An Analysis of Secondary Radiation Doses in a South African Neonatal High-Care Unit

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Declaration:

I, Dr Donovan Feeney, declare that this research report is my own work. It is being submitted for the degree of MMed (RadD) at the university of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other university.

Dr D. L. Feeney

On this ……th day of ………………… 2019.

Acknowledgements:

I acknowledge the contributions and assistance of Dr Linda Hlabangana, and Dr Tanyia Pillay from the University of the Witwatersrand and Chris Hani Baragwanath Hospital for supervising the research, Professor Debbie van der Merwe and Dr Kagiso Mahlangu from the University of the Witwatersrand Department of Medical Physics for assistance with methodology, Mrs Maryn Viljoen for consulting on the statistical analysis of the data, The South African Bureau of Standards Radiation Protection Services for providing assistance in obtaining the thermoluminescent dosimeters used in the study, and in reading the measurements from the dosimeters, particularly Mrs Sharron Tulloch, and Ernest Mathibe, and the radiographers at Chris Hani Baragwanath Hospital for performing the X-ray examinations and their role in the data collection.

Dedication

This work is dedicated to my loved ones.

Publications and Presentations

This work has never been published.

It has never been presented at a congress.

Abstract:

Introduction:
Neonates in a neonatal ICU or high care unit are a high-risk population. Besides a vulnerability to medical and surgical conditions, which often require radiological investigation, they are also at risk from the effects of radiation used in imaging. These risks increase with radiation dose. Numerous studies have assessed the dose due to primary radiation, however few have assessed the secondary radiation dose, and none have quantified the dose over time.

Aim:
To quantify the secondary radiation dose in our neonatal high care unit in order to determine if additional protective measures from secondary radiation are necessary.

Method:
A prospective analytic study was undertaken using multiple thermoluminescent devices in a cubicle of a neonatal high care unit, and control dosimeters outside the unit. Dosimeters were deployed for a 4 week period. Simultaneously, data was collected on patient numbers, and the X-rays performed in the unit. Results were compared to reference ranges for primary and secondary radiation (2-3 mSv per annum).

Results:
The average secondary radiation dose was 0.108mGy ($p=0.6553$) over 4 weeks, less than the expected background radiation dose of 0.17 – 0.25mGy. There was a large number of patients moving through the unit during the study period (89), with an average of 14 patients in the unit at a time, however this did not result a large number of X-ray exposures. Twenty one percent of patients were in the unit for less than a day, and 49 % were admitted for less than 3 days. Sixteen patients (18%) had X-ray investigations, with a total of 21 investigations and 30 exposures. Thirty percent of primary radiation dose was due to repeat exposures. Patients receiving X-rays had an average of 2 X-ray examinations (range: 1 to 4 studies) performed, with an average Entrance Skin Dose of 196.7µSv (0.197mGy) – range 77 to 554µSv (0.077mGy to 0.554mGy). There was no statistically significant difference between weeks or zones ($p=0.1060$ and $p=0.8237$ respectively), and differences in primary radiation doses was likely due to chance.

Conclusion:
Additional measures to protect patients in the unit from secondary radiation are unnecessary. There was a low probability of patients having a radiological investigation in the neonatal high care unit, and secondary radiation doses were not measurably higher than background radiation.

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Definition of Terms

Absorbed Dose - amount of energy from ionizing radiations absorbed per unit mass of matter

ALARA - acronym for: As low as reasonably achievable. Referring to the radiation dose to a patient.

Analysis - systematic examination and evaluation of data or information

Attenuation - removal of beam energy by scattering or absorption.

Beam - a transmission of radiation in a specific direction from a source

Cubicle - a square or rectangular room, in this study referring to a room that serves as the high care unit (HCU) of the Chris Hani Baragwanath Hospital neonatal intensive care unit (ICU).

Daily information form – a data collection sheet used in this study. A page printed for the study that showed the details required for the study, a new form was available for each day of the study, and was filled in on the day it was available.

Data - facts and measurements collected for analysis or reference. Unorganized information, before processing or analysis.

Day - a 24 hour period.

Detector - a device used to capture and measure energy from radiation, and which is used to form the image.

Dose - referring to absorbed dose, which is the energy imparted by radiation per unit mass, measured in Gray

Dosimeter - a small, light-weight device used to record ionizing radiation energy range, which is converted to tissue dose. In this study referring to a thermoluminescent dosimeter.

Entrance skin dose – radiation dose that is absorbed (mGy) by the skin as it reaches the patient. Entrance skin dose is a directly measurable quantity, often, measured using thermoluminescent dosimeters (TLD)

Entrance skin kerma – radiation intensity as the X-ray beam impinges on the skin surface. This is free of X-ray scattering in tissue. Used as a metric for comparing doses among radiographic procedures

Examination - detailed inspection, investigation or study, a test

Exposure - amount of electrical charge produced by ionizing electromagnetic radiation per mass of air. This is nearby proportional to dose, but only measures ionizing radiation. Measured in Coulombs per kilogram.

Gestation - synonymous with pregnancy, the period from conception to birth, the period of carrying an embryo and fetus within the womb

Gray - an international system of units used for measuring the absorbed dose of ionizing radiation on a mass; equivalent to Joules per kilogram. Used as a measure of absorbed dose, imparted energy and kerma

High care unit - also referred to as a high dependency unit. A ward in a hospital where patients can receive an intermediate level of care between the levels of care in a standard ward or an ICU. These units are often situated near intensive care units. In the CHBAH NICU setting, it refers to an area in the neonatal ICU where neonates requiring regular assessment, monitoring and treatment for their conditions by trained staff, but not requiring ventilation or continuous monitoring, are nursed.

Hospital - an institution that is designed to provide, and provides care for patients

ICU - abbreviation of intensive care unit.

Image - a visual representation of an object.

Imaging - the process of forming an image.

Information - analyzed or processed data providing facts or knowledge.

Intensive care unit - a specialized department in a hospital that is designed to provide and provides care to seriously ill patients.

Investigation - the act of finding information.

Investigator - person carrying out an investigation.

Ionizing - process of creating charged particles

Joules - unit of measure of energy or work. Abbreviated to “J”. Equated to kilogram meter squared per meter squared.

Kilogram - abbreviated to kg. unit of measure of mass.

Neonate - a newborn child, less than one month old

NICU - neonatal intensive care unit

Measure - determine a quantity by using an instrument marked in a standard unit; in the study referring to collection of information.

Medical imaging - images produced to aid in the diagnosis and management of patients, in the form of X-rays

Monitoring - the act of observing, checking and recording progress over time

Non-ionizing - does not create charged particles

Patient - a sick/ill/unwell person receiving care.

Phosphor - a substance that emits light when excited by radiation

Pregnancy - the period from conception to birth, the period of carrying an embryo and fetus within the womb, synonymous with gestation

Premature infant - a neonate born before 37weeks of gestation

Primary radiation – radiation that is useful in medical imaging. This is energy originating from a source (X-ray tube), passing through an intended object (the patient), then reaches a detector and is used to form an image.

Radiation - emission of energy as electromagnetic waves or as moving subatomic particles. In this study, referring to electromagnetic waves in the X-ray spectrum

Radiographer - a person who is trained to use X-ray equipment for imaging patients

Reliability - The degree of similarity of information obtained when the measurement is repeated on the same subject or the same group.

Scattered radiation – the trajectory of the radiation is altered by interaction with matter.

Secondary radiation – radiation an object is exposed to due to scattering and leakage, and which is not used in creating an image. Also referred to as stray radiation.

Sievert - derived unit of measure for the health effects of ionizing radiation for effective dose

Source Image Distance – distance from where an X-ray beam is made to where it is detected to create an image

Spectrum - a range of values

Staff - people working in a place

Study - an investigation and analysis of a subject or situation.

Thermoluminescent dosimeter – abbreviated to TLD; a dosimeter using a storage phosphor (lithium fluoride), in which electrons that are excited by ionizing radiation are trapped in excited states, and can later be released by heat, producing light. The intensity of this light is measured to determine ionizing radiation exposure

Validity - Extent to which a measure actually measures what it is meant to measure.

X-ray - electromagnetic waves with wavelength range between 10nm and 0.01nm, frequency range between 30petaHz and 30exaHz, and photon energy between 100eV and 100keV. An X-ray can also refer to an image produced using X-ray radiation.

1. Introduction

Patients in neonatal intensive care and high care units require medical imaging to assist with their diagnosis and monitoring. Neonates, particularly premature infants are a population at risk of multiple severe illnesses, that require long hospital admissions and frequent imaging investigations. These patients are also more vulnerable to the effects of ionizing radiation, risks that are higher with higher patient dose. The total dose accumulates over time, and is contributed to by both primary and secondary radiation.

Past studies have investigated the secondary radiation dose per exposure, but not measured the accumulated dose of secondary radiation over a period of time. Additionally, most studies focused on neonatal intensive care units, rather than high care units.

Since patients in neonatal high care units tend to have prolonged admissions, with multiple X-ray exposures, the dose over a period of time should be considered.

Chris Hani Baragwanath Academic Hospital (CHBAH) is a large institution, with busy neonatal high care units. Crowding can be of concern in this unit. Primary radiation doses can be monitored in these units from records kept on the exposures. However, there has been no measurement of secondary radiation in our unit.

The aim of this study is therefore to determine the secondary radiation dose to patients in our neonatal high care unit, and compare this to the primary radiation dose in the unit for that same period.

2. Literature Review:

Ionizing radiation is used in various modalities of medical imaging, including X-rays, computed tomography (CT) scans, and nuclear medicine imaging. The most commonly used imaging modality is the X-ray, which has been used in imaging since 1896 (1, 2).

There are numerous advantages and disadvantages to using X-rays in medical imaging. The advantages include that they are obtained rapidly, with minimum patient preparation or discomfort, giving relatively inexpensive and high-resolution images that correlate with the patient's anatomy (3).

The disadvantages are the stochastic and deterministic effects (4, 5, 6). Stochastic effects are random occurrences from radiation exposure and include carcinogenesis and genetic effects, while deterministic effects are dose dependent and include leukocytosis, burns, epilation, cataract formation and others (4, 5, 6).

The beams interacting with matter results in ion formation, matter including patients receiving diagnostic imaging, this can result in ion formation within tissues, which can, in turn, result in damage to macromolecules such as DNA. Some of this damage may be too complex for the cell to repair, and therefore result in cell death, change in cell function, or even neoplastic transformation (5, 7).

Various factors can influence the risk of cell damage from radiation (8, 9, 10, 11, 12); among others, these include:

- radiation factors, such as:
    - radiation quality (based on the type of radiation and the energy in the beam)
    - duration of exposure
    - dose rate
- patient factors, such as:
    - patient's age
    - past exposures
    - weight
    - tissue hypoxia
    - smoking
    - nutritional effects
    - alcohol use
    - cell repair ability

Since exposures to younger people, and in utero, are associated with a higher risk of the damaging effects from ionizing radiation with subsequent increase in cancer rate (6), the radiation exposure is of particular concern to neonates, and especially to premature neonates.

