms of effective dose and entrance skin dose. The aims of the study were to:

i) Measure the radiation doses received by the patient and determine a simple means of defining the DAP value to the radiographer in terms of the dose received by the patient.

ii) Determine the effective dose, entrance skin dose and the relationship with the DAP value to assist with developing a conversion co-efficient for dose indicators.

Method

Direct radiation dose measurements can be obtained through DAP meters attached to the diagnostic equipment, but the DAP value is not an direct indication of the effective dose received by the patient. The DAP values captured from the DICOM header information for barium fluoroscopic procedures at a large tertiary was analysed and Diagnostic Reference levels (DRL) were determined for barium swallow, meal and enema procedures. The effective and skin doses were calculated by means of the Monte Carlo program. The results were compared to published values. The relationship between the entrance skin dose and the DAP value was determined and conversion factors were calculated.

Results

Correlation between the DAP and entrance skin dose and comparative 75^{th} percentile threshold values were determined for barium swallow (BaS), barium meal (BaM) and barium enema (BaE) procedures. Effective to DAP conversation factors for BaS, BaM and BaE are 0.19, 0.26 and 0.60 respectively and 0.15, 0.11 and 0.14 for entrance skin to DAP.

Conclusion

The the research showed the relationship between the effective dose, entrance skin dose and DAP value and a simple, practical and applicable explanation of the DAP value by means of conversion factors.

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DEDICATION

I dedicate this work to all the radiographers, past and present, who contributed to my growth, development and to who I am today.

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CHAPTER ONE: INTRODUCTION

1.1 Background and Rationale

Ionising radiation is directly associated with fluoroscopy and therefore poses a potential radiation risk to the patient. The dose the patient receives is dependent on the type of procedure, the duration of the procedure, the area exposed, the exposure given and the size of the patient (Wambani, et al. 2013:2).

The radiation dose from fluoroscopic examinations contributes 17% to the overall total dose received by patients, but total barium related fluoroscopic procedures only contribute approximately 5% to the volume of procedures performed (Sulieman, et al., 2011:118). The radiation dose received by patients during fluoroscopic procedures has the potential for inducing skin damage or even cancer (Wagner et al., 1994:71-84).

At the research site there was no standard operating protocol for the amount of exposures during fluoroscopic procedures; neither was there any reference Dose Area Product (DAP) values set for the different procedures. There was also very little understanding of the DAP value. There was, however, a protocol for the standard views required for each barium procedure and under the guidance of the radiographer, the specific protocols were followed. This research was undertaken to assist with the understanding of the DAP value, determine if there is a relationship with the entrance skin dose and to assist with the explanation of the significance of the DAP value and threshold values recorded in the day to day running of the fluoroscopic department.

1.2 Fluoroscopy procedures

Fluoroscopy procedures aid with identification of anatomical, physiological and other abnormalities, by the administration of contrast media by means of ingestion, injection or infusion and are instrumental in imaging guidance for interventional procedures, e.g. stent and needle placements (Suleiman, et al., 2011:118-121).

Barium procedures are examinations making use of barium sulphate in suspension to better visualise and enhance the image contrast of the oesophagus (barium swallow), stomach (barium meal) and the colon (barium enema). The double contrast procedure is arguably one of the most cost effective diagnostic tests for evaluating structural and functional abnormalities of the gastrointestinal organs (Sulieman, et al., 2011:119). After the fluoroscopic procedure, the dose is indicated by a Dose area product (DAP) meter.

1.3 Radiation Dosimetry

Fluoroscopy in essence incorporates ionising radiation and therefore poses a potential

radiation risk to the patient. Fluoroscopy radiation doses can have either a stochastic; random probable cancer inducing, or deterministic; direct resultant skin effect on individuals after a lengthy exposure to radiation (Bushberg, 2012:32-40). Deterministic effects according to Nikolic, et al. (2000:121) “are those associated with a minimum threshold dose below which the effects is not seen” and “stochastic effects are those for which theoretically there is no threshold dose”.

The continuous measurement, recording and analysis of the radiation dose received by patients is paramount in assisting with the reduction in overall patient doses received, (Engel-Hills, 2002:7); prevent possible skin changes and reduce the associated increased risk of inducing malignancies (Nyathi et al., 2009:24).

In 2006, the Department of Health: Directorate Radiation Control regulated that as part of the x-ray units licensing conditions, all x-ray imaging units must have an acceptance test performed immediately after installation and before the equipment is put to clinical use. These tests had to be repeated on an annual basis, with final implementation set for 31 March 2009 (DoH SA, 2006).

1.4 Radiation dose measurement in fluoroscopy

Measurements of radiation doses received by the patient during radiological examinations should be recorded and be justified by the lowest achievable dose (Ramakrishnan & Padmanabhan, 2001:181-184; Sulieman, 2011:118). As per the 2006 regulations from the Directorate of Radiation Control in the Department of Health, it was mandated that a DAP meter be installed on all fixed fluoroscopic units and that as of 1 January 2008, the DAP meter reading be recorded with the patient and procedure details. In addition all new fluoroscopic units purchased after 1 January 2008 have a built-in DAP meter installed (DoH SA, 2006).

The Dose Area Product (DAP) meter measures and records the dose distributed over the exposed area. Varying patient and tube positions result in different dose distributions making it difficult to see the relationship between the entrance skin doses, effective dose and DAP values (Vano, et al., 2001:48). The DAP value indicated immediately after the procedure is not a clear indication of any possible damage caused (Dosimetry Working Party, 1992:1-31).

1.5 Rationale for the research

Amongst the radiology staff at the research site, there is very little understanding of what the actual dose area product (DAP) value means in real terms of effective dose and entrance skin dose, even though it has been legislated that the DAP values should be recorded since 2006 on fixed fluoroscopic units (DoH SA, 2006).

The study purpose was to measure the radiation doses, by recording and analysing the DAP values, received by adult patients undergoing gastrointestinal tract (GIT) fluoroscopic studies i.e. Ba-swallow, Ba-meal and Ba-enema and to develop a simple method to convert the DAP value to an understandable and applicable measure of the skin and effective dose received.

The objectives were to:

i) Determine the effective dose and entrance skin dose from the recorded DAP values.
ii) Derive the radiation doses received by the patient and determine a simple means of defining the DAP value to the radiology staff in terms of the dose received by the patient.
ii) Compare the dose values to other published values.

1.6 Significance of the study

The significance of the research has shown the relationship between the effective dose, entrance skin dose and DAP value which has created a simple, practical and applicable explanation of the DAP value. This knowledge will then be used by radiographers and radiologists on a daily basis to reduce radiation doses to patients and improve dosimetry and radiation protection, in line with the ALARA (as low as reasonable achievable) principles. To our knowledge this was the first study at this institution and in this province.

1.7 Overview of the methodology

The recorded DAP values from fluoroscopy procedures of GIT patients were analysed. The study sample included retrospective analysis of Digital Imaging and Communications in Medicine (DICOM) data from all adult barium related fluoroscopic procedures performed at a large tertiary hospital in Cape Town, from the time of installation of the Patient Archiving and Communication System (PACS) in 2012 which met the criteria. A minimum of 10 patients was seen as the clinical average representation of that procedure type (Dosimetry Working Party, 1992:31).

The data was analysed and the diagnostic reference level for the barium swallow (BaS), barium meal (BaM) and barium enema (BaE) procedures was determined and compared with previous published studies. The effective and entrance skin doses were computed and analysed using the Monte Carlo PCMXC software programme, to determine the relationship between the skin dose and the DAP value.

1.8 Delimitations of the research

- The study was limited by the availability of the Digital Image and Communication in Medicine (DICOM) data. Patients that did not have imaging data available on PACS were excluded from the study.
- The experience and techniques practiced by the radiologists were not considered.
- The weight of the patients and the DAP readings were not always recorded and thus impacted on the sample size.
- Not all radiographic projections were taken into account.
- The patient height was not known, the standard height was assumed to be 1.78 metres as used by the Monte Carlo program.

1.9 Introduction to thesis structure

To understand the dynamic of the relationship between the actual practice and the legislation when performing barium related fluoroscopic procedures at a large tertiary hospital, the following chapters will discuss the concepts of ionising radiation and fluoroscopy.

CHAPTER TWO Literature Review
In this chapter related literature is reviewed and discussed

CHAPTER THREE Research Methodology
This chapter discusses the data collection process and reports on the methods followed to determine the results.

CHAPTER FOUR Research Findings
In this chapter the Dose Area Product value, effective dose and skin dose measurements are reported.

CHAPTER FIVE Discussion and Recommendations
In this chapter results, reasons, limitations and recommendations are discussed.

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

Patients undergoing fluoroscopic procedures can potentially receive high radiation doses. The doses are usually monitored by a DAP meter (Hansson & Karambatsakidou, 2000:141). A primary concern is the lack of understanding of the DAP value, the significance of capturing this value and the relationship with effective and skin dose in barium related fluoroscopic procedures. In this chapter fluoroscopy, radiation dosimetry, dosimetry tools and regulations are discussed.

2.2 Fluoroscopic imaging

Fluoroscopy is an imaging technique used by radiologists whereby a fluoroscope, which consists of an x-ray tube/source coupled to a fluorescent screen/imaging intensifier (II) or flat panel detector, is used to image internal body structures. The patient is placed between the x-ray tube and the II and as one screens/switch on the radiation; the internal moving structures within the body become visible, which is then viewed on a monitor. The images are viewed in real-time and can be recorded to document findings (Bushberg, et al., 2012:231 - 240).

The research site is a large hospital associated with 3 academic institutions, training medical and radiology registrars, nursing and allied professions as well as radiographers. The radiology registrars enter the programme and start their rotation in the fluoroscopy department. They are responsible for performing all fluoroscopic procedures. In the fluoroscopy department, the different techniques practiced and the level of experience of the radiology registrar lead to differences in fluoroscopic times which equates to varying doses to patients (Wambani, et al., 2013:3).

2.3 Fluoroscopic procedures

For many decades, fluoroscopy procedures using barium sulphate have been instrumental in the diagnosis of diseases of the gastrointestinal tract (GIT). Barium procedures are routine examinations where barium sulphate in suspension is administered to differentiate between specific organs and to highlight abnormalities of the organs and body parts (Sulieman, et al., 2011:119).

2.3.1 Barium swallows

The patient takes a sip of barium sulphate then swallows the bolus to assist with the visualisation of the anatomy and passage of the barium as it is passes down the oesophagus until it enters the stomach. This aids in diagnosing difficulty in swallowing or perforation (Chapman & Nakielny, 2001:67).

2.3.2 Barium Meal

The patient is injected with a muscle relaxant to reduce stomach spasms and given some effervescent granules to extend the stomach. The barium sulphate is then ingested under fluoroscopic guidance to visualise the oesophagus and the oesophageal junction, coat the stomach wall, pass through the duodenal cap and then into the duodenum. X-rays of the passage of the barium are taken to exclude anomalies and pathology such as ulcers, tumours and gastric reflux (Chapman & Nakielny, 2001:68).

2.3.3 Barium Enema

The patient is injected with a muscle relaxant to reduce the peristaltic movements. The barium sulphate is then introduced via the rectum, with some air to visualise the entire colon and terminal ileum. The use of air and contrast (double contrast) for procedures of the gastrointestinal structures is a valuable diagnostic test for evaluation of structural and functional abnormalities of the large bowel (Sulieman, et al., 2011:118-121).

2.4 Radiation dose in fluoroscopy

Barium related fluoroscopic procedures are few, but the contribution to overall dose generated is very high as the procedures are complex and require longer screening times. Dose to the skin is greatest as it is the first point of entry for the x-rays (Parry, et al., 1999:4-5). Skin changes and radiation dose received are influenced by the length of time the skin is exposed to radiation. By monitoring the direct dose measurements, skin changes can be prevented (Nyathi, et al., 2009:26).