There is consensus that radiation exposures should be limited in children, and in particular in neonates and premature neonates (6).

Prematurity is associated with higher health risks. Preterm neonates can develop neurological conditions, respiratory illness, gastrointestinal illnesses, and various infections (13, 14, 15). The lower the gestation age and birth weight, the higher the risks to health, with many preterm infants requiring hospitalization, and intensive care unit admission for management (16).

As a result of illnesses associated with prematurity, many of these patients require imaging in Neonatal ICU for diagnosis and monitoring during their hospitalization (6, 17, 18). and their conditions lead to a higher number of exposures (19).

Studies by Iyer et al and by Ono et al found that lower birthweight and gestational age, as well as conditions associated with prematurity, are associated with longer ICU stays and more radiological investigations (19, 20).

The most frequently used medical imaging in a neonatal ICU is the X-ray of the chest, followed by other X-rays, including X-rays of the abdomen, babygrams (X-rays of the chest and abdomen), and limbs (20, 21, 22). Other imaging used includes fluoroscopic investigations, ultrasound (cranial and cardiac) and Computed Tomography (17).

The dose of radiation that a patient receives during an X-ray investigation includes primary and secondary radiation. Primary radiation is the radiation used during imaging on a patient, while secondary radiation is exposure received from radiation scatter and leakage, that does not contribute to the medical image being performed, and includes secondary radiation generated during exposure of the patient, or during exposure of other patients (6).

Numerous past studies have investigated the ionizing radiation dose within a neonatal ICU – considering primary radiation (19, 20, 21, 22, 23, 24, 25, 26, 27), secondary radiation (28, 29), or both (30, 31, 32). These studies found variations in primary radiation doses based on patient dependent and technical factors, and have determined that, in their settings, the secondary radiation is negligible per exposure or over multiple exposures (28, 29, 30, 32).

The secondary radiation accumulated over time has not been measured in previous studies. Since patients in neonatal high care units tend to have prolonged admissions, with multiple X-ray exposures, their dose over a period of time should be considered. This is of particular concern where patients are crowded in a unit.

No new studies on this topic were conducted during conduction of this study.

3. Aim:

To determine if the secondary radiation in a neonatal high care unit is significant enough to justify additional protective measures from ionizing radiation dose for the patients in the unit.

4. Objectives:

Primary objectives:

- Quantify the accumulated secondary radiation over a month (4 weeks) within a representative area of the neonatal high care using theromoluminescent dosimeters to measure the entrance skin dose.
- Provide for weekly variation in secondary radiation dose, by having multiple dosimeters in each area.
- Quantify the background radiation by having control dosimeters in a room next to the unit where no X-rays are performed, using control thermoluminescent dosimeters.

Secondary objectives:

- Determine the primary radiation used in the study area by using data sheets to record the number of studies performed and the total number of X-ray exposures, and using standard doses per examination to calculate the entrance skin dose.
- Map patient movement in the unit during the study, using data sheets.

5. Methods

5.1 Research Paradigm

A prospective analytic study was performed. The study measured and analyzed the secondary radiation exposure in the room, in proximity to the patients in a high care unit cubicle. This was performed over a period of 4 weeks. The secondary radiation exposure received in different areas within the cubicle was compared to the control dosimeter measurements, and to the primary radiation dose for the same cubicle and period.

5.2 Feasibility and Permission:

Study feasibility was approved by the Research Committee of the Department of Diagnostic Radiology at the University of the Witwatersrand.

Ethical clearance (Appendix 1) was received from the University of Witwatersrand Human Research Ethic Committee (Clearance Certificate number M160754).

The research protocol was reviewed by the protocol review committee, and discussed at a meeting in November 2016. Adjustments to the protocol were made according to recommendation of that meeting, prior to data collection. (See Appendix 2). Professor van der Merwe from the medical physics department was recommended as an additional supervisor for the study, and was consulted, however declined to become a supervisor.

Permission to conduct the study was obtained from the Heads of the Departments of Paediatrics, Radiography and Diagnostic Radiology, as well as from the Chief Executive Officer of Chris Hani Baragwanath Academic Hospital (CHBAH).

5.3 Sample

The study was conducted in a cubicle of the high-care unit of the neonatal ICU at CHBAH in Soweto, Johannesburg.

There are 5 cubicles in the Neonatal High Care unit (Cubicles A, B, C, D, E). The principal investigator was blind to the patient details, including the diagnoses of the patients in the cubicles of the unit, and the selection criteria for admission in each cubicle.

Two cubicles (Cubicles D and E) were excluded as a study area, as they are considerably smaller than the other two cubicles, and were considered non-representative of the size of the other cubicles in the neonatal unit. Cubicle C was randomly selected for the study area.

The principal researcher was informed after the study measurements started that patients in Cubicle C are admitted as step-downs from neonatal ICU, and often had an infection that required treatment. During the study period there were also post-surgical patients admitted in the cubicle.

Measurements of secondary ionizing radiation within subdivided areas of the high care unit, were made using thermoluminescent dosimeters.

The number of patients in each area of the cubicle, and number and type of X-rays used to image patients were made and recorded.

The location where X-ray studies were performed within the cubicle were documented.

Figure 1 (page 19) demonstrates cubicle dimension, area division, dosimeter and cot location.

The cubicle floor dimensions were measured, and used to sub-divide the cubicle into 6 equally sized zones.

The patients were located along the length of the cubicle, which measured six meters (m).

The left and right lengths of the cubicle were divided into three areas, with a length of two meters.

The area on the left were designated A, B and C, and the areas on the right were designated D, E, F.

The border between each area was marked by a strip of insulation tape on the wall, which allowed easy identification of each area, to aid the documentation of primary radiation exposures in each area.

Each area was allocated a set of four dosimeters. These were placed on the wall, in the center of their allocated area.

Four dosimeters were placed in the same location on the wall, in each area. One dosimeter was removed from each area per week.

This was a systematic sampling method where sampling followed a strict, predetermined grid, and was based on sampling methods for environmental monitoring (33, 34).

The dosimeters were placed at patient head and chest height, and this was based on the standardized method used by Tamras (35). Patients in the study cubicle were all lying down, and therefore head and chest heights are considered the same.

Each area was two meters along the length of the cubicle, the dosimeters for each area were placed in the center of their respective area's wall (one meter away from the borders of their area), and the patient's cots were positioned along the wall. Therefore, no patient could be kept more than one meter away from a dosimeter – as visible in Figure 1.

If there were more than two cots in an area, the distance to the nearest dosimeter would still be less than one meter.

This method of dosimeter placement avoided measurement bias due to number variations created by patients and cots moving into and out the unit during a day, and provide a constant – the cubicle dimensions – for determining dosimeter positions.

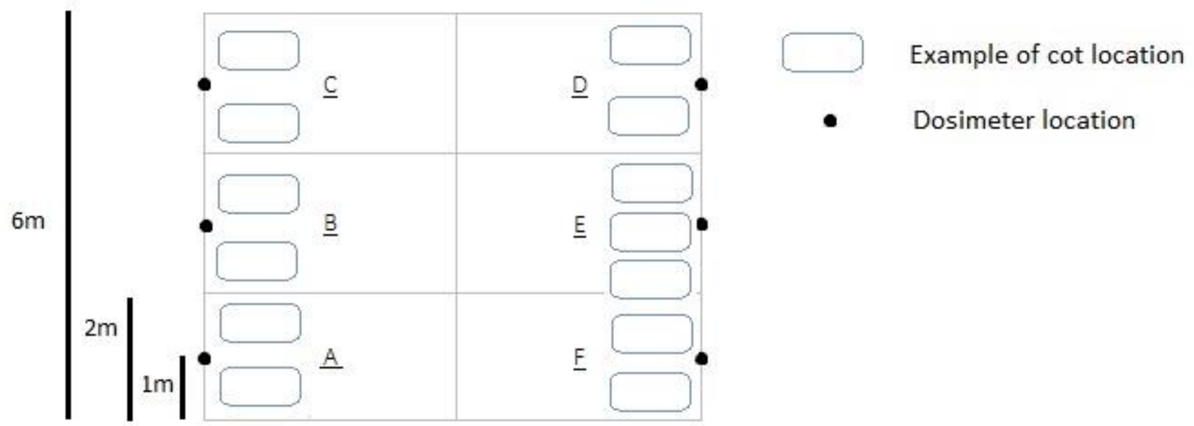

Figure 1 Cubicle dimension, Area division, Dosimeter and Cot Location

The dosimeters (in their bags), and the area identifying markers, were placed within the cubicle on the first day of the month.

One dosimeter was removed from each zone weekly, until the last dosimeters were removed, at the end of the study period (four weeks).

The four control dosimeters were placed within the doctor's tea-room adjacent to the neonatal ICU and High Care Unit for the duration of the study.

Twenty-eight dosimeters were needed for the study and were obtained from the South African Bureau of Standards (SABS). The SABS Radiation Services calibrated the dosimeters for an environmental study.

Dosimeters for measuring the secondary radiation were placed at equal interspaces within the cubicle, as described above.

For identification, each dosimeter was labelled according to the area it was placed, and the week in which it was removed.

This was based on methods used in other studies (28, 29, 30, 31, 32, 35), and adapted to the circumstances in our study location.

Dosimeters were placed on the wall, packed within a sealable, clear, see-through, 55micro thick, plastic document sleeve with a piece of paper that has printed "Do Not Touch" sign and writing – stating "Do not Touch!" and "Ungathinzi!" (meaning "avoid" in isiXhosa, and understandable in local languages including Zulu and Ndebele). This label will be placed in front of the dosimeter, and with the print of the sign facing away from the dosimeters, and therefore visible to a person looking at the dosimeters (see Figure 2).

Figure 2 Dosimeter package with "Do Not Touch" sign

After placing the dosimeters and labels in the bags, the bags were sealed, and placed at their designated positions in the cubicles.

The sealed bags with dosimeters were attached to the wall using "Presstik" (a sticky non-permanent contact adhesive putty), placed on the outside of the bag, behind the dosimeter, and insulation tape, placed on the anterior bag surface, with the sticking part of the tape facing posteriorly. Insulation tape colour match the zone colour identification on the data sheet.

These bags were only moved and reopened for collection of the dosimeters.

Retrieved dosimeters were placed in a lead lined container to avoid contamination from background radiation.

At the conclusion of the study period, the retrieved dosimeters were taken to the South African Bureau of Standards (SABS) Radiation Services office in Pretoria by the principal investigator for measurement reading.

The SABS Radiation services thereafter emailed the results to the principal investigator.

The raw data was requested for these results.

A data sheet (Appendix 3) was used to document the number of patients in the cubicle and in each zone during a day, the patients that received X-ray studies, the type and number of X-rays received by the patients.

A new data sheet was placed at the entrance of the cubicle twice a day for the study period. This location was to enable radiographers to easy access to the data sheet.

A strip of coloured insulation tape was placed on the data sheet next to each zone label, that matched the insulation tape colour on the dosimeter packages in each zone. This was done in order to assist with identification of the zones for documentation.