Skin injuries due to radiation exposure dose have been reported mostly for cardiac catheterization procedures with the maximum skin dose recorded as 1.0 Sv for diagnostic and 2.6 Sv for interventional procedures (Hansson & Karambatsakidou, 2000:141). Transient erythema can be noted at an entrance skin dose of less than 2 Gy, and 3 Gy for temporary epilation (McPharland, 1998:1288).

Ruiz-Cruces, et al., (2000:752) recorded average effective doses of 1. 04mSv and 13.99mSv for barium swallow and enema procedures and entrance skin dose of barium swallow of 16 mGy, which was 10 times lower than for barium enemas.

2.5 Radiation Protection

According to the Annals of the ICRP 103 (2007), the "*3 key principles of radiological protection are the principles of justification, optimisation and application of dose limits and are defined as follows:*

The principle of Justification: Any situation that alters the radiation exposure situation should do more good than harm.
The principle of Optimisation of Protection: The likelihood of incurring exposure, the number of people exposed, the magnitude of their individual doses should all be kept as low as reasonably achievable, taking into account economic and societal factors.
The principle of Application of Dose limits: The total dose to any individual from regulated sources in planned exposure situations other than medical exposure of patients should not exceed the appropriate limits specified..."

In essence any request for an image must be reasonable, must be needed, must be achieved with the lowest possible dose to patient and must be of good diagnostic quality. There should be no repeat imaging required. The only way patients and staff can be protected is by wearing external lead protection, monitoring of the doses received and providing dose quantities that allows for quantification of the extent of the exposure of the human body from ionising radiation (Annals of the ICRP 2007).

2.6 Biological effects of radiation and optimisation

It is widely recognised that extended fluoroscopic screening times present a risk to the patient (McPharland, 1998:1288). Radiation doses can have either a stochastic; random probable cancer inducing, or deterministic; direct resultant skin effect on individuals after a lengthy exposure to radiation. Radiation burns can happen in exceptional life-saving instances, such as interventional cardiac procedures and are not typical to standard fluoroscopy procedures (Bushberg, 2012:32-40). There is an increased likelihood of deterministic effects at doses higher than 100 mSv, according to ICRP 103 (2007), whether it occurred at one exposure or over a period of a year.

The need for radiation protection within fluoroscopy resulted in the adoption of many different techniques to reduce radiation dose. According to Mahadevappa (2001:1037) the techniques included intermittent fluoroscopy (to control the beam 'on-time') in conjunction with last image hold and pulsed fluoroscopy (x-ray emission as a series of short pulses, instead of continuous screening).

Other methods include electronic collimation with automatic kilovoltage adjustment as the body part becomes thicker or thinner; electronic magnification with different dose settings, within the different magnification factors and intermittent moving of the receptor from the exposed area to allow for dose spreading over the patient skin (Robert, et al., 1999:5). Updating of operators in current radiation practices and continuously training in specialised procedures is another optimisation technique (Eman working group, 2014:19).

2.7 Radiation Dosimetry

Measuring and recording radiation doses are important in assisting with reasonable means to reduce patient doses and maintain ways of sustaining and improving this practice in line with doses that are as low as reasonable achievable (Engel-Hills, 2002:7-10).

The observation of skin changes is generally difficult due to radiation effects at lower doses only appearing long after the actual incident. (Engel-Hills, 2002:7-10). Records of the measured radiation doses during radiological procedures should be standard practice and the dose justified at all times. The use of ionising radiation to assist medicine in accurate diagnosis of disease is ever increasing, but its benefits should always outweigh the risks (Sulieman, 2011:118-121). Dose can be defined in many different ways and understanding these different terms will aid improved dosimetry practices.

2.7.1 Absorbed dose

Absorbed dose is dose quantity given where energy is transferred to a mass or tissue by ionising radiation. The SI unit for absorbed dose is Joule per kilogram, also known as gray (Gy) (ICRP 103, 2007:17).

2.7.2 Equivalent dose

Equivalent dose is a term given to the mean absorbed dose from radiation to any tissue or organ multiplied by the radiation weighting factor. The unit for equivalent dose is also joule per kilogram or Sievert (Sv) (ICRP 103, 2007:23).

2.7.3 Effective dose

Effective dose is used to describe the potential for long-term radiation effects. It is the sum of the organ weighted equivalent doses and indicative of tissue changes caused by cells undergoing changes due to exposure to ionizing radiation. Effective dose includes the radiation sensitivity of the organs. The SI unit for effective dose is Sievert (Sv), 1 Sv = 1 Joule/kg for x-rays (Brenner & Huda, 2008:503-508).

2.7.4 Entrance skin dose

Entrance skin dose also known as entrance surface dose (McPharland, 1998:1288-1295)," is the dose to the skin tissue at the entrance point of the beam". This dose is indicated in Sieverts (Sv) (Compagnone, et al., 2005:101). Changes to the focus-to-skin (FID) distance has an impact on skin dose calculated, however Jones et al. (2014) showed that the calculations of the skin dose by keeping the FID constant and the calculations of the skin dose by changing the FID resulted in values with a 50% difference.

Hansson and Karambatsakidou (2000:144) derived that there was no easy procedure to measure the maximum entrance skin dose (MESD). They found that the ESD mean values calculated in their study for interventional procedures were below the threshold value for developing skin changes; but that cumulative doses received by patients from previous interventional procedures and follow-up procedures had the potential for inducing skin changes.

Typical entrance exposure rates for fluoroscopic procedures in the average individual, of medium build is 30mGy/min (Bushberg, 2012:32). Barium enema entrance dose recorded by Aweda (2005:49 - 50) had a mean value of 5.270 x 10^{-3}Sv and entrance dose described by Ruiz-Cruces et al. (2000:752-761) was 16 mGy for barium swallow which was 10 times lower than for barium enema procedures.

2.8 Dosimetry Tools

According to the Dosimetry Working Party (DWP, 1992:3-4), “professionals directing or conducting exposures must be familiar with the typical exposure doses, methods of measuring these doses and means of ensuring dose reductions.” Dose estimates can either be determined by direct or indirect methods. Dose measurements can be derived mathematically by means of calculations such as the Monte Carlo simulations (indirect method), ionisation chambers such as DAP meters or thermo-luminescent dosimeters (direct methods) (Mahadevappa, 2001:1037-1039).

2.8.1 Monte Carlo simulations

The PCXMC 2.0 (Finland, 2008) is a Monte Carlo software computer program that has the ability to compute the organ and effective doses of patients undergoing fluoroscopic and radiographic procedures, when certain parameters are known. The program simulates photon energy propagation through tissue. These simulations are based on the passage of the photons and the random interactions that they encounter as they pass through the tissue. Individual photons are chosen by statistically sampling the probability for each angular deflection per encounter and scattering event as they interact with tissue. The organ doses are calculated from the sampling histories generated and the mean values of the energy deposits. Active bone marrow, adrenals, brain, breasts, colon (upper and lower large intestine), extra-thoracic airways, gall bladder, heart, kidneys, liver, lungs, lymph nodes, muscle, oesophagus, oral mucosa, ovaries, pancreas, prostate, salivary glands, skeleton, skin, small intestine, spleen, stomach, testicles, thymus, thyroid, urinary bladder and uterus are the organs considered by the program (Servomaa & Tapiovaara, 1998:213-219).

According to Servomaa & Tapiovaara (1998:215) the calculation of the effective dose in the

program is done with both the tissue weighting factors of ICRP Publication 103 (2007) and the old tissue weighting factors of ICRP Publication 60 (1991) and requires certain input parameters. The input data for the calculations of the effective dose are the patient height, patient weight, age, field size (FS), projection and focus-to-skin distance (FSD), source to detector distance (SDD) exposure data (anode angle and filtration material), DAP value, kilovoltage (kVp), milli-Amperage multiplied by the exposure time in second (mAs) (Bor, et al., 2004:319).

Entrance skin doses are measured by means TLD's (Sulieman, et al. 2011) and effective doses and skin doses by means of DAP meters (Compagnone, et al., 2005:101-103), but the exact quantity of these values still need to be calculated (Kothan & Tunhjai, 2011:923). Mathematical calculations by means of the Monte Carlo simulations can be done after the fact from available DAP values and the skin and effectives doses can be determined. The patient is not disadvantaged by having to be irradiated a second time to collect the data and there is no need for the TLD's to be placed on the patient to capture the direct skin dose (Servomaa & Topiavaara, 1998:216).

2.8.2 Dose Area Product (DAP) meter

The DAP meter is an ionisation chamber that measures the product of the dose and the collimated area. The DAP meter reads and measures the dose for the entire procedure over the exposed field area. An ionisation chamber is a vessel, filled with air with a positively and a negatively charged electrode. As the current from a power source passes through this vessel it is measured by a current meter. This device can be either mobile or fixed and requires calibration against a free air ionisation chamber (DWP, 1992:7).

The DAP meter measures 15 x 15 cm^2 and is found on the tube head. If installed retrospectively it is attached to the tube housing in front of the collimator window (as shown in Figure 2.1) or built into the diaphragm housing. The meter needs to be reset to zero after recording the reading and before starting the next procedure. The reading is either displayed on the operator console when built–in or printed on a sticker (refer to Figure 2.2) after the procedure if the DAP meter is fitted retrospectively (Figure 2.1). Backscatter radiation and the location of the DAP meter does not affect the reading. The quality assurance tests performed on the modality should include the DAP calibration and this should be performed on installation and annually (DWP, 1992:12). The DAP reading, the patient details, procedure details and fluoroscopy time must also be recorded for each procedure (DoH SA, 2006).

Figure 2.1: Retrofitted Dose Area product (DAP) meter with reading display on the Philips unit at the research site

Figure 2.2: DAP meter thermal sticker printer used on the Philips unit at the research site

Hart and Wall (1994:1-57) reported that a definitive and simple means of estimating the effective dose for fluoroscopic procedures can be achieved by multiplying the total DAP value by an appropriate conversion factor which will result in a value within a 25% error margin and greatly simplify the assessment of potential risk. This can be done by a radiographer or radiologist, immediately after the procedure.

The conversion factor E/DAP and ESD/DAP is derived by dividing the effective (E) and skin doses (ESD) by the DAP value and determining the constant factor for each type of procedure. (Hansson & Karambatsakidou, 2000:142)

2.8.3 Thermo-luminescent dosimeter

The thermo-luminescent dosimeter (TLD) (Figure 2.3) is either powdered lithium fluoride or lithium borate crystals in a compact Teflon coated casing. The radiation energy is trapped by the powder or crystals and when heat is applied, this stored energy is released as light. The light emitted is captured and measured. The measurement of the emitted light is directly proportional to the radiation dose absorbed (Ball & Moore, 1994:213-226). The TLD requires a calibration before it can be re-used. Multiple TLDs are required when measurements are taken during fluoroscopic procedures as the patient position as well as the image intensifier can change. The TLD's can be placed in the collimated field to measure tissue dose or inside a body cavity to measure organ dose (Sulieman, 2011:118 -119).

Figure 2.3: Thermo-Luminescent Dosimeter (TLD) used at the research site

2.9 Dose limits

2.9.1 Radiation Control Regulations

In South Africa, since 2006, the Directorate of Radiation Control regulated that all fixed fluoroscopic units must have a DAP meter installed and all new fixed units purchased after 2007, had to have a built in DAP meter (DoH SA, 2006). This became part of the licensing conditions for all fluoroscopic equipment. Radiation regulations require that the DAP reading be captured for each procedure, yet the DAP value indicated immediately after the procedure is not a clear indication of any possible damage caused to the patient (Vano, et al., 2001:48-55).

As per the reviewed literature (Bogaert, et al., 2009; Chida, et al, 2006; Ramaktishnan, 2001; Suleiman, 2011; Wambani, et al., 2013) there is a strong indication that the effective and skin doses calculated can greatly assist with improved radiation protection and hence,

reduce the radiation doses to patients. The DAP value, if understood; can assist with tracking patients to determine if any skin changes has occurred. Setting reference levels is no easy task, but it can be achieved (McPharland, 1998:1289). Making use of these indicators from the published South African studies would have gone a long way in establishing set DRL's and awareness of improved radiation protection principles at the study site.