The principal investigator confirmed the data sheet information by comparing the data sheet recordings to the radiographer's daily statistics record in the Paediatric Radiology unit.

5.3.1 Inclusion criteria

All X-rays performed within the selected high care cubicle were included. This included X-ray exposures resulting in adequate images, and exposures that were inadequate for images and therefore required repeat exposures.

5.3.2 Exclusion criteria

No exclusion criteria for using the readings from dosimeters could be devised, since the method has been designed to avoid tampering.

5.4 Materials and Methods

5.4.1 Available Materials

Literature reviews using PubMed and Google Scholar were performed for articles pertaining to X-ray practices in neonatal high care and intensive care units, and for articles on the secondary and primary radiation in such units. Literature reviews were performed prior to the initiation of the study and at the conclusion of the data collection and analysis.

The high care cubicle at Chris Hani Baragwanath Academic Hospital had the necessary equipment and staff required for daily functioning of the unit, including radiographers for performing X-rays.
Stationery was available for the requesting of X-rays in the hospital.

A mobile radiography unit was available for X-rays in NHCU, and radiographers employed by the department of Health and the Hospital were allocated for performing X-rays in the unit.

The mobile radiography unit was up to date with services, and quality control on the unit was performed by the medical physicist at Chris Hani Baragwanath Hospital prior to the study. Additionally, standard exposure factor references were placed on the unit for radiographers to refer to and use.

For the dosimeters to measure secondary radiation, thermoluminescent devices were obtained from the South African Bureau of Standards (SABS) Radiation Protection Services. The SABS calibrated the dosimeters for study of environmental radiation. A total of 28 dosimeters were obtained.
Other materials, needed for the study, were provided by the principal investigator, including: ”Do not Touch” signs, Presstick, Adhesive tape, measuring tape, and bed number labels.

5.4.2 Methods

- To quantify the secondary radiation dose:
    - Measurements of secondary ionizing radiation were made using dosimeters within the zones of the high care unit cubicle.

- Thermoluminescent dosimeters (TLD) were used as they are small, lightweight and mobile, require no additional equipment during the measurement, have a wide dose response range (100microSv to 10 Sv), and the reading from the dosimeter is proportional to the exposure and the time of exposure (11, 36, 37, 38).
- Additionally, these dosimeters would not interfere with daily activities in the unit, as other measurement methods could.
- Dosimeters calibrated for environmental studies were obtained from the South African Bureau of Standards.
- For additional precision in measurement, the readings from the $CaSO_4$ elements will be assessed in addition to the total reading, as $CaSO_4$ better suited to low radiation doses and higher ambient temperature environments (39, 40)
- Multiple dosimeters were used within the high care cubicle, placed in evenly spaced zones, as radiation dose reduces with distance by the inverse square law.
- Prior to the study, the principal researcher was informed by the head of the unit that the number of patients in the cubicle vary between 8 and 16 patients, and this number could change throughout a day. This could result in variations in patient spacing.
- Due to the variation in the number of patients in the cubicle over time, placing a dosimeter on each patient's cot, or at a predetermined distance from each cot – as was done in previous studies (28) – would have resulted in variations in the number of dosimeters in the cubicle and in the spacing between dosimeters. This is inappropriate for the circumstances of this study. In order to eliminate this variation, the cubicle dimensions, which are constant, were used to determine the positions of the dosimeters, as opposed to individual cot locations.
- The cubicle was measured, and divided into six areas of equal dimensions.
- The cots consisted of open and closed Perspex cots that were occupied by patients. No high-attenuating material was positioned between the dosimeters and the patients.
- Dosimeters were placed along the walls where cots were kept, at patient head-height level. As the patients are lying flat, and head height is the same as chest height (35).
- Four dosimeters were placed in the same location on the wall, in each area. One dosimeter was removed from each area per week.

- To quantify the background radiation
    - Control dosimeters measured the background radiation outside the unit. Past studies

in this field do not demonstrate a standard method for determining a location for controls (28, 29, 30, 31 32). A previous review by Segall (41), indicates film-badge and scintillator dosimeters can be used to study background radiation. These readings were compared to international and local standard measurements of 2.4 mSv per annum (42, 43) – 0.2mSv per month.

  - For comparable units with the measured ESD, a radiation weighting factor of 1.0 was used to convert the annual dose to mGy
  - 4 control dosimeters outside the unit were used to account for background radiation, which was not related to imaging. These dosimeters were placed in the same building to represent the environment in the cubicle if X-rays were not performed there.
- Dosimeters were packaged in sealed plastic envelopes to avoid infection risk to patients.
- The dosimeter packages were labeled "Do Not TOUCH" with an accompanying sign to avoid tampering.
- Dosimeters were to be numbered, and serial codes recorded to help correctly allocate measurements for data capture. A second data sheet for the principal researcher to complete was designed (see Appendix 4). This additional data sheet was later found to be unnecessary, as the SABS allowed for naming dosimeters when they were ordered. Dosimeters were named according to zone and week of allocation, and the names were allocated to specific dosimeter serial numbers for confirming that results were allocated to the correct badge names.
- Dosimeters and their packaging were inspected to ensure they had not been tampered with when data sheets were collected.

- To assess primary radiation for comparison to the secondary radiation
  - Data sheets were used to collect data on number of patients per zone for each day, the total number of patients in the cubicle, the part of the body X-rayed (type of X-ray), and the number of X-rays done, including repeated X-rays.
  - Patient beds were numbered, to track patient movement into, within, and out of the high care unit, to assist with data collection on the period patients are in the cubicle. Checking for new cots/patients was performed twice daily, at the same time as datasheet collection. When new patients were found they were allocated a number. This also ensured that patients were anonymized.

- The data sheets were collected and replaced twice per day for the duration of the study.
- Primary radiation dose references were found in the literature (26, 44, 45, 44), with some variation between values. The findings of Huda et al (46) were used for comparison (see table 1).

Table 1 Entrance Skin Dose for X-rays, adapted from Huda et al (44)

X-ray type	Entrance Skin Dose (µGy)
Head	100
Chest	77
Abdomen	100
Babygram (head, chest and abdomen)	277
Limb	NA

- The medical physics department performed quality control on the X-ray machine and exposure factors used by radiographers for taking X-rays in the NHCU. This ensured that our primary radiation calculations are comparable with the reference studies and are reproducible.

5.5 Data Collection

A prospective, analytic study was performed in a cubicle of the CHBAH Neonatal High Care Unit.
Thermoluminescent dosimeters measured secondary radiation in the cubicle and control dosimeters measured background radiation.
All the dosimeters were placed in the different zones within the study area at the beginning of the study. One dosimeter was removed from each zone at the end of each seven day week.
All dosimeters were returned to the SABS at the end of the study. Dosimeters were read with a thermoluminescent dosimeter reader. The principal investigator thereafter received this data from the SABS. Appendix 4 shows the raw data received from the SABS.
Data sheets were exchanged twice daily by the principal investigator, and the data captured at this time by the principal investigator.

The make, model and year, maximum settings, and last service/calibration of the X-ray machine that is used within the high care unit was recorded for quality control purposes. The mobile X-ray unit used was a Shimadzu MobileDArt Evolution. Quality control was carried out and monitored by the medical physics department.

The radiographers working in the Neonatal High-care unit were informed of the study, as they had to write on the daily information forms when X-rays were performed in the high care unit.

The radiographers who worked in the high care unit, were divided into three rotating shifts.

Two workshops were held for the radiographers before the study initiation, and were presented at morning shift changes to include all the staff involved across the three shifts.

The workshops included a presentation using visual aids from Microsoft PowerPoint (see Appendix 5), to inform the radiographers of the study rationale, aims, methods, study duration and their role in the study. Additionally, the workshop introduced the radiographers to the daily information forms (data sheets), and educate them on how to complete the forms once they had completed their X-rays in the neonatal high care unit. The radiographers were given examples of how to complete the forms, and an opportunity to practice completing the forms. This was followed by a question and answer session to assist with clarification. The principal investigator also made his contact information available to the radiographers at these workshops for further queries, and showed the radiographers where to find his contact details on the data sheets should queries arise.

The radiographers were encouraged to contact the principal investigator with any queries or concerns, before, during or after the study.

Printed notes of the study and their role in the study were provided for the radiographers.

Responsibilities of the radiography staff included:

- Performing their daily duties, by performing X-rays within the high care unit.
- Correctly completing the data sheet when each X-ray was performed in the NHCU cubicle.

5.6 Data Analysis

Data was captured electronically in Microsoft Excel by the principal researcher. Any further analysis was done by a statistician using SAS Version 9.2. Descriptive statistics namely frequencies and percentages were calculated for categorical data and means and standard deviations were calculated for numerical data. Analytical statistics namely Fisher’s exact test was used to compare percentages and the analysis of variance (ANOVA) was used to compare the mean values between weeks or zones. A significance level (α) of 0.05 was used.

5.7 Reliability and validity

The study was carried out over a period of one month to improve the reliability of findings, and the use of multiple dosimeters, with removal of a dosimeter in each area weekly, was to account for weekly variations.

The limited number of dosimeters, type of dosimeters and measurement methods enable reproducibility of the study.

Thermoluminescent dosimeters provide reliable, easily reproducible, and cost-effective measurements over a period of time, with no impact on the high care unit environment, and with reduced variation in data from day to day changes in the high care unit.

Using multiple dosimeters in each area within the High care unit, with dosimeters removed weekly allowed weekly dose to be calculated.

Using control dosimeters improved the validity of the study by providing a local reference of background radiation, which was used to calculate the secondary radiation dose.

Past studies of secondary radiation in neonates made use of dosimeters (30, 31, 32) for measurement, however these studies had shorter periods of time, only measuring dose per X-ray, and not over a prolonged period of time. Since many of the neonates in a high care were expected to have extended admissions, and thermoluminescent dosimeters were appropriate for measuring radiation dose for a period, and for an environmental study, our selected methodology is appropriate.

The reading $CaSO_4$ element of the dosimeter will be used in addition to the total reading, to increase the precision of a low radiation dose measurement at a higher ambient temperature (39, 40).

Our placement of dosimeters against the cubicle walls is in keeping with environmental radiation monitoring practices (33, 34), and with methods used in previous studies (28, 35).

Determining the primary radiation in the cubicle areas provided a reference point for determining the contribution of the primary and secondary radiation to the total dose.

Studies of primary radiation dose by Chapple et al, Mettler et al and Huda et al (44, 45, and 46) have previously determined the dose per investigation.

In order to ensure that our primary radiation doses, based on exposure factors, were comparable to these studies, quality control of the X-ray unit and the exposure factors used in the Neonatal unit was carried out by the Medical Physics Department.

5.8 Bias

Measurement bias could have been introduced by incorrect data collection on the daily information forms. To reduce this bias, radiographers working in the high care unit were informed of the study, as they had to complete the daily information forms.

Training workshops for the radiographers working in NHCU, were performed after ethics approval, and before commencing data collection.

The principal investigator confirmed the data sheet information by comparing the data sheet recordings to the radiographer's daily statistics record in the Paediatric Radiology unit. This was a safety net to confirm the data sheets were accurate.

In two instances, the number of X-ray exposures were not recorded by the radiographers. In these occurrences, the exposures were marked as "Unknown" (U), and were allocated the value of 1 X-ray of that type for statistical purposes. A value of one was allocated as an X-ray was performed and therefore the value could not be 0. At least one X-ray was performed, but if there were no repeats – as was the case for the majority of X-rays performed during the study period, allocating more than a value of one would result in over-counting the number of X-rays.

Measurement bias of the secondary radiation in the study was expected to be negligible, as a standard measurement method was used with the dosimeters.

The clinical head of the unit for NHCU was aware of the study, and the principal investigator wished to keep other clinicians working in the area blind to the study in order to minimize the impact of the study on their clinical practice and to minimize bias in the results. The head of the unit however felt that no bias from change in practice would occur by informing the clinicians in the NHCU, and that they needed to be informed of the study in order to avoid potential tampering with the dosimeters. The clinicians were informed according to the head of unit's wishes.

Attenuation of X-rays by distance from the mobile X-ray unit and by intervening patients was anticipated. As distance between patients, and other patients in the cubicle were a part of the high care unit environment, the dosimeter measurements would still equate to secondary radiation and background radiation in this environment.

The cubicle in which the study was conducted was used as a step down unit for patients discharged from neonatal ICU who had been diagnosed with infections, and was also used for neonatal surgery patients.

The principal investigator was only made aware of this patient demographic after data collection had already started.

This specific patient sample, as opposed to a random sample, could therefore have introduced a measurement bias to the study, although the investigator was blind to this detail about the sample on initiating the study.

6. Ethics

A submission for approval was submitted to the University of the Witwatersrand Human Research Ethics Committee (HREC) - Clearance Certificate number M160754. See Appendix 1.
This study was a prospective study involving radiation and written approval has been obtained from the Director of the Radiation and Health Physics Unit, Mr James Larkin (Appendix 7).
Permission for the study was obtained from the Chief Executive Officer of CHBAH (Appendix 8).
Permission for the study was obtained from the Head of the Department of Paediatrics at CHBAH, Prof Velaphi (Appendix 9).
Permission was obtained from the unit manager of the CHBAH neonatal unit, Sr Dube. (Appendix 10).
Permission for the study has been obtained from the Head of Diagnostic Radiology at CHBAH, Dr T. Hlabangana (Appendix 11).
The Head of Radiography, Mrs G. N. Tsoeu and the radiographer supervisor for maternity and neonatal ICU, Mr Johan Radebe, were both consulted on the study, and gave verbal permission to the principal researcher.

Patient anonymity was maintained during the study – no patient identifying data was collected for the purpose of the study, and the data analysis does not pertain to individual patients, but rather an environment for a select group of patients.

To avoid potential risks to patients, there was no contact between the patients, their caregivers – including medical personnel and parents – and the dosimeters (Dosimeters placed within sealed packages to reduce the risk of contamination/infection). Infection control procedures were followed by the principal researcher. No allergens were introduced in the environment due to the study.
The study did not result in an increase in the ionizing radiation dose received by the patients above the dose they would have received in the unit outside of the study period, as no intervention or procedure was performed on any patient because of the study.
Standard ALARA and radiation protection procedures are followed within the unit.
No excessive radiation exposure to a patient was found during the study.

The principal investigator of the study had no conflict of interest.

6.1 Data Safety

The principal investigator collected the data.

Access to the data was only available to the principal investigator, supervisors and statistician.

No patient names or personal details were recorded in the study.

7. Budget

The principal investigator covered all costs of the study.

Records were displaced for the costs of Printing and stationery (Estimated R1200), and Transport costs (Estimated R2000), and telecommunication (estimated R330). The cost for the dosimeters came to: R2805,13; Consultation (with a statistician) costs came to: R1100. Total costs came to approximately R7435.13

Summary of Costs:

Item	Cost
Printing and Stationery	R1200
Transport	R2000
Telecommunication	R330
Dosimeters	R2805.13
Consultation	R1100
Total	R7435.13

8. Results:

Eighty-nine infants were admitted in the cubicle during the 4-week study period. The average length of admission was 4 days (range 0.5 to 23 days), with between 9 and 16 patients in the unit at any time (mean 14; median 14).

As demonstrated in Table 2, 21% of the patients were in the unit for less than 1 day, 49% were admitted less than 3 days, and 82 % were admitted less than 1 week (7 days). Eighteen percent of patients were admitted more than 7 days.

The data also showed minimal movement of patients between zones in the cubicle after admission. Figure 3 graphically represents the patient map for this data, with colour-coding for areas A to F using a colour spectrum for easy visual assessment. As shown, only a few patients were in more than one area, and if they moved between areas, the movement was to an adjacent cubicle, likely due to changes in spacing between cots. Only 3 patients did not follow this trend.

Table 2 Duration of Admission

Duration of admission	**Percent**
<1 day	21.35 *(19)*
1-1.5 days	16.86 *(15)*
2-2.5 days	11.24 *(10)*
3-3.5 days	7.87 *(7)*
4-4.5 days	8.98 *(8)*
5-5.5 days	10.11 *(9)*
6-6.5 days	5.62 *(5)*
7-7.5 days	2.24 *(2)*
8-10.5 days	7.87 *(7)*
11-13.5 days	4.49 *(4)*
14-21 days	2.24 *(2)*
>21 days	1.12 *(1)*

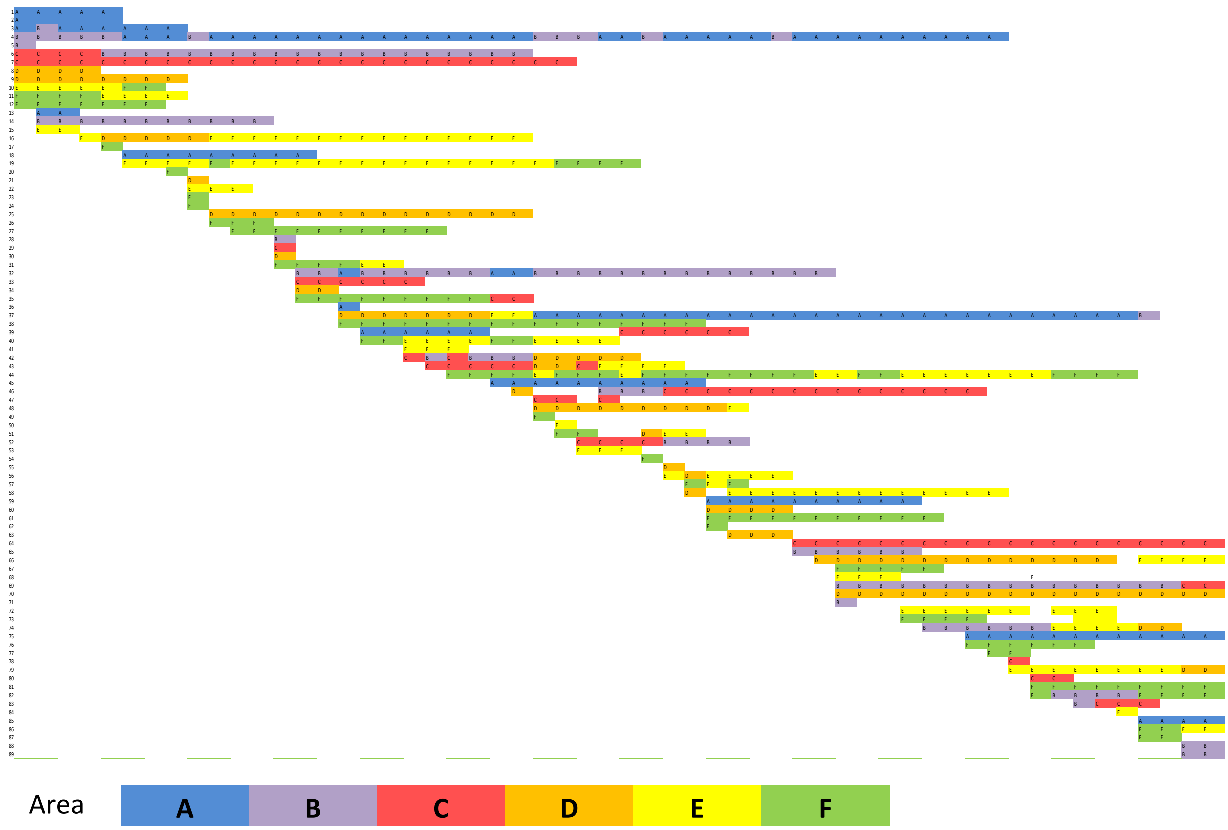

Figure 3. Admissions and area in the NHCU cubicle for the duration of admission

Twenty-one X-rays were performed in the study period, with 15 (71%) during normal work hours (day shifts) and 6 (29%) during afterhours (night shifts).

Most of the X-rays were performed during the second and forth weeks of the study (shown in Table 3 and Figure 4), and the majority of the studies were performed on patients in Zone B, but the majority of the repeat X-rays were performed in Zone C (as shown by Table 4 and Figure 5).

Table 3. X-ray performed per week and Zone

Week	Frequency of X-ray Examinations (%)	Frequency of Exposures (%)	Breakdown of Exposures (ESD in mGy) in each Zone					
			Zone A	Zone B	Zone C	Zone D	Zone E	Zone F
1	3 (14.29)	6 (16.67)			2 (200)	4 (400)		
2	7 (33.3)	12 (40)	3 (300)	3 (277)	3 (654)		1 (77)	
3	4 (19.05)	5 (16.67)		2 (144)	4 (354)			
4	7 (33.3)	8 (26.67)	1 (77)	2 (200)			4 (377)	1 (77)

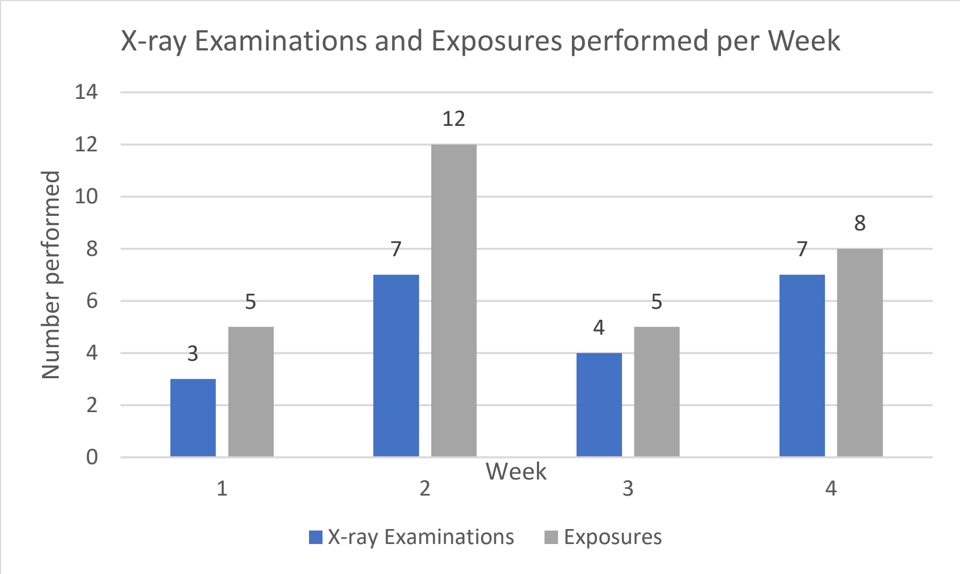

Figure 4. X-ray Examinations and Exposures performed per week

Table 4. X-ray examinations performed per zone

Zone	Frequency of Examinations	Examination as a Percentage (%)	Frequency of Exposure	Exposure as a Percentage (%)
A	3	14.29	4	13.33
B	6	28.57	7	23.33
C	5	23.81	9	30
D	2	9.52	4	13.33
E	4	19.05	5	16.67
F	1	4.76	1	3.33