2.9.2 Diagnostic reference level

The diagnostic reference level (DRL) is a set baseline dose level that will indicate whether the patient dose received from a specific procedure is either higher or lower than the baseline value for the specific procedure as per the ICRP 103. Gray, et al., (2005:355) stated that DRL's should be an aid for dose optimisation and radiation protection and not set as a constraint. The set value should be reviewed on a regular basis and be specific for each institution or region. Generally the 75th percentile values of the surveyed data are set as the reference value for each procedure or protocol (Aroua, et al., 2007:1625). Table 2.1 shows a comparison of previously published DAP values.

Table 2.1: Published DAP values for barium swallow, meal and enema procedures

Procedure	DAP reference DRL (ICRP 103)	Nabasenja (2009) DRL	NRPB/HPA (2010)	IAEA (2014)	Hull & East (2006)	ARPANSA (2011) AR protection
Barium swallow	11		7.5	10	11	11
Barium Meal	14	20.1	12	15	13	13
Barium enema	29	36.5	21	40	31	31

DAP values in mGy.cm²

Hull and East (2006) proposed reference levels for barium procedures, which had to be reviewed on a 3 yearly basis, with a minimum of 10 patients. The 3rd quartile values were 11, 13 and 31 mGy.cm² for barium swallow, meal and enema procedures respectively. The National Radiation Protection Board (NRPB), Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) and International Atomic Energy Agency (IAEA) have set reference levels ranging between 7.5 – 11, 12 – 15 for barium meals and 21 – 40 mGy.cm² for barium swallow, meals and enema procedures as shown in Table 2.1. A study done by Engel-Hills and Hering (2001:693-696) measured the doses from barium enema procedures received by adult patients at 3 hospitals in the Western Cape, South Africa, and compared

this to international dose reference levels. The doses measured were higher than doses measured in the United Kingdom and it was anticipated that the doses would reduce when there were improved radiation protection practices. In 2009, Nabasenja published reference levels for barium enema and barium meal procedures done at 3 institutions. The study by Nabasenja was the first in the Western Cape for barium meal procedures and showed an improvement in the reference level for barium enema procedures. Since the publication of the studies in 2001 (Engel-Hills & Hering) and 2009 (Nabasenja), very little information is available to indicate change at an institutional level even though the study was conducted at a tertiary hospital. Radiation regulations for improved radiation practices were only instituted in 2006 for the DAP meter installation on fixed fluoroscopic units and reference levels were only regulated in 2009 as part of the licensing conditions (DoH SA, 2008).

In 1998, Servomaa and Topiovaara compared the organ, effective and skin doses for age ranges 1, 5, 10 and 15 years and adult patients from phantom calculations to those published by Hart, et al. (1994), for projections of coronary artery procedures. The results were comparable with very small differences. These were attributed to the different types of phantoms used in the specific studies.

The literature reviewed showed that the calculation of the effective and entrance skin doses play an important role in radiation dosimetry. There are different methods to derive these values and the DAP value recorded has the potential to be a useful indicator of dose and risk to the patient. The following chapter will delve into the methodology followed to achieve the objectives of the research.

CHAPTER THREE: RESEARCH DESIGN AND METHODOLOGY

3.1 Introduction

The practice of recording the DAP values, registered by the DAP meter, as required by Radiation Control Code of Practice, is a good tool for optimising radiation protection (DWP, 1992:7) , however it is not an easily understood value and neither does it indicate a measure of radiation dose received by the patient for the specific procedure. The measured doses from procedures are recorded by the DAP meter, but the relationship between the entrance skin dose, effective dose and DAP values is not so easily observed, as different projections result in different skin dose distributions (Vano, et al., 2001:49). In this chapter the methods used to obtain the effective and skin doses will be discussed.

The research site was a large tertiary hospital, training radiology registrars as well as radiographers. The radiology registrars start their rotation in the fluoroscopy department. The different techniques applied and the varying fluoroscopic exposure times equate to various doses to patients (Wambani, et al., 2014:1-2).

The study was conducted to determine the entrance skin dose and calculate the effective dose of barium procedures and to determine the diagnostic reference levels for each procedure and compare it to previously published diagnostic reference levels in South Africa and abroad, without the patients receiving any additional radiation exposures.

3.2 Research design

There were 2 parts to the study:-

The first part was a retrospective quantitative research component where the DAP readings captured for barium swallow (BaS), barium meal (BaM) and barium enema (BaE) procedures were analysed to determine the mean and 75^{th} percentile values. The values obtained for each procedure type was set as a diagnostic reference level and then compared to previously published studies.

The second part was a descriptive correlative research design component. The patient procedure data were entered into the PCMXC Monte Carlo software program to compute the effective dose as well as the entrance skin dose for BaS, BaM and BaE procedures, for each patient from the recorded DAP values and to determine a relationship between the DAP value and the skin doses received . The program calculates the doses of the 25 predefined organs.

3.3 Research site

The study was conducted at a large tertiary hospital, affiliated to three academic institutions. The hospital has 964 beds and has active medical and surgical departments. From the collated 2015 hospital statistics, 160 000 radiological examinations were performed and of this, 2% were barium related fluoroscopic procedures (Barnard, 2015). All the barium related fluoroscopic procedures were performed on the two dedicated fluoroscopic units installed in the Radiology department.

3.4 Radiographic equipment

The fluoroscopy department at the research site had two fluoroscopy units. One unit was a Philips Duodiagnost and the other was a Siemens Iconos R200. The Philips fluoroscopy unit was unable to automatically capture and send the examination parameters to PACS, as the DAP meter was fitted retrospectively in 2007 as per the DIrectorate of Radiation Control regulations. The total DAP reading per procedure, as well as the screening time was captured by the DAP meter and printed onto a sticker; the sticker was then pasted into the patient register by the radiographer after each procedure. The Philips x-ray unit had a mechanical problem that required repairs and it was decommissioned at the end of 2015.

The records of patients imaged on the monoplane Siemens, Iconos manufactured in 2008 as depicted in Figure 3.1, were therefore selected for the study.

Figure 3.1: Siemens Iconos R200 Fluoroscopy x-ray machine at the research site

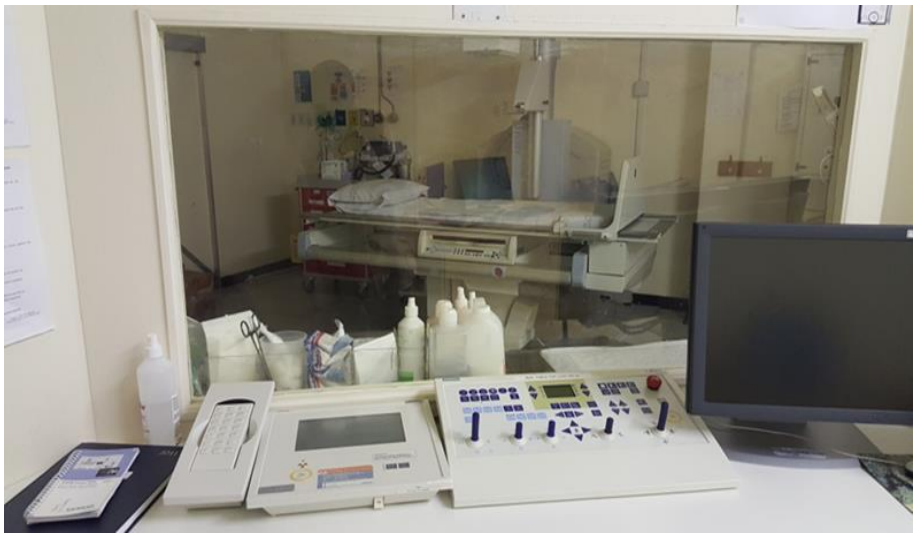

Figure 3.2: Siemens Iconos R200 Controls and display monitor at the research site

The Iconos R200 (refer to Figure 3.1 and 3.2), with a 65 kW generator was used for all general fluoroscopic imaging procedures. It consists of a floor-mounted C-arm with undercouch Image intensifier. The tube voltage ranges between 70 kV and 125 kV, depending on the patient size and projection. The unit had a built-in DAP meter and the capability to send the generated DICOM header information directly to PACS (Siemens, 2008, Germany). Information such as the DAP reading; kilovoltage and milliAmpere, for each examination were collected.

A DAP meter (Diados 0821, Siemens User Manual, 2008) was mounted into the tube housing and a readout is given for each exposure, a total dose is generated at the end of the procedure. This reading is noted by the radiographer and captured in the fluoroscopy register. The DAP meter was calibrated on installation of the machine and is done on an annual basis when the unit undergoes the yearly quality assurance tests as per the Directorate of Radiation Control regulations (Refer to Appendix A). It is also checked at six monthly intervals when the unit undergoes a planned maintenance service, as per the maintenance agreement between the vendor and the institution.

3.5 Selection of participants

3.5.1 Sampling

The study sample included all adult barium swallow, meal and enema procedures done on the Siemens unit between March 2012 and June 2015. According to the Dosimetry Working Party (1992:8), 10 patients is a minimum requirement for a clinical average representation of

a procedure population. All patients who met the criteria were included in the study. A total of 161 patients' procedures were included in the sample.

3.5.2 Inclusion criteria

The sample included all adult patients that underwent barium swallow, meal and enema procedures between 2012 and 2015; with a captured DAP value and screening time. Dosimetry Working Party guideline stated that the patient must weigh more than 60 kilograms, but less than 80 kilograms (DWP, 1992:8). It was decided to increase the sample size by expanding the weight range from 50 – 90 kg, as this was representative of the patient population referred for barium procedures at the specific institution.

3.5.3 Exclusion criteria

Procedures of adult patients that did not have the desired information in the patient register or on the PACS were excluded from the study. Patients with body weights lower than 50 kg or higher than 90 kg were excluded, as well as patients where the weight/mass was not available in either the patient file or the fluoroscopy register.

3.6 Assumptions

The assumption was made that the geometry of the Antero-Posterior projection will be indicative of the total distribution of all the projections. Previous studies and surveys indicated that a nominal geometry can be identified and assumed that each of the type of procedures is performed with the geometry specific to it (McPharland, 1998:1289). This is a limitation for the study. It was assumed that each patient had the same morphology within the weight spectrum of 50 - 90kg.

3.7 Data collection

3.7.1 Meta Data

The hospital has a Philips PACS and Radiology Information System (RIS) installed since 2012. All the imaging units were set up to send DICOM information captured, automatically to PACS for storage; this included the technical parameters used for the procedure, the dose measurement, the patient demographic details as well as the equipment details. This information was manually retrieved from the PACS for each procedure. The DAP value available on the PACS was for each image and not the total value for each procedure. The total DAP reading was collected from the patient register.

DICOM is the international standard for medical images and related information to communicate across different platforms, different modalities and different vendors. The

DICOM standard defines the format and manner for medical images to be exchanged with the data and image quality necessary for use in clinical practice (Parisot, 1995:171-177).

3.7.2 Retrospective data

The patient data was retrospectively collected from March 2012 - July 2015. The details were derived from the patient register, available in the screening room. As per the Directorate of Radiation Control, Code of practice (DoH SA, 2006) each patient must have their demographic details, screening time, procedure, DAP reading and type of procedure recorded.

The total DAP reading and screening time was manually captured by the radiographer directly from the Siemens unit, after each procedure. This resulted in many procedures being excluded from the study as the DAP readings were not captured and noted in the register.

The patient files had to be requested and manually checked for the weight of the patients. The data was manually captured in Excel and each entry was anonimised and allocated a number and stored on an external device. The sample consisted of 161 procedures, 55 barium swallow (mean weight = 62,4kg), 50 barium meal (mean weight of 66, 6 kg) and 56 barium enema (mean weight of 69,2kg) (Refer to Appendix B).

The mean weight according to Hart, D (1991) should not be less than or exceed 5 kg from 70kg, as this is an indication of a typical mean weight of an average patient to calculate the average dose. It was decided to increase the sample size to include the weight range from 50 – 90 kg, as this is representative of the patient population referred for barium procedures at the specific institution. All samples that were between 50 – 90 kg were selected, this resulted in 111 procedures in total, 34 (10 more than the 65 – 75kg range) barium swallow, 39 (14) barium meals and 41 (11) barium enema procedures that met the set criteria.