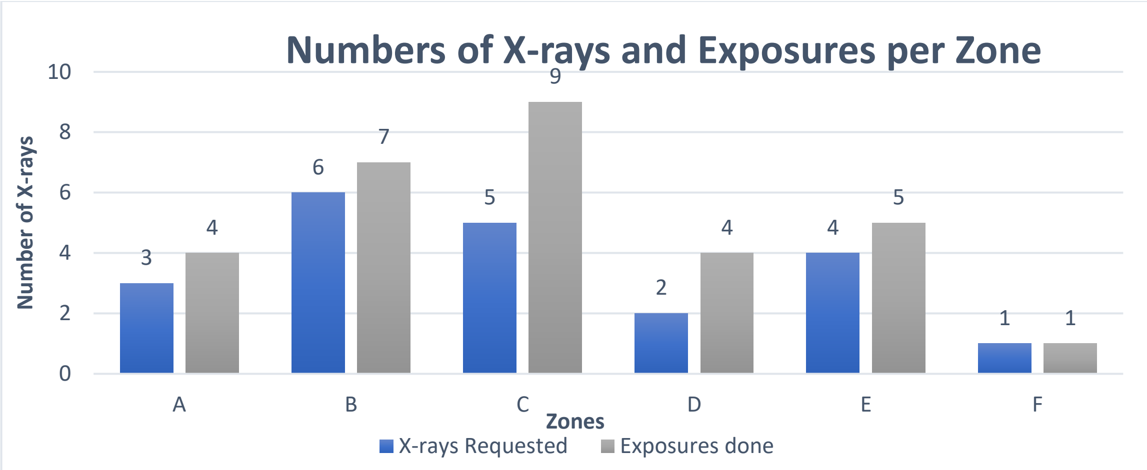

Figure 5. Number of X-rays and X-rays per Zone

A total of thirty X-rays were performed for twenty-one requested X-rays. This indicates that 9 (30%) of the total exposures were due to repeat X-rays, with most of the repeat X-rays performed during the second week of the study.

The 21 X-rays were requested and performed on sixteen patients (eighteen percent of the total patients admitted). Of the patients who had X-rays, an average of two X-rays (range: one to four studies) were performed per patient. There was an average Entrance Skin Dose of 196.7 µGy (0.197 mGy), with a range of 77 to 554 µSv (0.077 mGy to 0.554 mGy). The X-rays performed are shown in Table 5. In one instance, an X-ray was recorded, but the cot number was not recorded, and could not be traced to a cot. Marked as "U" for Unknown cot number.

Table 5. Table Summarizing the X-rays and Entrance Skin Dose for Patients who received X-rays

		Table Summarizing the X-rays and Entrance Skin Dose for Patients who received X-rays					
Week	Day of study	Examination number	Zone	Cot Number	X-ray type	Number of Exposures	ESD (mGy)
1	2	1	C	14	A	2	200
	2	2	D	6	A	2	200
	5	3	B	U	A	U	100
2	9	4	D	6	A	2	200
	9	5	C	35	A	1	100
	10	6	C	42	B	2	554
	13	7	A	37	A	2	200
	13	8	B	32	A	2	200
	13	9	C	47	A	2	200
	14	10	B	52	C	U	77
3	17	11	B	32	C	1	77
	19	12	C	64	C	2	154
	21	13	B	69	C	1	77
	21	14	E	44	C	1	77
4	22	15	B	74	A	1	100
	23	16	A	75	C	1	77
	24	17	A	37	A	1	100
	25	18	E	79	A	1	100
	25	19	E	74	C	1	77
	26	20	E	79	A	2	200
	26	21	F	81	C	1	77

The most frequently performed examination was an abdominal X-ray (57% of all X-rays, 63.3% of all exposures), followed by a chest X-ray (38% of X-rays, 30% of X-rays). One babygram was performed (5% of X-rays, 6.7 % of X-rays), and no other X-ray types were performed. (see Table 6 and Figure 6).

Table 6. Summary of the X-rays performed

	Frequency of X-ray Examinations performed	Frequency of X-rays
Abdomen	12 (57%)	19 (63.3%)
Babygram	1 (5%)	2 (6.7%)
Chest	8 (38%)	9 (30%)
Skull	0	0
Limb	0	0
Other	0	0
TOTAL	**21**	**30**

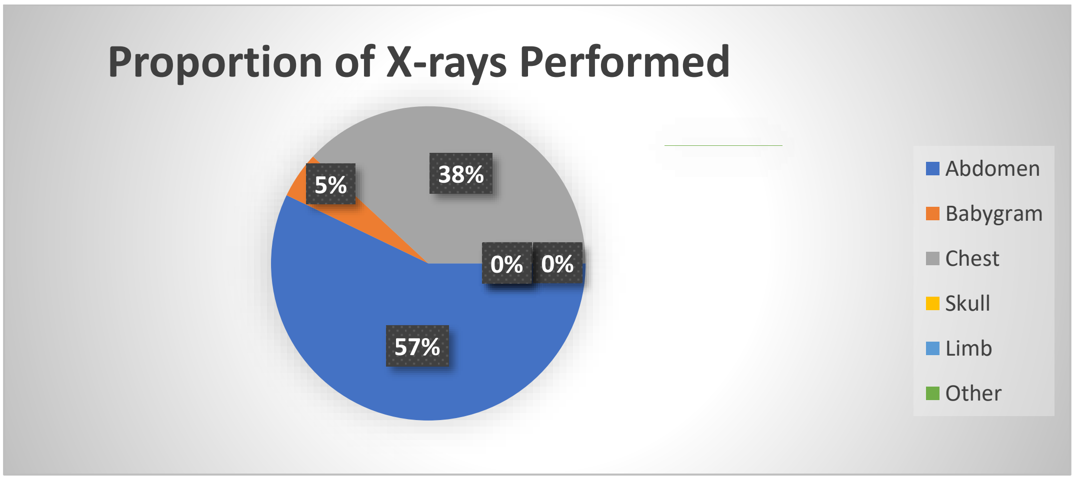

Figure 6. Proportion of X-rays performed

The most repeat X-rays (7 in total) were performed for abdominal X-rays (with a frequency of 58%). Although the babygram required the most frequent repeat X-ray (100%), there was only 1 babygram performed (6.7% of all X-rays performed). (As seen in Table 6 and Figure 7).

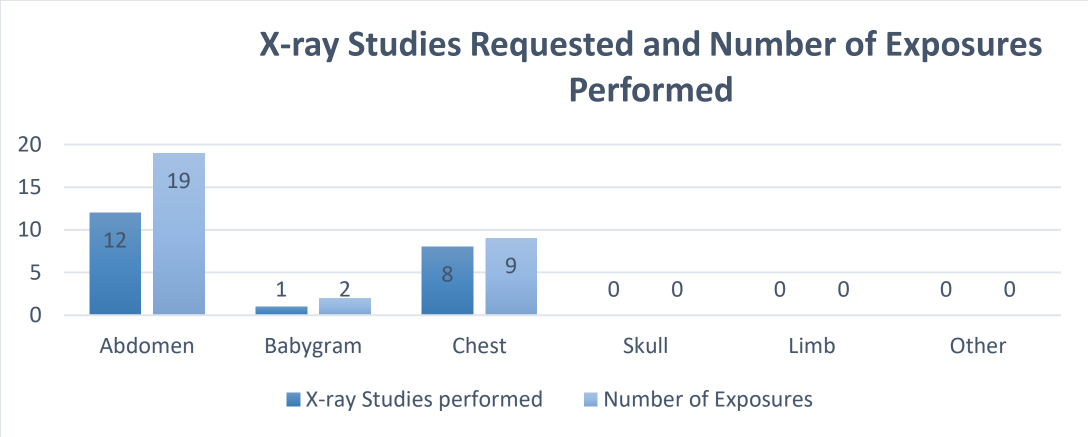

Figure 7. X-ray Studies Requested and Number of Exposures Performed

Due to the distribution of exposures performed, the calculated entrance skin dose from primary radiation was highest during Week 2 (1531 µGy; 1.53 mGy), and in Zone C (1208 µGy; 1.21 mGy) – as shown in Figure 8, Table 7 and Table 8.

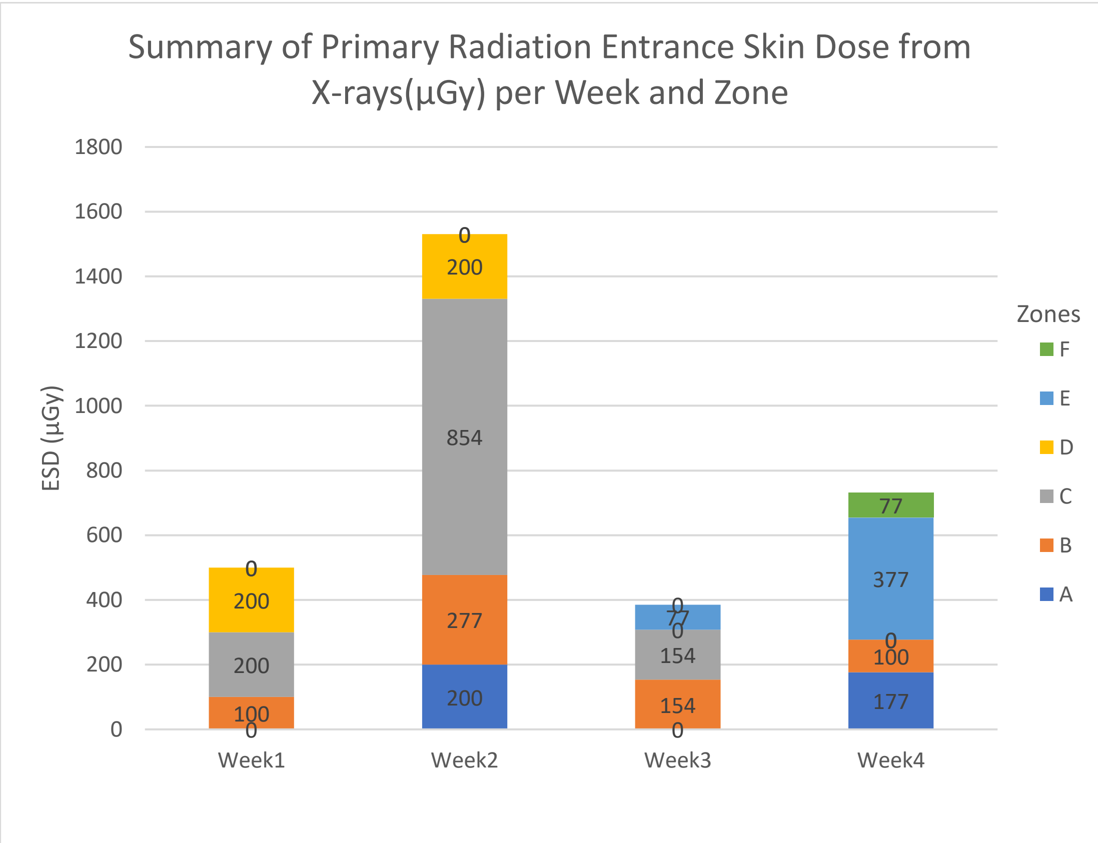

Figure 8. Summary of Primary radiation Entrance Skin Dose from X-rays per week and Zone

The total ESD received from an X-ray was calculated, with values of 77 μGy (for single chest X-ray), 100 μGy (for single abdomen X-ray), 154 μGy (for chest X-ray and repeat), 200 μGy (for abdomen X-ray and repeat) and 544 μGy (for a babygram and repeat).