The DAP values available on the PACS system for the particular procedures, were not the total for the entire study, but rather the DAP reading for the selected image. The images stored on PACS were selected by the radiologist performing the study and was not a true indication of all the images taken (Refer to Appendix B).

3.8 Fluoroscopy protocol

3.8.1 Barium Swallow

The barium sulphate suspension is introduced orally, under fluoroscopic guidance, to visualise the oesophagus, Oesophageal – Gastric (OG) junction and flow into the stomach to assist with diagnosis. The views done are Antero-posterior (AP), Right Anterior Oblique

(RAO) and a lateral view of the oesophagus, and an AP of the OG junction and stomach as shown in Figure 3.3 (Chapman & Nakielny, 2001:67).

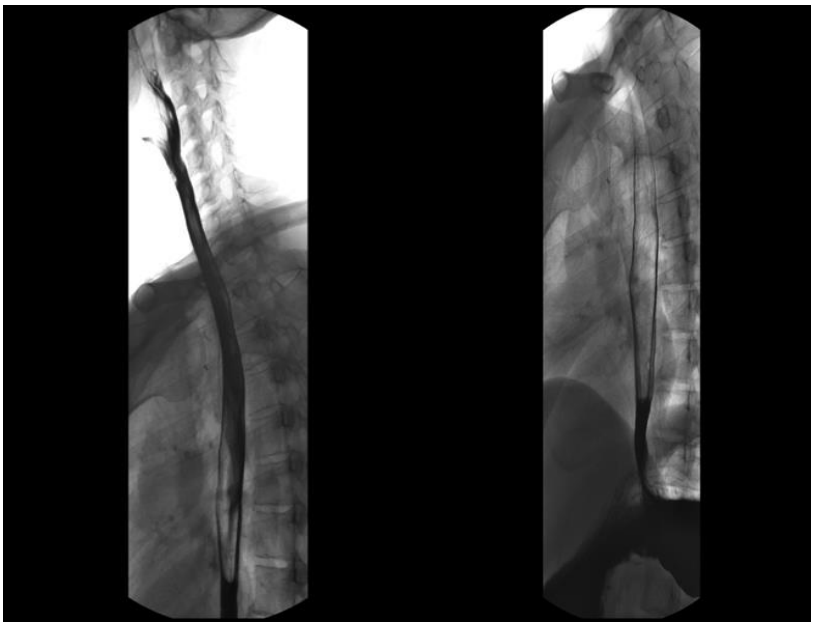

Figure 3.3 Barium Swallow (images from the PACS at the research site)

3.8.2 Barium meal

This is the introduction of barium sulphate suspension, orally, under fluoroscopic guidance, to coat and visualise the oesophagus, stomach and first part of the small intestines. The views for a barium meal are; erect AP and RAO of the oesophagus, erect RAO and Left anterior oblique (LAO) of the stomach, supine and prone views of the stomach and erect views of the duodenal cap (Refer to Figure 3.4) (Chapman & Nakielny, 2001:68).

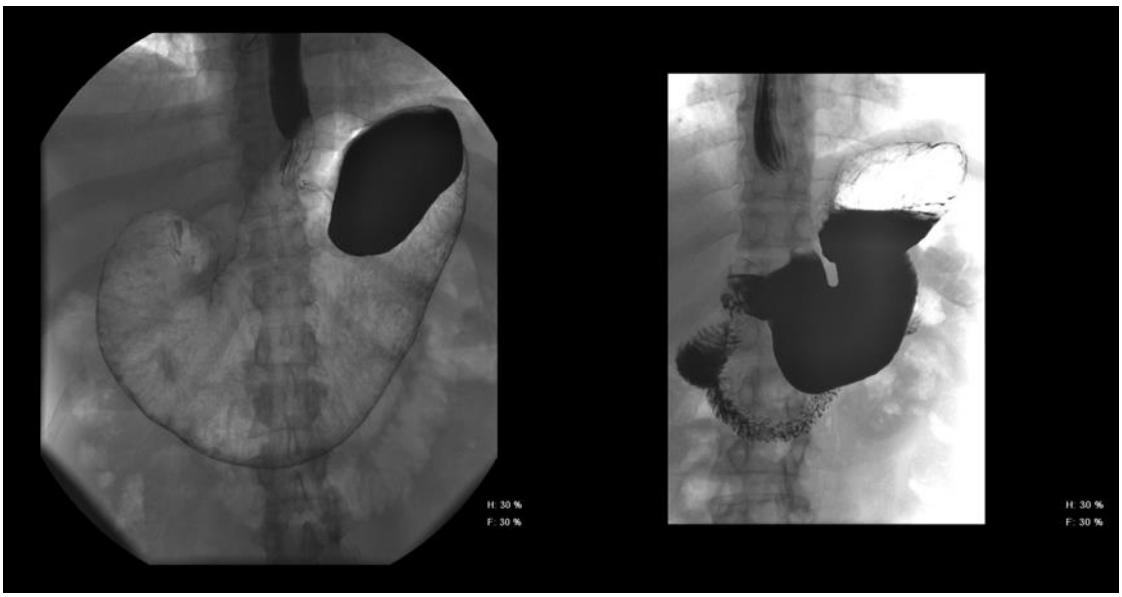

Figure 3.4 Barium Meal: Supine and erect view of the stomach (images from the PACS at the research site)

3.8.3 Barium Enema

Under fluoroscopic guidance barium sulphate suspension is introduced via the rectum to visualise the rectum, the large intestines and the last part of the small intestines (Chapman and Nakielny, 2001:69-70). The standard views for barium enema examinations are lateral of the rectum, RAO of the sigmoid colon, AP or RAO/LAO views of the descending, splenic, transverse, hepatic, ascending colon and caecum. A plain AP supine and prone abdomen and a 30 degree caudad-prone of the rectum are done as additional views (Refer to Figure 3.5 and 3.6).

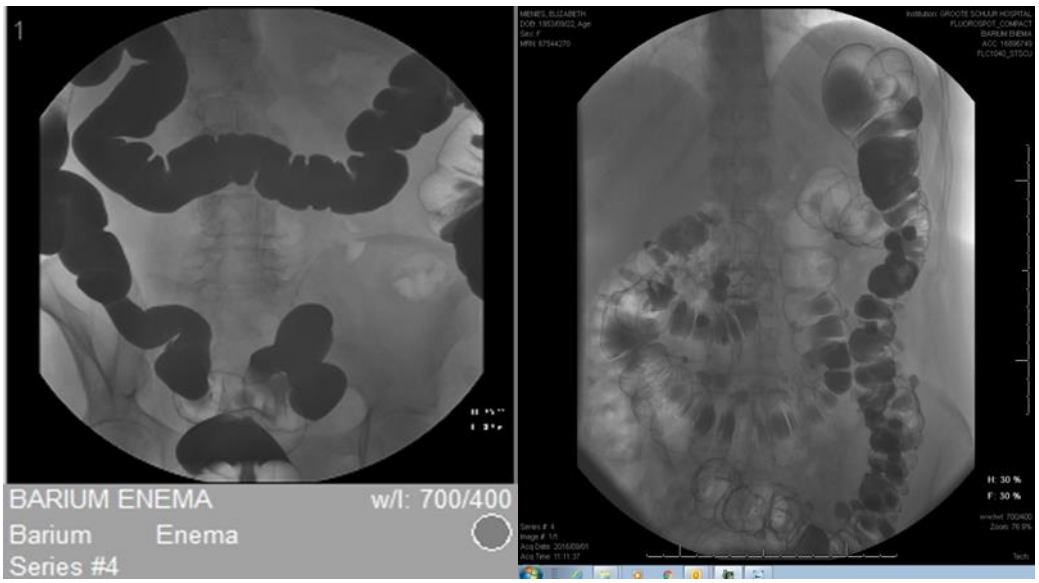

Figure 3.5: Barium enema: Antero-posterior (AP) view of the sigmoid, ascending, transverse and descending colon under fluoroscopy (images from the PACS at the research site)

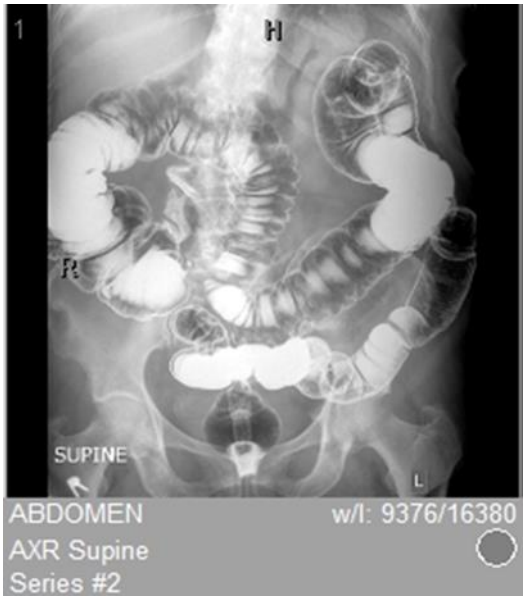

Figure 3.6: Barium enema Abdomen Overview

3.9 Ethical considerations

Ethics approval was requested from Cape Peninsula University of Technology Research Ethics Committee as well as the Hospital Ethics Committee as patient imaging data was used. Permission was also requested from the Head of the Radiology department. No patient

identification details were disclosed and all the collected information was stored in a separate database without patient identifiers.

No demographic data were used and total anonymity and confidentiality was maintained. The ethics certificate is attached as Appendix C. No patient was exposed to any additional radiation whilst gathering the information.

The data was collected by the researcher. The collected data was stored on a portable password protected, external device. The researcher, with the assistance of a representative from the Department of Medical Physics analysed the data.

3.10 Dose Calculations

3.10.1 Method to determine reference DAP value

The DAP values in mGy.cm², captured for the respective barium swallow, meal and enema procedures were entered into an excel spread sheet (Refer to Appendix B). The mean DAP value for each procedure was calculated as well as the 75th percentile values. The value obtained was compared to the DRL calculated by Engel-Hills (2001) for barium enema and by Nabasenja (2009) for barium meal and enema procedures. The results for all three procedures were compared to international DRL's as published by International Atomic Energy Agency(IAEA), Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) and National Radiation Protection Board (NRPB of Europe). There was no local DRL available for barium swallow procedures.

3.10.2 Method to determine the effective and skin dose values

The input data for the calculations of the effective and skin doses were the patient age, weight, height, field size, projection, focus-to-skin distance (FSD), exposure data (anode angle and filtration material) DAP value, kilovoltage (kVp), milli-Amperage per second (mAs) and source to detector/image distance (SID) were also be captured for each patient and used to calculate the effective dose (Bor, et al., 2004:319)(Refer to Appendix B).

The software programme that was used to analyse the data was the Monte Carlo PCXMC 2.0 (Finland, 2008) software programme. The program is in use since 1997. The Monte Carlo program is a method to simulate photon energy propagation through tissue. The simulation is based on the random interactions that photons experience as they pass through the tissue. Individual photons are chosen by statistically sampling the probability for each angular deflection per scattering event. The sampling histories were generated and the mean values of the energy deposits were used to calculate the skin dose and effective dose for each procedure. The software also calculates the doses to 25 different organs as stated by

Servomaa & Tapiovaara in 1998, as per the ICRP 60 (1991) and ICRP 103 (2007). The skin is seen as an organ.

The patient height, patient thickness, distance from the source to the patient skin (FSD) and field size on the skin were not known. It was assumed that all patients were 1.78 meters which is the default height setting of the PCMXC 2.0 program. The height of the patients was not available. The SID was fixed at 1150mm as the Siemens Iconos fluoroscopy unit had a fixed C-arm.

Different patient weights were entered into the program in variations of 5 kilograms and measurements were done to determine the AP diameter of each patient, as patient size influences dose (Chapple, et al., 1995:1083). The diameter for the different weight ranges were then calculated as 50 – 60 kg = 16 cm, 61 – 80 kg = 18 cm and 81 – 90kg = 20 cm. The actual filed size as measured by the researcher and entered into the program, for each procedure, was 15 x 25 cm^2 for barium swallow, 25 x 28 cm^2 for barium meal and 19 X 24 cm^2 for barium enema procedures. The SID and patient diameter were entered to calculate the FSD which ranged between 95 – 99cm for all the procedures and the field size (beam height and width) ranged between 12.4 – 21.7cm^2 for barium swallows, 20.7 – 24.1 cm^2 for barium meals and 15.7 - 20.7cm^2 for barium enemas procedures. The actual kV was entered for each dose computation. The other parameters entered into the Monte Carlo program are tabled below (Refer to Table 3.1).

Table 3.1: The parameters selected for entry to the Monte Carlo program for BaS, BaM and BaE procedures

Parameters	Ba swallow	Ba Meal	Ba enema
X ref and Y Ref	0	0	0
Z Ref	70	35	5
Projection angle	270 degrees	270 degrees	270 degrees
Cranio-caudal angle	0 degrees	0 degrees	0 degrees
Maximum energy	100 kV	110kV	110kV
Number of photons	100 000	100 000	100 000
Anode angle	12 degrees	12 degrees	12 degrees
Filtration	2.5mm Al	2.5mm Al	2.5mm Al

The selected parameters assumed that each patient had a similar shape and size, as the same height and similar diameters were selected for the different weight ranges.

The lung and breast tissue are now seen as the most sensitive organs in the ICRP 103, as opposed to the gonads in the ICRP 60. The weighting factors for the effective doses have changed and were higher in the ICRP 60 than in the ICRP 103.

The times required for the simulations depended on the photon histories entered as well as the processing speed of the PC and “ranged between 1 minute and 2 hours” (Servamaa & Topiovaara, 1998:213 - 219).

Simulations were done with 10 000, 50 000, 100 000 and 1000 000 photon histories for each type of procedure and a decision was made to select 100 000 photon histories for simulation for each type of procedure. The difference in skin and effective doses between 100 000 and 1 000 000 photon histories was very small with the end result being less than 1%, but the 1 000 000 photons history simulations significantly slowed down the program and the computer as shown in Table 3.2.

Table 3.2: PCMXC dose results when utilising different simulation histories

Photon histories	10 000	50 000	100 000	1 000 000
Skin dose (mSv)	0.286	0.286	0.285	0.284
Effective dose (mSv)	0.388	0.388	0.388	0.384

3.11 Data Analysis

The Microsoft Excel 2010 computer program was utilised to capture and analyse the raw data. The data included the patient weight, equipment parameters as well as imaging parameters. The initial aim of the research project was to have at least 20 patients for each procedure. During the data capture process 50 plus patients were recruited; however we had to discard some that did not meet all the criteria, resulting in about 30 patients for each procedure for the weight range of 50 -90 kilogram. The average weights of the barium swallow, meal and enema patient participants were calculated. The amount of males and females were noted. The DAP to ESD (entrance skin dose) conversion factor is the ratio of ESD/DAP and the DAP to EF (effective) dose conversion factor is the ratio of EF/DAP as utilised by McPharland in 1998.

3.11.1 Sources of uncertainty

The DAP meter is calibrated by the manufacturer, then on installation and on an annual basis. The difference between the actual measured DAP meter reading and the calculated DAP reading by the machine is not allowed to be more than 30% of the baseline value set at specific kV and mAs exposures as per the manufacturers and Radiation Control specifications. The actual reading of the DAP difference is 24%. This means that the DAP meter ‘over-reads’ the DAP value by about 20 - 24% per study (see Appendix A).

The weight for each patient was obtained from the patient folder; the type of scale used and the accuracy of the scale could not be verified. All data collected that did not fall within the 50 – 90 kg weight range was excluded from the study. Procedures that did not have the weight captured, or when the patient weight could not be found in the patient folder, were also rejected.

3.12 Statistical tests used for data analysis

3.12.1 Correlation

According to Harris and Taylor (2003:48) “when there is a linear relationship between two variables there is said to be a correlation between them”. Measured on a scale from -1 (perfect negative correlation), through 0 (no relationship between the variables at all), to +1 (perfect positive correlation).” Correlation measures the strength of the association between variables.

3.12.2 Regression analysis

The regression line is a line on a graph trying to fit through a set of points to make the line as representative as possible. It is used to find how one set of data relates to another and how best the line goes through all the points on the data set on a graph. Regression quantifies the association between variables. The regression lines indicate the slope of the graph (Harris & Taylor: 2003, 53-54). The regression line was used to illustrate the DAP and skin dose as calculated and plotted for the barium swallow, meal and enema calculations.

3.12.3 Linear Correlation co-efficient

The correlation coefficient (R) is the measure of the strength of a linear relationship between two variables also known as the correlation between 2 variables. The linear co-efficient is denoted by the letter R. It can be calculated using the Microsoft Excel computer program. Part of this research study was to determine a relationship between the measured DAP value and the calculated skin dose. According to Harris and Taylor (2003:48): “A positive correlation coefficient means that as one variable is increasing the value for the other variable is also increasing – the line on the graph slopes up from left to right, denoting a positive correlation. A negative correlation coefficient means that as the value of one variable goes up the value for the other variable goes down – the graph slopes down from left to right.” The value of R is greater or equal to negative 1, or less than or equal to positive 1 ($-1 \leq R \leq 1$). When R is positive or negative and close to unity then there is a strong correlation between two variables, alternatively if R tends toward zero, then there is a weak or no correlation between the variables. Linear correlation coefficient, R of 0.8 or greater is described as a strong linear correlation and 0.5 as weak, whilst there is no linear correlation when the R value is less than 0.5 (Harris and Taylor 2003:48; Mathbits, 2009). This statistical

tool showed the correlation between the captured DAP values for each procedure and the calculated skin dose.

3.12.4 Co-efficient of determination, R^2

The co-efficient of determination, R^2 is an indication of how well the regression line represents the data on the graph. R^2 is therefore greater than or equal to 0 and less than or equal to 1 ($0 \geq R^2 \leq 1$). A strong correlation between 2 variables is suggested when R^2 is equal to 1 and passes through all the data points. R^2 indicates the data points closes to the regression line as a percentage. For example if $R = 0.85$ then $R^2 = 0.7225$; therefore 72.25% of the total variation of y values can be explained by the linear relationship between x and y, whilst 27.75% remained unexplained (Harris &Taylor 2003:53– 54; Mathbits, 2009).

3.12.5 Chauvenet's criterion test

The Chauvenet's criterion is a statistical test used in the rejection of a single data point, called an outlier, for data sets of up to 1000 data values of any sample distribution. Knowledge of the standard deviation and mean of the sample is required. One data point may be discarded using the Chauvenet's test, for a study sample. A data point is discarded when the critical deviation is larger than the observed deviation. The standard deviation is obtained by subtracting the suspected data point from the mean of the sample (Harris & Taylor, 2006:16; Lin & Sherman, 2007:1-11). In this research study, the Chauvenet's criterion test was used to reject or retain suspected data points when they were very different from the mean for each type of procedure or when the data point did not have an effect on the result.

The DAP values for each of the procedures that was very different from the mean was interrogated to determine if they had any effect on the results. It was decided to retain the data points as it did not affect the results significantly.

3.12.6 Pearson's Co-efficient of skewness

This is a statistical test done to determine the normality of distribution of the data points. The coefficient compares the sample distribution with a normal distribution. The skewness value can either be negative, positive or undefined. If the data is very skewed, one has to be careful of rejecting the outliers (Statictics How To, 2014).

3.13. Limitations of the research

- The study was limited by the availability of the DICOM data. Patients that did not have imaging data available on PACS were excluded from the study.

- The study did not take into account the experience of the radiologist, as the current practice at the study site was for registrars to train registrars and the different techniques practiced.
- The total recorded DAP value may not be a true indication of the area exposed to radiation as only one projectional view was taken into account.
- The availability of the patient weight had an impact on the sample size and it was then decided to increase the weight range.

The entrance skin and effective doses were calculated from the collected DAP values. The 75^{th} percentile values were determined for the skin, effective and DAP values for each procedure type. The 75^{th} percentile DAP value was then compared to other published values. Conversion factors were derived from these calculated values. These results are discussed in the next chapter.

CHAPTER FOUR: RESEARCH RESULTS

4.1 Data analysis and research findings

The research study determined the entrance skin dose for barium swallow, meal and enema procedures, measured the effective dose for different organs for each type of procedure and investigated whether there was a correlation between the DAP value and the skin dose for each type of procedure.

Furthermore, an assessment of the relationship between the DAP value recorded and the patients' calculated skin dose was done using linear regression, correlation coefficient, R and coefficient of R determination, R^2.

For the calculation of diagnostic reference dose levels, the DWP (1992: 8-13) recommended that dose measurements be carried out on at least 10 patients weighing 50 kg to 90 kg for any examination. Such a weight range would ensure that the mean weight of the study sample lay close to 70 kg (65-75 kg) which is the average weight of an adult.

The data collected consisted of 161 procedures in total, 55 Barium swallow (mean weight = 62,4kg), 50 Barium Meal (mean weight of 66,6 kg) and 56 Barium enema (mean weight of 69,2kg)

A total of 114 patients met the criteria. The breakdown of the sample size, weight and age for the 3 procedures is shown in Table 4.1

Table 4.1: Sample size, mean age and weight for each type of procedure

Procedure	*n*	Age Range	Mean Age	Weight Range	Mean weight
Ba swallow	34	23 – 79 years	50.6 years	50 – 89 kg	65.5 kg
Ba meal	39	32 – 80 years	52.7 years	51.3 – 84 kg	65.5 kg
Ba enema	41	51 -80years	64.6 years	51 – 86 kg	66.5 kg

4. 2 Barium Swallow

A total of 34 patients were analysed for the barium swallow procedures, 16 males and 18 females, with a mean age of 50.6 years and a mean weight of 65.5 kg (Table 4.1).

The mean DAP was calculated as 9.3 Gy.cm², with a minimum of 1.216 Gy.cm² and a maximum measured reading of 27.56 Gy.cm². The mean skin dose calculated by the PCMXC 2.0 program was 1.4 mGy and the mean effective dose was 1.8 mSv. The 25th percentile was 3.83, 75th percentile for the DAP was 12.8 Gy.cm², skin dose was 1.9 mGy and the effective dose was 2.4 mSv (Refer to Table 4.2).

Table 4.2: DAP, Skin dose and effective dose from Barium swallow data

DAP (mGy.cm²)	DAP (Gy.cm²)	Skin dose (mSv)	Effective dose (mSv)
Mean	9.3	1.4	1.8
Median	7.2	1.2	1.4
75th percentile	12.8	1.9	2.4

A regression line was drawn to connect the data points. Pearson's co-efficient of skewness indicated a positive distribution at 0.91. Outliers were identified by means of the Chauvenet's criterion and 2 data points were identified as outliers. Each data point was compared to the mean value and was found that it did not have a significant influence on the result and was not discarded as shown in Figure 4.3.

Table 4.3: Mean, median and DRL DAP values with outliers and without outliers for Barium swallow

DAP (mGy.cm²)	With	without	without
Mean	9.3	8.9	8.8
Median	7.2	5.9	5.9
DRL	12.8	12.6	12.6

Figure 4.4 and 4.5 are graphic representations of the total DAP values compared to the calculated skin dose for a linear and power fit. There was a direct relationship between the DAP value and the skin dose, for both the linear and power fits. The linear equation had a

more accurate fit at high readings but not as accurate at the lower readings as opposed to the power equation, but the linear equation is easier to work with in a day to day setting.

There was a strong correlation between the DAP value and the skin dose for patients between the weight range of 50 -90 kg at the research site.