There was no statistically significant difference when comparing the proportion of entrance skin dose between the four weeks (p=0.1060) (Table 7) and between the 6 zones in the study area (p = 0.8237), when using Fisher's Exact test. (Table 8)

Analysis of the variance, using the mean values and the comparison of the weekly ESDs, shows no statistically significant difference in ESD between the weeks (p = 0.1533), although there was a difference in the ESD calculated from the X-rays performed.

Table 7 Entrance Skin Dose by Week

Entrance Skin Dose from X-rays by Week						
X-ray performed (ESD value)	Number of X-rays performed in a week					
	1	2	3	4	Total Number of X-rays	Total Dose from an X-ray (μGy)
Single Chest X-ray (77 μGy)	0	1	3	3	7	539
Single Abdomen X-ray (100 μGy)	1	1	0	3	5	500
Chest X-ray and repeat (154 μGy)	0	0	1	0	1	154
Abdomen X-ray and repeat (200 μGy)	2	4	0	1	7	1400
Babygram and repeat (554 μGy)	0	1	0	0	1	554
Total number of X-rays	3	7	4	7	**21**	
Total ESD	500	1531	385	731		**3147**

Fisher's Exact Test	
Table Probability (P)	2.105E-05
Pr <= P	0.1060

Sample Size = 21

Interpretation of the p-value

- If p ≥ 0.05 then there is no significant difference in proportions between the 4 weeks.
- If p < 0.05 then there is a significant difference in proportions between the 4 weeks.

Table 8. Entrance Skin Dose by Zone

Entrance Skin Dose from X-rays by Zone								
X-ray performed (ESD value in µGy)	**Zone**						**Total number**	**Total Dose**
	A	**B**	**C**	**D**	**E**	**F**		
Single Chest X-ray (77 µGy)	1	3	0	0	2	1	**7**	**539**
Single Abdomen X-ray (100 µGy)	1	2	1	0	1	0	**5**	**500**
Chest X-ray and repeat (154 µGy)	0	0	1	0	0	0	**1**	**154**
Abdomen X-ray and repeat (200 µGy)	1	1	2	2	1	0	**7**	**1400**
Babygram and repeat (554 µGy)	0	0	1	0	0	0	**1**	**554**
Total X-rays	3	6	5	2	4	1	**21**	
Total ESD	377	631	1208	400	454	77		**3147**

Statistics for Table of Entrance Skin Dose by Zone

Fisher's Exact Test	
Table Probability (P)	1.546E-05
Pr <= P	0.8237

The actual dosimeter readings (in mGy) as per the raw date from the SABS are shown in Table 9 (a). The secondary radiation dose calculated for each week per zone (dosimeter reading, less the control's reading and less the dose calculated for the previous week, as per the methodology protocol), are shown in Table 9 (b). The values cannot be less than zero, and where the calculation resulted in a value less than zero, then zero was used

As Tables 9 (a and b) indicate, the secondary radiation dose in each zone was not larger than the background radiation.

Table 5 (a and b) Secondary radiation Entrance Skin Dose.

9(a) Dosimeter reading (in mGy) according to SABS raw Data

9 a		Week			
		1	2	3	4
Zone	A	0.01	0	0.01	0
	B	0.006	0.01	0.01	0
	C	0	0	0	0
	D	0.01	0	0	0.01
	E	0	0	0.01	0
	F	0.01	0	0	0
	Control	0.01	0	0.01	0.01

9(b) Calculated Dose (in mGy) using methodology equation

9 b		Week			
		1	2	3	4
Zone	A	0	0	0	0
	B	0	0.01	0	0
	C	0	0	0	0
	D	0	0	0	0
	E	0	0	0	0
	F	0	0	0	0

The results are similar when using the raw data from the $CaSO_4$:Tm elements of the dosimeters (more stable and accurate at higher ambient temperatures with plastic cover which would give the most reliable reading). Tables 10 (a) shows the readings from the dosimeter element, and Table 10 (b) shows the calculated dose (reading less control dosimeter dose).
Higher measurements were recorded in the control area than in most zones in the study area, resulting in secondary radiation doses calculated as 0 mGy in those zones.

Table 6 (a and b) Secondary radiation Entrance Skin Dose from dosimeter's CaSO4 readings, 9 (b)
10 (a) Actual readings as obtained from the SABS raw data Dosimeter $CaSO_4$

10 a		Week			
		1	2	3	4
Zone	A	0.115	0.072	0.097	0.097
	B	0.131	0.095	0.097	0.068
	C	0.077	0.107	0.101	0.08
	D	0.117	0.125	0.085	0.09
	E	0.129	0.105	0.126	0.085
	F	0.089	0.118	0.113	0.104
	Control	0.11	0.108	0.106	0.109

Table 10 (b) Calculated Dose (in mGy) from $CaSO_4$ elements, using methodology equation

10 b		Week			
		1	2	3	4
Zone	A	0.005	0	0	0
	B	0.02	0	0	0
	C	0	0	0	0
	D	0.007	0	0	0
	E	0.019	0	0.02	0
	F	0	0.01	0	0

NPAR1WAY procedure was used by the statistician to provide exact p-values to assess statistical significant. There was no statistical difference between the secondary radiation measured in the zones and the control (p = 0.6553) (as per table 11).

Table 7. Comparison of the Proportions of Secondary Entrance Skin Dose from CaSO4 readings per zone

The NPAR1WAY Procedure

Analysis of Variance for Variable $CaSO_4$ reading Classified by Variable Zone		
Zone	**N**	**Mean**
A	4	0.095250
B	4	0.097750
C	4	0.091250
Control	4	0.108250
D	4	0.104250
E	4	0.111250
F	4	0.106000

Source	**DF**	**Sum of Squares**	**Mean Square**	**F Value**	**Pr > F**
Among	6	0.001299	0.000217	0.6965	0.6553
Within	21	0.006531	0.000311		

Of note, in Table 10, is that the average reading of the control dosimeters was 0.108 mGy (p = 0.6553), which is lower than, but in keeping with the expected background radiation (2 to 3 mSv per annum, 0.17 to 0.25 mSv per month).

9. Discussion

This study found that the secondary radiation dose to patients in our neonatal high care unit over a month (four weeks), could not be high as it was not greater than background radiation for the same period.

This finding was also independent of the distribution of primary radiation exposures in the study area, with no increase in measured secondary radiation in close proximity to where the majority of X-rays occurred.

As the secondary doses were not higher than background radiation as per control dosimeter measurements, X-rays from outside the study area did not influence our results, and the close spacing of patients, due to limited space, has no measurable contribution to secondary radiation dose.

The dosimeter readings indicate that the secondary radiation in the study area was too small to distinguish from background radiation, with no change in this result over time. This is in keeping with the results in previous studies that the secondary radiation dose is not significant. Notably, the control dosimeter readings were the similar across all 4 weeks, where one would expect the dose to increase. This suggests that the storage of the dosimeters removed from the study environment earlier in the study period did not completely eliminate background radiation.

The study area had 89 patients admitted to the unit, with a large number of patients in the cubicle at a time (average 14).

This large number of patients had a short duration of admission, and a progressively smaller number of patients required prolonged admission, which showed an inverse proportional ratio between the number of patients and the duration of their admission to the unit. This indicated that the patients in the high care unit were predominantly admitted for acute illnesses, or had mostly recovered from their illness in neonatal ICU prior to admission to the NHCU, resulting in few patients admitted to NHCU for a prolonged period.

Only 21 X-rays were performed in the cubicle, with less than one X-ray was performed per patient admitted to the unit, and less than one in five patients (18%) admitted to the unit received X-rays.

With the expected clinical profile of high-risk patients admitted in the unit, this quantity and frequency of X-rays appears to be low, and may be due to the short admission duration to the unit, with an average admission of four days, and more than a fifth of patients admitted less than a day. No reference could be found in the literature for comparing the duration of admission to our neonatal high care unit.

An additional finding was that the most commonly performed X-ray examination in our NHCU was an abdominal X-ray. This was an unexpected incidental finding, as the chest X-ray was expected to be the most common examination. (20, 21, 22, 26). However, most studies report on information from neonatal intensive care units, or do not differentiate neonatal high care from intensive care units, and this may explain the differences in the profile of X-rays performed and duration of admission.

As expected, repeat X-rays were required in imaging the patients, with 30% of the X-rays performed as a result of repeat exposures. With the repeat exposure contribution to total dose, the entrance skin dose from primary radiation to patients who did have X-ray investigations was, on average (0.197 mGy), which is higher than the measured background radiation 0.108 mGy, but comparable to reference background radiation levels (0.17 to 0.25 mGy). There was no statistically significant difference between the primary radiation doses in the zones of the cubicle, and no statistically significant difference primary radiation doses per week ($p = 0.1060$ and $p = 0.8237$ respectively).

The difference in radiation dose per zone is likely due to chance, from the random placement of patients, and their need for X-ray examinations.

The lack of statistical difference between the zones is likely due to the small sample size from a low number of X-rays performed.

These findings suggest that the deterministic risk from ionizing radiation due to primary radiation is, on average, approximately double that for patients not receiving X-rays examinations within the unit. The highest primary radiation dose received by a patient was 5 times larger than the background radiation for the same period – 0.554 mGy primary ESD vs 0.108 mGy background ESD.

With the low number of X-rays in our neonatal high care unit, brief admission periods, and secondary radiation over a period of time not causing any dose higher than background radiation, additional measures for radiation protection in the unit are unnecessary.