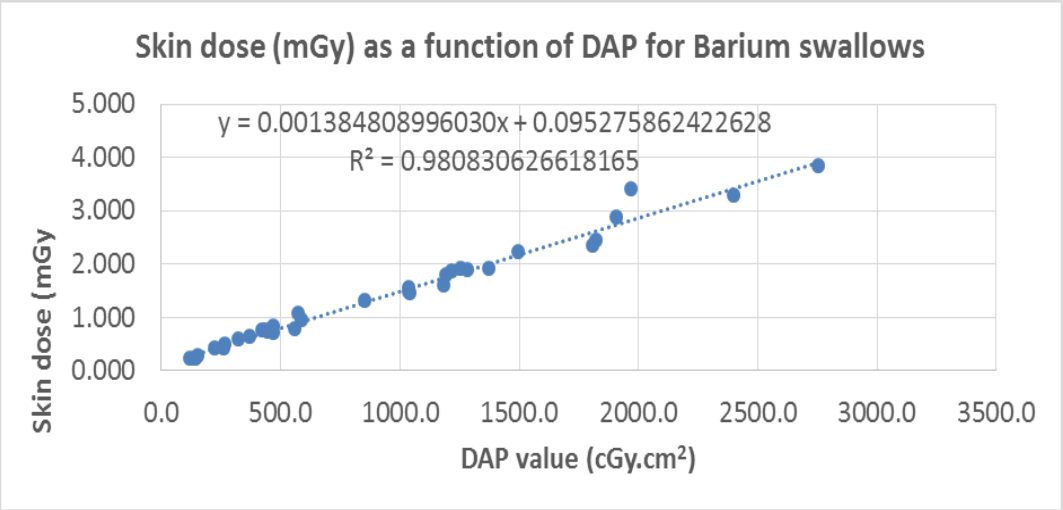

Figure 4.1: Linear fit for Barium Swallow procedures comparing skin dose and Dose Area Product (DAP)

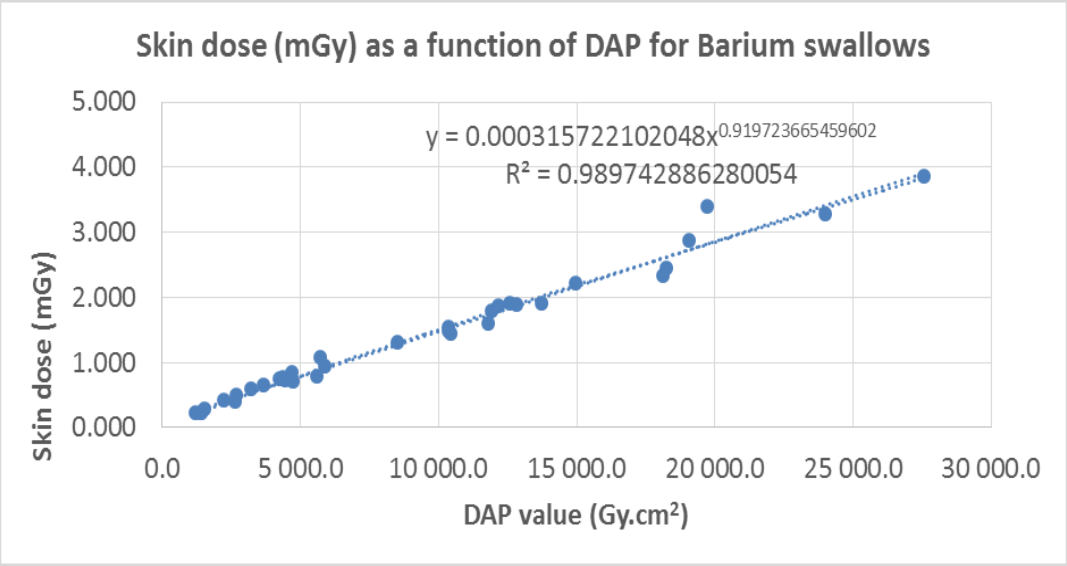

Figure 4.2: Exponential fit for Barium Swallow procedures comparing skin dose and Dose Area Product

4.3 Barium Meal

A total of 39 patients were analysed for the barium meal procedures, 17 males and 22 females, with a mean age of 52.7 years and a mean weight of 65.5 kg.

A regression line was drawn to connect the data points. Pearson's co-efficient of skewness indicated a positive distribution at 1.11. Outliers were identified by means of the Chauvenet's criterion and 2 data points were identified as outliers. Each data point was compared to the mean value and was found that it did not have a significant influence on the result and was not discarded.

Table 4.4: Mean, Median and DRL DAP values for Barium meal procedures with and without outliers

DAP (mGy.cm²)	With	without	without
Mean	11.9	11.4	11.4
Median	9.1	8.7	8.7
DRL	17.4	16.9	16.9

The mean DAP was calculated as 11.9 mGy.cm², with a minimum of 6. 2mGy.cm² and a maximum measured reading of 27.9 mGy.cm². The mean skin dose calculated by the PCMXC 2.0 program was 1.4mGy and the mean effective dose was 3.3 mSv. The 25th percentile was 6. 57Gy.cm², 75th percentile for the DAP was 17. 4 Gy.cm², skin dose was 2.0 mSv and the effective dose was 4.6 mSv.

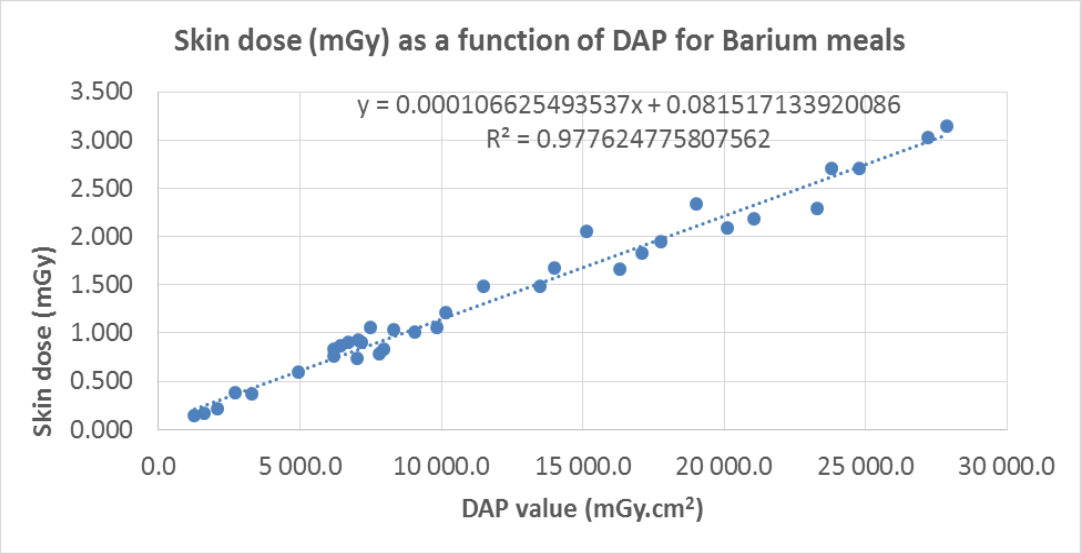

Figure 4.3: Linear fit for Barium meal procedures comparing skin dose to Dose Area Product

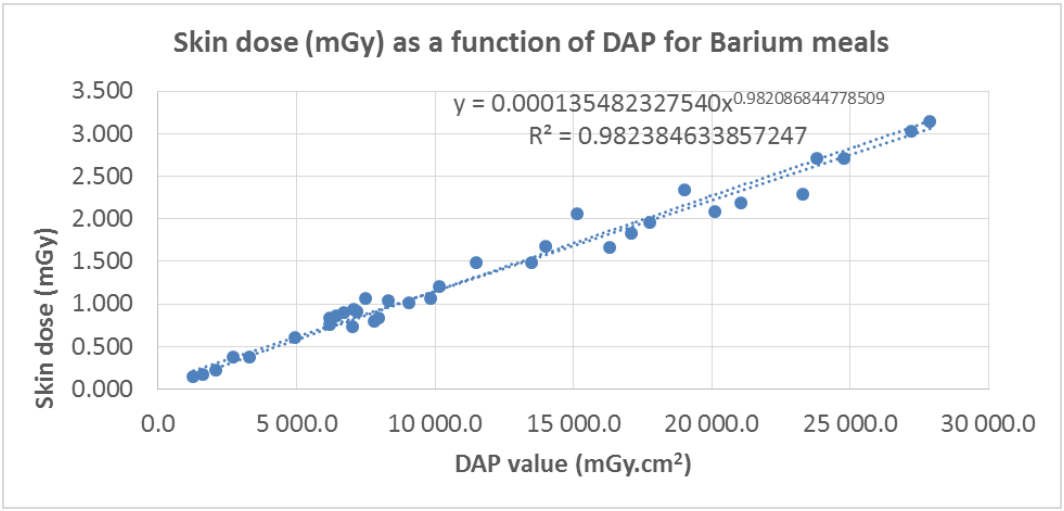

Figure 4.4: Exponential fit for Barium meal procedures comparing skin dose and Dose Area Product

4.4 Barium Enema

A total of 41 patients were analysed for the barium swallow procedures, 15 males and 26 females, with a mean age of 64.6 years and a mean weight of 66.5 kg.

A regression line was drawn to connect the data points. Pearson's co-efficient of skewness indicated a positive distribution at 0.61. Outliers were identified by means of the Chauvenet's criterion and 3 data points were identified as outliers. Each data point was compared to the mean value as shown in Table 4.5 and was found that it did not have a significant influence on the result and was not discarded.

Table 4.5: Mean, median and DRL DAP values for Barium Enema procedures with and without outliers

DAP (mGy.cm²)	With	Without	without	without
Mean	12.8	12.5	12.5	12.3
Median	11.4	11.1	11.1	11.1
DRL	16.0	15.5	15.5	15.5

The mean DAP was calculated as 12.8 mGy.cm2, with a minimum of 9.13 mGy.cm² and a maximum measured reading of 32.84. mGy.cm². The mean skin dose calculated by the PCMXC 2.0 program was 1.8 mGy and the mean effective dose was 7.5mSv. The 25th percentile was 7.72 mGy.cm², 75th percentile for the DAP was 16.0 mGy.cm², skin dose was 2.4 mGy and the effective dose was 9.8 mSv.

Table 4.6: Mean, median and 75th percentile values for DAP, skin dose and effective dose from barium enema data

	DAP (mGy.cm²)	Skin dose (mSv)	Effective dose (mSv)
Mean	12.8	1.8	7.5
Median	11.4	1.6	6.7
75th percentile	16.0	2.4	9.8

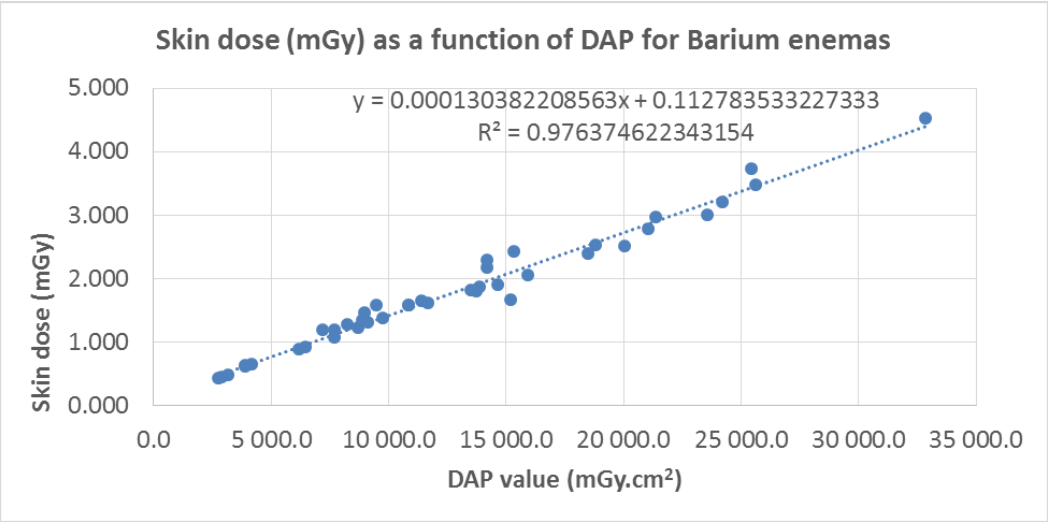

Figure 4.5: Linear fit for Barium Enema procedures comparing skin dose and Dose Area Product

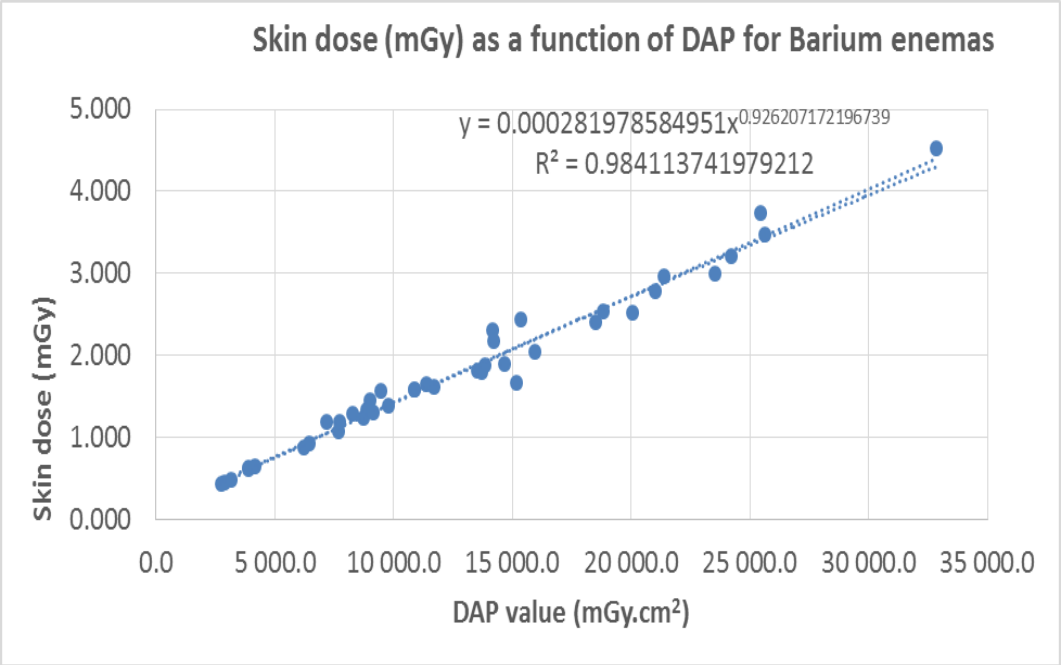

Figure 4.6 Exponential fit for Barium enema procedures comparing skin dose and Dose Area Product

The highest organ dose is generally when the organ is directly in the x-ray field (Annals of the ICRP, 2007). The organs with highest dose for barium swallow procedures were the clavicles, thyroid and the thoracic airway, the stomach and gallbladder for BaM and the colon, testes and pelvis for BaE procedures.

Table 4.7: Comparison of organ doses for BaS, BaM and BaE procedures

	Ba Swallow (mGy)	Ba Meal (mGy)	Ba Enema (mGy)
Thyroid	5.72	0.0093	0
Testes	0	0.00062	11.8
Ovaries	0	0.054	2.80

Comparison was made of the thyroid, gonads and ovaries organ doses as computed by the Monte Carlo program for the 3 barium procedures (Table 4.7). The data showed that the barium meal procedures had the most consistent dose spread over all the organs, while the highest doses were computed for barium enema procedures.

Table 4.8: Conversion factors for Barium Swallow, Meal and Enema for Effective and Entrance skin doses

	Effective Dose (mSv)	Entrance Skin Dose (mSv)
Barium Swallow	0.19	0.15
Barium Meal	0.26	0.11
Barium Enema	0.60	0.14

The effective and entrance skin doses were calculated according to the ICRP 60 and 103 by the Monte Carlo Program from the known DAP values (Hansson & Karambatsakidou, 2000) to establish conversion factors. The conversion factor for effective dose (E) was E/DAP and for entrance skin dose (ESK) ESK/DAP was calculated for each procedure type and shown in Table 4.8.

The results obtained showed a good correlation between the calculated entrance skin dose and the DAP value for each procedure. The 3rd quartile values compared well to other published values for barium swallow and barium enema procedures. The derived conversion factors for the skin and effective doses will assist with a simple and practical means of calculating the effective and skin doses after each procedure from the captured DAP value. In the following chapter the results are discussed and recommendations made.

CHAPTER FIVE: DISCUSSION AND RECOMMENDATIONS

5.1 Discussion

Barium related fluoroscopic procedures provide a cost effective diagnosis for various clinical needs. The study intended to determine the effective and entrance skin doses from recorded DAP values and to provide an understanding of the DAP value, by measuring the DAP for each type of procedure, comparing this value to previously published diagnostic reference levels and deriving a simple means of understanding of the DAP value to indicate the dose received by the patient.

Entrance skin dose is an important parameter for dose assessment with DAP as a diagnostic reference level for dose optimisation (Bogaert et al., (2009), Compagnone et al., (2004) Mehdizdeh et al., (2007), Ruiz-Cruces et al., 2000), Suleiman et al., (2011) and many others made use of TLD's to measure effective and skin doses, but required multiple TLD's and calibration resources for each procedure and dose orientation. In this study there is a linear correlation between the DAP and skin dose for procedures between the weight range of 50 - 90kg, however there is an even better relationship shown at the lower doses with the power fit. Using DAP readings and inferring the skin dose is less intrusive and can be done retrospectively and the dose values are reasonable for an upper threshold value (Servomaa & Tapiovaara, 1998:).

The effective doses calculated by the Monte Carlo software of the ICRP 60(1991) is higher than that of the ICRP 103 (2007) and could be due to the adjustment in weighting factor of some of the sensitive organs (Obed et al., 2015:175). Computing the effective and skin doses for the three common procedures showed that deterministic effects were unlikely (Leng, et el., 2011:100), but this should not be a deterrent to collecting data and improving current practices.

Aroua (2006:1623) stated that DAP is not the ideal value to monitor dose, but when skin measurements are not available and not to expose the patient to additional radiation, then conversion factors may be utilised to determine skin dose from DAP (Hansson & Karambatsakido, 2000; Koichi, 2006). Directorate of Radiation Control (DoH SA, 2006) requires an annual mean DAP and mean screening time for each procedure to be measured as part of the annual QA, even though Nyathi (2009) reported a weak correlation between screening time and DAP reading for barium procedures.

The median value, according to the IAEA, is the most representative of the "typical" DAP value at an institution for a specific procedure type. Several studies have documented the use of the 3rd quartile value (Figure 5.1) or the mean (Aroua et al., 2006:1627) to indicate typical DRL values. Even though different methods are used to display the typical DAP value, the importance of this value as a monitoring tool is not diminished. The method used to

display the DAP reference value can be used as a baseline for dosimetry. For comparative purposes it would be ideal if all methods to derive the DRL are standardised, but this would mean that the skin dose must be measured for each instance, during the procedure, and that is not practical. Use of conversion factors and indirect measurements to determine skin dose is much more practical and can be done retrospectively as reported by Hart and Wall (1994:1-57) to within a 25% error margin.

The median DAP value for BaS was 7.2 mGy.cm² with outliers included in the calculation and 5.9 mGy.cm² without the outliers, but this had no effect on the resultant 12.8 mGy.cm² DRL, calculated at the 75th percentile. There was a small but not significant change to the median BaM results from 9.1 to 8.7 (mean 11.9 to 11.4) as shown in Table 4.5 and median BaE results changed from 11.4 to 11.1 (mean 12.8 to 12.3) as shown in Table 4.7 when the outliers were removed.

Table 5.1: Comparison of DRL (Diagnostic reference levels) for BaS, BaM, BaE procedures with published studies

	Barium Swallow (mGy.cm²)	**Barium Meal (mGy.cm²)**	**Barium Enema (mGy.cm²)**
This study	**12.8**	**17.4**	**16.0**
Nabasenja (2009)	-	20.1	36.5
Engel-Hills (2001)	-		84
ICRP 103 (2007)	11	14	29
Aroua et al.(2007)	-	67 (mean value)	114 (mean value)
DWP, (1992)		23	61
NRPB (2005)	9	14	24
NRPB (2010)	7.5	12	21
IAEA (2014)	10	15	40
ARPANSA (2011)	11	13	31

The effective and entrance skin values were utilised to determine a conversion factor for entrance to DAP and effective to DAP values. Effective to DAP conversation factors for BaS, BaM and BaE are 0.19, 0.26 and 0.60 respectively and 0.15, 0.11 and 0.14 for entrance skin to DAP. The conversation factors for effective and entrance skin dose is a simple tool than can be utilised on a daily basis to determine the effective and entrance skin doses, from the recorded DAP reading, immediately after the procedure. This will be an immediate indication

if the dose exceeded the threshold value and will allow for immediate reflection for a possible reason for this. These values can then be recorded with the DAP value in the patient file and departmental register. This can assist the radiologist and radiographer to become aware of how the doses achieved compares to the benchmark value or whether the threshold value has been reached or not (Hansson, et al., 2000).

The reference levels for the Ba swallow, meal and enema procedures compare well with other published values (Refer to Table 5.1). Based on previously published South African data by Engel-Hills (2001) and Nabasenja (2009) there was a significant improvement of the DRL for barium enema, previously 36.5 Gy.cm², a slight improvement on the DRL for barium meal procedures and a first local DRL was established for barium swallow procedures. The values compare well to ICRP, IAEA, ARPANSA (Australian Radiation and Nuclear Protection Agency) for all procedures. No previous available threshold value for local BSw procedures was established at this institution.

The improvement from the previous published values could be due to the fact that new digital equipment was installed at the research site in 2009 and that Radiology registrars entering the programme must have completed their Radiation Physics module. This was started in 2014. To date there has been no radiation effects documented for any of the patients at the research site undergoing barium related fluoroscopic procedures, but a note must be taken that there was no previous documentation of patient DAP readings made prior to the regulations enforced in 2006.

The Monte Carlo simulation does not take the spread of the dose over the skin for all imaging positions into account as stated by Mehdizadeh, et al. (2007:106) and Servomaa & Topiovaara (1998:215), but their research still suggests a single conversion factor from DAP reading to skin dose will give a reasonable indication of an upper skin threshold dose limit.

The conversion factors calculated for this study indicates a simple means that can be applied to the recorded DAP value to determine the skin and effectives doses for these common procedures. This information is now available to all the Radiology staff at the research institution.

Proper radiation technique coupled with dose awareness will not remove the risk of radiation injuries, but will reduce the likelihood of deterministic effects and improve radiation protection practices.

5.2 Recommendations and conclusions

The 75th percentile DAP distribution compares well with published values, but an optimisation strategy need to be implemented to improve these values and reduce the dose to the patient. The strategy can include:

1. Creation of awareness by displaying the reference values for DAP, skin and effective dose for each procedure in the fluoroscopy room, indicating the threshold values.

2. Recording the total DAP values with the imaging onto the PACS system immediately post procedure.

3. Reviewing the current DAP readings on an annual basis and compare these values with the set threshold values.

4. Implementing action levels to be instituted for values that exceed the threshold values.

5. Relooking at and reviewing the imaging protocols and techniques to further improve the threshold values on an annual basis.

The table below can be utilised by the radiology staff to track the doses received by patients as part of the improvement process to be implemented.
ESD to DAP and ED to DAP conversation factor, derived for the weight range 50 -90kgs is multiplied to the DAP value.

Procedure	Conversion factor	DAP	Effective dose	Skin dose

The results obtained can be used to design a strategy and propose the use of the DAP values to be recorded in the patient record for future follow-up of total cumulative dose received. Easy to follow conversion factors can be applied to determine the effective and skin doses for barium related fluoroscopic procedures on a daily basis, by the radiographer, radiologist or student which will assist with continued awareness and procedure justification.

The development of a written protocol to standardise the procedure protocol and thereby reducing the variations in radiographer practices and unnecessary exposures to the patients will go a long way to improve radiation protection practices for both patients and staff.