10. Limitations

Based on the patient profile in a high care unit and concerns from radiographers that a large number of X-rays were performed in our unit, significantly more X-ray examinations were expected - at least several X-rays in the unit per day. The lower than expected number of investigations in the study area limited the statistical significance of the data.

Additionally, the investigator was blind to the admission statistics and diagnoses of the patients in the unit, and the study assumed that patients stayed in the unit for prolonged periods. This assumption was found to be incorrect in this study setting, due to the inverse proportional ratio of the number of patients to duration of admission, with the average patient admitted only four days, and the majority (82%) admitted less than seven days (as per Figure 3).

Patients were also assumed to move in an out of the unit and the cots numbered to keep track of this movement. Although we were able to obtain data by this method, we were unable to determine if patients who had been discharged from the unit were readmitted later and had therefore been allocated a new or different number later in the study period.

The radiographers were meant to complete the data sheets in the unit, when they performed studies, which was inconsistently done. The data had to be double checked in the radiographers' daily records and on X-ray request forms that were marked as completed studies.

The method of storing the dosimeters after collection from the study area may have been inadequate to eliminate background radiation, and therefore influenced the calculation of secondary radiation.

The influence of bias from informing the attending clinicians of the study was not assessed during the study, and the study design did not consider whether the quantity of X-ray examinations performed during this study were representative of the normal practice, as retrospective and prospective records of X-rays performed in the cubicle outside of the study period were not checked.

A retrospective attempt to determine the normal frequency of X-rays in the study area after completing data collection was not possible, as the radiographer statistical records were incomplete regarding which cubicle X-rays were performed in, what studies were performed, and how many exposures were performed.

The principal researcher noticed the unexpectedly low number of X-rays performed in the cubicle after the first week of the study, and this coincided with a complaint to the radiology department, from the neonatal unit, that requested X-rays were not being performed. An attempt to assess whether the X-rays were requested and not performed in the neonatal high care unit was made from the end of the second week of the study period. The principal researcher checked the "X-ray examination request book" in the neonatal unit daily to assess if examinations were requested but not performed, and observed that requests were not documented regularly. Thereafter the request book was misplaced, and could not be found at its designated place again for the study duration. An alternative to the request book was designed in the form of a request record data sheet, that was placed at the same location that X-ray requests are placed by the requesting clinicians, and the clinicians were notified in person about the request sheets and their purpose. For the remainder of the study, requests and examinations were still made and performed, however the request data sheet was not used to document requests. This made confirming whether investigations were requested and were not performed impossible. Although an audit of requests and examinations was beyond the scope of this study, this suggested that documentation failures occur at multiple levels.

Literature tends to focus on care in neonatal ICU, with little mention of high-care unit practice regarding radiological investigations, making comparison to other units difficult.

11. Recommendations for future research

This study demonstrated that assumptions about the number of studies performed and the duration of patient admission are incorrect, as evident by the low number of x-ray examinations performed relative the number of patients admitted, and the predominantly short duration of admission.

Prior to undertaking such a study, the total number of studies performed in the high-care unit over a period of time, patient population and duration of admission should be checked, to plan an appropriate study period to obtain statistically significant results.

Recording patient identifying features, such as name and hospital number, as opposed to only numbering cots will increase the accuracy of mapping patient movement by helping identify readmissions, however this would have ethical implications, and the unit clerk or nurses, would likely need to be recruited in the study to help identify patients who have changed cots or been readmitted. Since multiple level documentation failures were a limitation of the study, this may not be a reliable option.

Anticipating that occasionally data sheet entries can be omitted, and correlating the data sheet information with the radiographers' daily records assists with improving data collection on the studies performed. Additionally, if radiographers on duty in the unit were not rotated as frequently, data collection would be more consistent.

Daily reminders to the radiographers on duty could also be used to try improve data collection about the studies performed.

Poor data sheet completion should be anticipated, in spite of pre-study attempts to prevent this problem, and additional methods of double checking the completion of data collection should be considered, prior to the study period – such as checking records of the radiographers' daily statistics on examinations, and the clinicians' records on X-ray examination requests.

Sending the dosimeters to the SABS for reading at the end of each week, instead of at the end of the study period (4 weeks), may have improved the accuracy of eliminating background radiation influence on readings, and the problem of dosimeters storage when they were no longer in use within the study area.

Reviewing retrospective and prospective records of X-rays performed in the cubicle outside of the study period could provide a reference to normal practices in the unit to assess if the study period was representative, or if the study resulted had in measurement bias due to change in practice.

Improving record keeping and quality control of the records in the X-ray department's data record (radiographers' daily statistics book) would facilitate retrospective data collection in future studies.

Encouraging and enforcing good record keeping and documentation at multiple levels in daily practice should help improve communication between departments, and in data collection.

Performing the study in the neonatal intensive care unit rather than the high care unit would have made the study results more comparable to prior studies, however this was beyond the scope of this study's objective to assess the high care unit (19, 20, 26).

12. Conclusion:

Secondary radiation over a period of time in our neonatal high care unit does not cause a measurable ionizing radiation dose that is higher than background radiation.

The radiation dose from primary ionizing radiation is also relatively low.

Our unit does not have a large number of X-rays in the high care unit relative to the number of patients admitted there. Only 18% of patients admitted had X-ray examinations. The causes for the lower than expected number of examinations in the unit was beyond the scope of this study, however was likely related to the predominantly short duration of admission to the unit – 21% of patients were admitted for less than 1 day, and 82 % less than 1 week.

While stochastic effects of radiation are still theoretically possible, the risk of deterministic effects of radiation from secondary radiation in our neonatal high care unit is the same as from background radiation.

Therefore, this study concludes that additional measures for protecting from secondary ionizing radiation are not necessary in our neonatal high care unit.

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Appendix 1

R14/49 Dr Donovan Feeney

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M160754

NAME: (Principal Investigator)	Dr Donovan Feeney
DEPARTMENT:	Diagnostic Radiology Chris Hani Baragwanath Academic Hospital
PROJECT TITLE:	An Analysis of Secondary Radiation Doses in a South African Neonatal High Care Unit
DATE CONSIDERED:	29/07/2016
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Tanyia Pillay and Linda Tebogo Hlabangana
APPROVED BY:	Professor P Cleaton-Jones,Chairperson, HREC (Medical)
DATE OF APPROVAL:	16/09/2016

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary in Room 10004, 10th floor, Senate House/3rd Floor, Phillip Tobias Building, Parktown, University of the Witwatersrand. I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in July and will therefore be due in the month of July each year.

Principal Investigator Signature Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix 2

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

FACULTY OF HEALTH SCIENCES

PROTOCOL ASSESSORS MEETING

Candidate Full Name: Feeney Donovan

Student Number: 1319509 Date: 10-11-2016

School / Department / Division: Clinical Medicine / Radiation Sciences / Radiology

1. Type of study *(tick all that apply)*:

- ○ Quantitative
- ○ Qualitative
- ✓ Mixed Methods
- ○ Laboratory
- ○ Clinical
- ○ Other, please specify……

2. Is title of the study appropriate (*preferably fewer than 20 words*)? Yes ✓ No

Comments:

3. Are the study objectives clear and linked to the research aim and title? Yes No ✓

Comments: Study too broad. Need to simplify + focus on clear objectives.

4. Is the design of the study appropriate to meet the study objectives? Yes No ✓

Comments: As above. Methods need to revised + variables limited.

03/03/2016

1

5. Are the proposed methods and tools appropriate to meet the research objectives? Yes / No ✓

Comments: As above

6. Is the study feasible within the resources of:

a) The applicant? Yes ✓ / No

b) The department? Yes ✓ / No

c) The time frame? Yes / No ✓ Too long

7. If this is a PhD protocol assessment:

a) Is the content original? Yes / No

b) Does the content show the scope and depth of a PhD? Yes / No

Comments: N/A

Do you recommend:

i. Additional revision/amendment of the protocol? Please be specific on the recommendations being made:

Simplify + focus with guidance from Medical Physics to make project feasible for MMed

ii. The appointment of a Co-Supervisor? Yes ✓ / No

Nominee/s: Prof D. v.d. Merwe (30%)

03/03/2016

2

Overall recommendation regarding the protocol: Prof W. Vangu + Prof D. v.d Merwe

i. Revision of the protocol to the satisfaction of the Supervisor (**NB: if HoD approval is also required, please specify**): [Yes ✓] [No]

***(Candidate**: submit a hard copy of your revised protocol, a list of corrections you have undertaken in line with the recommendations of the assessors, referring to the page and paragraph in your proposal where you have made the changes and a letter from your supervisor indicating that he/she is satisfied and that all the assessors' comments have been addressed submit to PG Office).*

ii. Revision of the protocol to the satisfaction of the Assessor Group/Chair: [Yes] [No ✓]
***(Candidate**: one copy, list of corrections with page numbers, Supervisor approval letter – submit to PG Office and PG Office to forward to the Assessor Group Chair).*

iii. Revision of the protocol and resubmission of the revised protocol to the next Assessor Group Meeting: [Yes] [No ✓]
***(Candidate**: six copies, list of corrections with page numbers, Supervisor approval letter – submit one copy to PG Office / 5 to school assessor group administrator / for PhD, all six copies to be submitted to the PG Office).*

iv. Candidate goes ahead (*no revision required*): [Yes] [No ✓]

Details of Assessors:

Name:	Email:	Sign:
VICTOR MNGOMEZULU		[signature]
D. VAN DER MERWE		[signature]
PROF VANGU		[signature]

Details of Assessor Group Chair:

Name:	Email:	Sign:
P. Ruff	[signature]	paul.ruff@wits.ac.za

Date: 10/11/16

03/03/2016

3

health and
social development
Department: Health and Social Development
GAUTENG PROVINCE

CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL
DEPARTMENT OF RADIOLOGY
Tel: 011 933 9406/8411

25th July 2017

To Whom it may concern

Re: Review of Mmed Protocol Corrections of Donovan Feeney (Student #: 1319509)

I have reveiwed the amendments made by Dr Donovan Feeneya to his Mmed protocol entitled, "An Analysis of Secondary Radiation Doses in a South African Neonatal High-Care Unit." The corrections are to my satisfaction.

Kind regards

Dr Linda Tebogo Hlabangana
Head of Department
Diagnostic Radiology Department
Chris Hani Baragwanath Academic Hospital

Appendix 3

<u>Data Sheet:</u> Day: ....

Total Number of patients: ....

Area:

<u>C</u> Number of patients:.........	<u>D</u> Number of patients:.........
<u>B</u> Number of patients:.........	<u>E</u> Number of patients:.........
<u>A</u> Number of patients:.........	<u>F</u> Number of patients:.........

Zone and bed number	*X-ray*	*Number of exposures*
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		
13		
14		
15		
16		
17		
18		
19		
20		
21		
22		
23		
24		
25		

Key for x-rays:
C = Chest; A= abdomen, L=Limb, B=Babygram, S=skull, O=other.................................
For queries: Contact Dr Feeney #7200, 0837160489, donovan.feeney@gmail.com

Appendix 4

Dosimeters:

Number	SABS Serial number	Location	Week of study removed	Collected? Y/N	Reading result
1		A	1		
2		B	1		
3		C	1		
4		D	1		
5		E	1		
6		F	1		
7		A	2		
8		B	2		
9		C	2		
10		D	2		
11		E	2		
12		F	2		
13		A	3		
14		B	3		
15		C	3		
16		D	3		
17		E	3		
18		F	3		
19		A	4		
20		B	4		
21		C	4		
22		D	4		
23		E	4		
24		F	4		
25		Control1	1		
26		Control2	2		
27		Control3	3		
28		Control4	4		

Appendix 5

__Raw data table received from SABS__

Study designation	Badge	R Exp1	R Exp2	R Exp3	R Exp4	C Exp1	C Exp2	C Exp3	C Exp4	Deep	Skin
	========	========	=======	========	========	========	=======	=======	========	=======	========
		(mRem)	(mRem)	(mRem)	(mRem)	(mRem)	(mRem)	(mRem)	(mRem)	(mRem)	(mRem)
A1	407919	13,9	15,7	11,5	11,9	8,5	11	1	1	1	1
A2	631871	17,4	13,9	7,2	8	6,1	1,2	1	1	0	0
A3	727953	19,1	20,9	9,7	8,2	11,5	14,8	1	1	1	1
A4	418058	12,2	16,5	9,7	9,7	0,7	5,6	1	1	0	0
B1	313226	24,4	20,2	13,1	15,1	14,7	5,8	1	0,6	0,6	0,6
B2	633373	24,3	22,6	9,5	10,4	18,2	12,6	1	1	1	1
B3	511881	33	26,1	9,7	9,5	28,4	12,5	1	1	1	1
B4	632105	8,7	15,7	6,8	6,7	1	4	1	1	0	0
C1	207565	19,1	18,3	7,7	7,6	6,3	2,1	1	1	0	0
C2	408985	12,2	7,8	10,7	11,4	2	1	1	1	0	0
C3	409272	11,3	10,4	10,1	9,5	0,1	1	1	1	0	0
C4	632282	12,2	13,9	8	9,4	1	0,8	1	1	0	0
D1	693935	19,1	23,5	11,7	10,8	14,5	18,4	1	1	1	1
D2	410958	12,2	10,4	12,5	10,4	3,9	1	0	1	0	0
D3	210527	14,8	13	8,5	9,4	3,9	0,2	1	1	0	0
D4	208346	20	18,3	9	10,5	10,7	7,5	1	1	1	1
E1	401827	15,7	15,7	12,9	13,2	5,1	3,2	1	1	0	0
E2	419309	8,7	9,6	10,5	10,3	1	1	1	1	0	0
E3	214258	20	14,8	12,6	11,2	10,6	1,8	1	1	1	1
E4	415436	10,4	6,1	8,5	9,9	0,7	1	1	1	0	0
F1	711032	20,9	29,6	8,9	12,7	13,9	23,6	1	1	1	1
F2	126149	19,1	20,9	11,8	11,8	8	7,5	1	1	0	0
F3	143819	18,3	15,7	11,3	10,7	5,8	2,9	1	1	0	0
F4	402207	19,1	10,4	10,4	9,5	8	1	1	1	0	0
Control 1	427903	13,9	18,3	11	10,9	5,4	11,1	1	1	1	1
Control 2	431074	14,8	20,9	10,8	11,6	4,8	9,2	1	1	0	0
Control 3	427082	23,5	33,9	10,6	10,3	14,8	23,3	1	1	1	1
Control 4	9016	17,4	27	10,9	11,3	6,1	18,2	1	1	1	1

Appendix 6

Workshop Presentation slides

AN ANALYSIS OF SECONDARY RADIATION DOSES IN A SOUTH AFRICAN NEONATAL ICU HIGH-CARE

DR DONOVAN FEENEY
CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

CONTENTS

Introduction
Rationale
Aim
Method
Time frame
Your role: Daily information form
Examples and practice

Questions and answers

INTRODUCTION

Secondary Radiation

Primary radiation exposures

Patients

Cubicle

RATIONALE

Ionising radiation bio-effects
Secondary radiation not usually considered.

NICU/HCU patients – neonates, premature, ill

Susceptible to ionising radiation
Long period in NICU/HCU
Frequent exposures

Previous studies: measured 2° radiation per exposure

AIM

Measure the 2° radiation over a period of time.

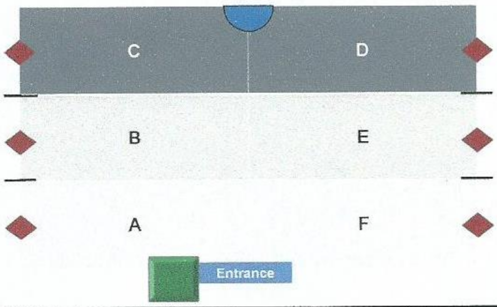
Compare to 1° radiation.

METHOD

Dosimeters - 2° radiation
- TLDs
- *Positioned in HCU cubicle*

Data sheets - 1° radiation
- At entrance to the HCU
- Daily
- Pt numbers and distribution
- Exposure in cubicle data: type, number, distribution

CUBICLE



DAILY INFORMATION FORM

DIF - EXAMPLE

TIME FRAME

TLD – 28 days total, 1 dosimeter removed per zone per week

Data sheet – 2/day x 28 days

QUESTIONS?

CONTACT DETAILS

Principle investigator: Dr Donovan Feeney

Cell.: 0837160489

Email: donovan.feeney@gmail.com

Appendix 7

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Radiation and Health Physics Unit,
East Campus

Date: 2nd March 2016

To; Prof. Cleaton – Jones,
Chairman, HREC,
University of the Witwatersrand,
Johannesburg

Research Protocol Title: *Analysis of Secondary Radiation Doses in a South African Neonatal ICU High-care Unit. Donovan Feeney*

Research Protocol Number:

Dear Sir,

I have reviewed the above mentioned research protocol, and I am satisfied that it may proceed subject to the following conditions;

A. No additional requirements ☑

B. The following requirements are needed; ☐

Yours sincerely,
James Larkin,
Director, Radiation and Health Physics Unit

(Digital signature)

James F. S. Larkin
2016.03.02
12:47:09 +02'00'

Radiation and Health Physics Unit, Professional Development Hub, Gate 6, 92 Empire Road, Braamfontein, Johannesburg, South Africa.
Tel: +27 11 717-6961 | Email: james.larkin@wits.ac.za | www.wits.ac.za

Appendix 8

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

MEDICAL ADVISORY COMMITTEE
CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

PERMISSION TO CONDUCT RESEARCH

Date: 14 June 2016

TITLE OF PROJECT: An analysis of secondary radiation doses in a South African neonatal high-care unit

UNIVERSITY: Witwatersrand

Principal Investigator: DL Feeney

Department: Diagnostic radiology

Supervisor (If relevant): T Pillay, LT Hlabangana

Permission Head Department (where research conducted): Not yest

Date of start of proposed study: June 2016
Date of completion of data collection: Dec 2017

The Medical Advisory Committee recommends that the said research be conducted at Chris Hani Baragwanath Hospital. The CEO /management of Chris Hani Baragwanath Hospital is accordingly informed and the study is subject to:-

- Permission having been granted by the Human Research Ethics Committee of the University of the Witwatersrand.
- the Hospital will not incur extra costs as a result of the research being conducted on its patients within the hospital
- the MAC will be informed of any serious adverse events as soon as they occur
- permission is granted for the duration of the Ethics Committee approval.

....
Recommended
(On behalf of the MAC)
Date: 14 June 2016

....
Approved/Not Approved
Hospital Management
Date: 15/06/16

Appendix 9

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

DEPARTMENT OF RADIOLOGY
UNIVERSITY OF WITSWATERSRAND
CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL
Tel: 011 933 8411/9406

20 June 2016

The Chairperson
HREC
University of the Witswatersrand

Dear Chairperson

DR DONOVAN FEENEY RESEARCH PROJECT AT CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

Dr Donovan Feeney is preparing to do a prospective study on the "Analysis of Secondary Radiation Doses in a South African Neonatal High Care Unit", for the purpose of his MMed degree.

As the Head of Department of Paediatrics at Chris Hani Baragwanath Academic Hospital, I give permission to Dr. Feeney to conduct this study in the division of Neonatology at the Department of Paediatrics at Chris Hani Baragwanath Academic Hospital

Yours Sincerely

Prof S Velaphi

Appendix 10

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

DEPARTMENT OF RADIOLOGY
UNIVERSITY OF WITSWATERSRAND
CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL
Tel: 011 933 8411/9406

20 June 2016

The Chairperson
HREC
University of the Witswatersrand

Dear Chairperson

DR DONOVAN FEENEY RESEARCH PROJECT AT CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

Dr Donovan Feeney is preparing to do a prospective study on the "Analysis of Secondary Radiation Doses in a South African Neonatal High Care Unit", for the purpose of his MMed degree.

As the Unit Manager at Chris Hani Baragwanath Academic Hospital Neonatology unit, where the study will be performed, I support his research project, and give him permission to conduct his study in the neonatal high care unit at Chris Hani Baragwanath Hospital.

Yours faithfully

Sister Dube

Appendix 11

health and social development
Department: Health and Social Development
GAUTENG PROVINCE

DEPARTMENT OF RADIOLOGY
UNIVERSITY OF WITSWATERSRAND
CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL
Tel: 011 933 8411/9406

10 May 2016

The Chairperson

HREC

University of the Witwatersrand

Dear Chairperson

DR DONOVAN FEENEY RESEARCH PROJECT AT CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

Dr Donavan Feeney is preparing to do a prosective study on the, "Analysis of Secondary Radiation Doses in a South African Neonatal High Care Unit" for the purpose of his MMed Degree.

As the Head of the Department, I support his research project and give him permission to conduct his study in the radiology department at Chris Hani Baragwanath Academic Hospital.

Yours faithfully

Dr L T Hlabangana
Head of Department: Radiology

10/05/2016
Date

Appendix 12

health and social development
Department: Health and Social Development
GAUTENG PROVINCE

CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL
Directorate. Clinical Support (Radiography)
Enquiries. Mrs. N.G.Tsoeu
Tel. number. (011) 933 8434; Fax No. 011 9339261; Email. nonhlanhla.tsoeu@gauteng.gov.za

Date. 20 May 2016

PERMISSION TO CONDUCT RESEARCH

DR DONOVAN FEENEY RESEARCH PROJECT AT CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

Dr. Donovan Feeney is preparing to do a prospective study on the "An Analysis of Secondary Radiation Doses in a south African Neonatal High Care Unity", for the purpose of his MMed Degree.

As the Head of the Radiography unit, I support his project, and give him permission to conduct his study in the neonatal high care unit at Chris Hani Baragwanath Academic Hospital.

NGTsoeu
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Recommended
DD. Radiography
Date. 20/05/2016