This research can serve as a stepping stone for future research in radiation dosimetry and dose optimisation in other fluoroscopic procedures as well as other modalities towards creating institutional, provincial and national diagnostic reference levels.

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APPENDICES

Appendix A: Calibration certificate

NACHWEIS DER KALIBRIERUNG
Certificate of Calibration

Interne Ref. Nr. / *Internal Ref. No.* 1412277

PTW

PTW-Freiburg, Lörracher Str. 7, 79115 Freiburg, Germany ☎ +49-(0)761- 49055-0 FAX +49-(0)761- 49055-70 E-Mail info@ptw.de

Elektrometer / *Electrometer*: DIADOS [REF] T11003 [SN] 001461

Hiermit wird bestätigt, dass das oben genannte Messsystem unter Beachtung eines Qualtitätssicherungssystems nach **DIN EN ISO 9001:2008** kalibriert wurde.

Die für die Kalibrierung verwendeten Messeinrichtungen werden regelmäßig kalibriert und sind rückführbar auf die nationalen Normale der Physikalisch Technischen Bundesanstalt (PTB).

Das Gerät entspricht vollständig den Spezifikationen des Datenblatts und der Gebrauchsanweisung.

Das Gerät ist erfolgreich auf seine elektrische Sicherheit gemäß IEC 61010-1 und IEC 60601-1 geprüft worden.

Die für diesen Vorgang angefertigte Dokumentation kann bei Bedarf eingesehen werden.

Der Selbstablauf während der Kalibrierung war $\leq \pm 3{,}0 \cdot 10^{-14}$ A

We hereby confirm that the above mentioned measuring system was calibrated according to **DIN EN ISO 9001:2008** *under the observation of a certified quality assurance system.*

The measuring installations used for calibration are regularly calibrated. The calibration of these systems is traceable to standards of the German National Laboratory (PTB).

The instrument fully complies with the specifications given in the data sheet and the user manual.

The instrument has been successfully checked for electrical safety acc. IEC 61010-1 und IEC 60601-1.

The documents established for this procedure are available for inspection on request.

Leakage during calibration was $\leq \pm 3.0 \cdot 10^{-14}$ *A*

Freiburg, 06-Aug-2014

PTW-Freiburg
Physikalisch-Technische
Werkstätten Dr. Pychlau GmbH

(Unterschrift/Signature)

Dokumentenkennung Doc: D 022.1 V: 1.10 / Ini: I-022.1 V: 1.9

CALIBRATION CERTIFICATE
No. 1412279

PTW-Freiburg, Lörracher Str. 7, 79115 Freiburg, Germany ☎ +49-(0)761- 49055-0 FAX +49-(0)761- 49055-70 E-Mail info@ptw.de

Calibration Object

Radiation Dosemeter

Electrometer	**DIADOS E [REF] T11035 [SN] 000299**
Detector	**[REF] T60005 [SN] 001053**
Detector Type	Semi-Conductor
Manufacturer	PTW Freiburg, Germany
Customer	AEC-Amersham SOC Ltd
	Private Bag X 11 ZA-1685 Halfway House

Order No. : R142033
Order Date : 2014-07-21

Calibration Results

Measuring Quantity: Air Kerma (K_{air})

Detector Calibration Factors

Beam Quality	N_K [Gy /C]	Uncertainty [%]
RQR-M 2	$5.930 \cdot 10^4$	3.0
MRV 28	$5.776 \cdot 10^4$	3.0
WRV 28	$5.607 \cdot 10^4$	3.0
WAVa 28	$5.690 \cdot 10^4$	3.0
WSV 28	$5.628 \cdot 10^4$	3.0
RRV 28	$5.800 \cdot 10^4$	3.0

Reference Conditions

Temperature:	293.2 K (20°C)
Air Pressure:	1013.25 hPa
Relative Humidity:	50 %
Chamber Voltage/Polarity:	0V
Ion Collection Efficiency:	100 %

Calibration Date: **2014-08-08**
Recalibration Interval: 2 years (recommended)

Electrometer Calibration Factor: k_{elec} **= 1.000 +/- 2.0 %**

Freiburg, 2014-08-11

PTW-Freiburg
Physikalisch-Technische
Werkstätten Dr. Pychlau GmbH

(Signature)

CALIBRATION CERTIFICATE
No. 1412278

PTW-Freiburg, Lörracher Str. 7, 79115 Freiburg, Germany ☎ +49-(0)761- 49055-0 FAX +49-(0)761- 49055-70 E-Mail info@ptw.de

Calibration Object

Radiation Dosemeter

Electrometer	**DIADOS E [REF] T11035 [SN] 000299**
Detector	**[REF] T60004 [SN] 002369**
Detector Type	Semi-Conductor
Manufacturer	PTW Freiburg, Germany
Customer	AEC-Amersham SOC Ltd
	Private Bag X 11 ZA-1685 Halfway House
	Order No. : R142033 Order Date : 2014-07-21

Calibration Results

Measuring Quantity: Air Kerma (K_{air})

Detector Calibration Factor: N_K = **2.078 · 10^4 Gy / C** (for RQR 5)

Beam Quality Correction

Beam Quality	KV	Correction Factor k_Q	Uncertainty
RQR 3	50	1.02	3.0 %
RQR 5	70	1.00	3.0 %
RQR 7	90	0.98	3.0 %
RQR 9	120	0.97	3.0 %
RQR 10	150	0.97	3.0 %

Measuring Quantity: Air Kerma (K_{air})

Detector Calibration Factor: N_K = **1.977 · 10^4 Gy / C** (for RQA 5)

Beam Quality Correction

Beam Quality	KV	Correction Factor k_Q	Uncertainty
RQA 3	50	1.03	3.0 %
RQA 5	70	1.00	3.0 %
RQA 7	90	0.97	3.0 %
RQA 9	120	0.98	3.0 %
RQA 10	150	1.03	3.0 %

Electrometer Calibration Factor: k_{elec} = **1.000 +/- 2.0 %**

Calibration Date: **2014-08-08**

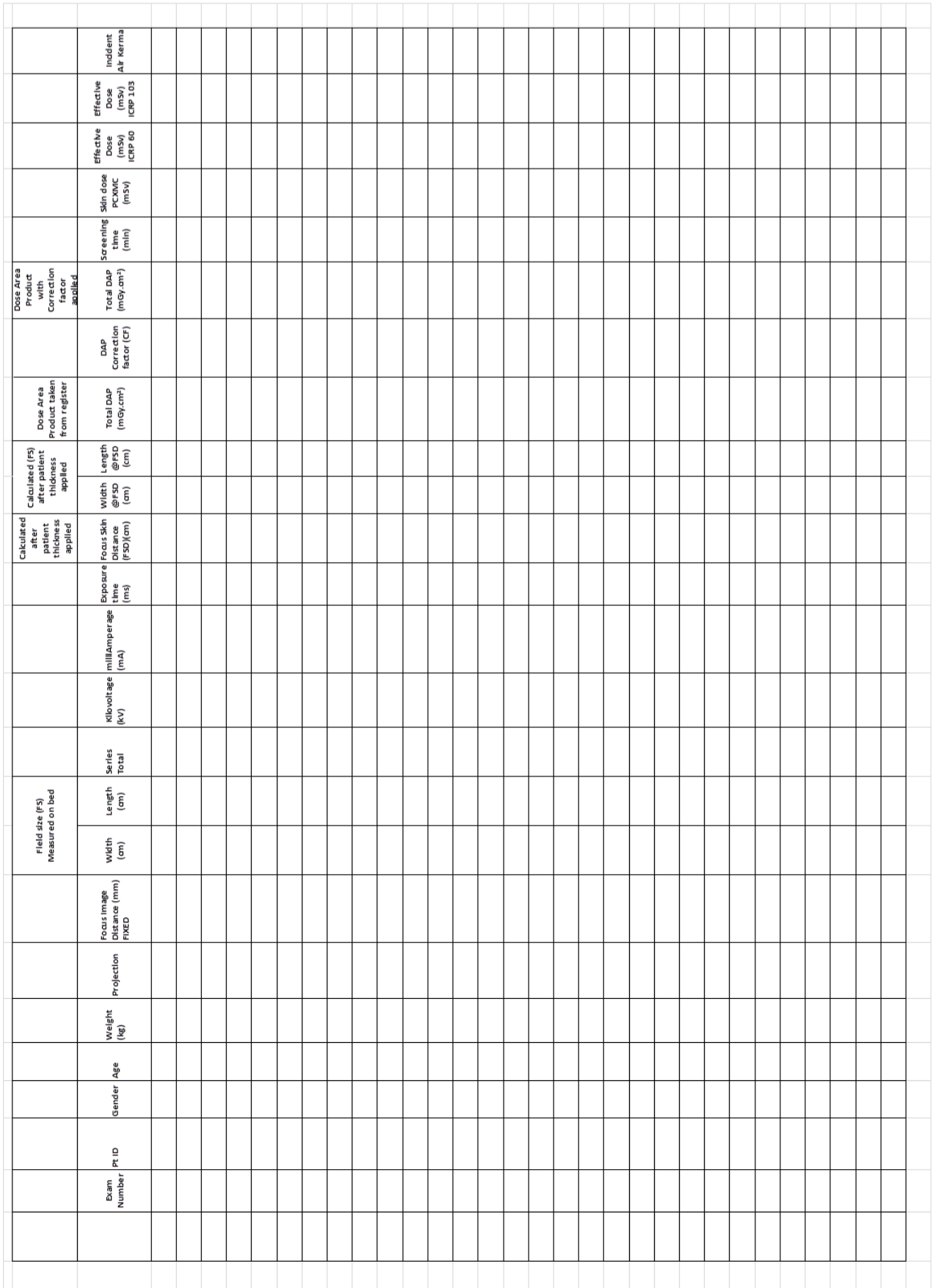
Recalibration Interval: 2 years (recommended)

Freiburg, 2014-08-11

PTW-Freiburg
Physikalisch-Technische
Werkstätten Dr. Pychlau GmbH

(Signature)

Appendix B: Data Capture sheet



Appendix C: Ethics Certificates

Cape Peninsula University of Technology

HEALTH AND WELLNESS SCIENCES RESEARCH ETHICS COMMITTEE (HWS-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: sethn@cput.ac.za

24 April 2015
REC Approval Reference No: CPUT/HWS-REC 2015/H05

Faculty of Health and Wellness Sciences

Dear Ms Nazlea Behardien - Peters

Re: APPLICATION TO THE HWS-REC FOR ETHICS CLEARANCE

Your application for ethics approval has reference. This serves to inform you that approval was granted by the Health and Wellness Sciences-REC on 17 April 2015 to Ms Behardien- Peters for ethical clearance. This approval is for research activities related to the MTech: Radiography at this Institution.

TITLE: Determination of effective dose and measurement of entrance skin dose values for barium studies at a tertiary hospital in the Western Cape.

Internal Supervisor:
1. Mrs F Davidson
2. Dr T Kotze

Comment:
Approval will not extend beyond 25 April 2016. 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

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

Cape Peninsula
University of Technology

HEALTH AND WELLNESS SCIENCES RESEARCH ETHICS COMMITTEE (HWS-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: sethn@cput.ac.za

25 April 2016
REC Approval Reference No:
CPUT/HWS-REC 2015/H05(renewal)

Faculty of Health and Wellness Sciences

Dear Ms Nazlea Behardien - Peters

Re: APPLICATION TO THE HWS-REC FOR ETHICS CLEARANCE

Your application for ethics approval has reference. This serves to inform you that approval was granted by the Health and Wellness Sciences-REC on 14 April 2016 to Ms Behardien- Peters for ethical clearance. This approval is for research activities related to the MTech: Radiography at this Institution.

TITLE: Determination of effective dose and measurement of entrance skin dose values for barium studies at a tertiary hospital in the Western Cape.

Internal Supervisor:
1. Mrs F Davidson
2. Dr T Kotze

Comment:
Approval will not extend beyond 26 April 2017. 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

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