ESTABLISHMENT OF LOCAL DIAGNOSTIC REFERENCE LEVEL (LDRLS) FOR DIGITAL MOBILE RADIOGRAPHY IN NEONATE POPULATION

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by

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$mGy.cm^2$	Mili-Gray centimetres squared
$Gy.cm^2$	Gray centimetres squared
mGy	Mili-Gray
$\mu Gy.m^2$	Micro-Gray centimetres squared
kV	Kilo-Volt
mA	Milli-Ampere
s	Second
d	Day
mAs	Milli-Ampere second
cm	centimetre
cm^2	centimetre squared
mm Al	Millimetres of Aluminium
mGy/s	Mili-Gray per second

LIST OF ABBREVIATIONS

DRL	Diagnostic Reference Level
LDRL	Local Diagnostic Reference Level
HUSM	Hospital Universiti Sains Malaysia
ALARA	As Low as Reasonably Achievable
P_{KA}	Air Kerma-Area Product
KAP	Kerma Area Product
DAP	Dose Area Product
ESAK	Entrance Surface Air Kerma
ESD	Entrance Surface Dose
IAK	Incident Air Kerma
BMI	Body Mass Index
AP	Anterior-Posterior
PA	Posterior-Anterior
FOV	Field of View
NICU	Neonatal Intensive Care Unit
ICRP	International Commission on Radiological Protection
IAEA	International Atomic Energy Agency
CXR	Chest X-ray

CT	Computed Tomography
CBCT	Cone Beam Computed Tomography
MRI	Magnetic Resonance Imaging
IXRPC	International X-ray and Radium Protection Committee
MOH	Ministry of Health
RPOP	Radiation Protection of Patients
Q1	1st Quartile
Q2	2nd Quartile
Q3	3rd Quartile
IQR	Inter-Quartile
MDR	Mobile Digital Radiography
ROSe	Radiology Oncall Services
S-DAP	Samsung-Dose Area Product
HVL	Half Value Layer
R/F	Radio-Frequency
PACS	Pictures Archiving and Communicating System
PACSZFP	Pictures Archiving and Communicating System-Zero Footprint Client
PACSUV	Pictures Archiving and Communicating System- Universal Viewers
DICOM	Digital Imaging and Communications in Medicine
SDD	Source-to-Detector Distance

SID	Source-to-Image Distance
CF	Correction Factor
ADI	Area of Diagnostic Interest

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PENUBUHAN ARAS RUJUKAN DIAGNOSTIK TEMPATAN (LDRLS) UNTUK RADIOGRAFI DIGITAL BERGERAK DALAM POPULASI NEONATAL

ABSTRAK

Pengenalan: Teknik radiologi seperti pemeriksaan radiografi seperti dada AP, abdomen AP, dan dada-abdomen sering dijalankan pada pesakit neonatal untuk pemeriksaan pelbagai masalah klinikal. Namun, aras rujukan diagnostik (DRL) yang menyeluruh yang mengambilkira keperluan spesifik mengikut kategori neonatal pada masa ini masih lagi kurang. Penubuhan DRLs sangat penting bagi mengoptimumkan dos radiasi dan memastikan amalan pengimejan yang selamat serta sepadan dengan fisiologi neonatal. **Objektif:** Kajian ini bertujuan untuk menilai taburan dos (Produk Kerma Udara Kawasan, P_{KA} dalam $mGy.cm^2$) untuk pemeriksaan dada, abdomen, dan dada-abdomen bagi unit sinar-X bergerak dalam kalangan neonatal dan untuk menubuhkan aras rujukan diagnostik tempatan (LDRLs) untuk pemeriksaan ini khususnya dalam kalangan neonatal. **Kaedah:** Dalam kajian ini, tinjauan retrospektif data pemeriksaan radiografi telah dijalankan ke atas 694 sampel neonatal, berumur 1 hingga 28 hari, yang menjalani pemeriksaan radiografi dada AP, abdomen AP dan dada-abdomen AP dalam tempoh Januari 2022 sehingga Disember 2023 di Hospital Universiti Sains Malaysia (HUSM) menggunakan unit sinar-X bergerak Samsung GM85. Taburan dos (P_{KA} dalam $mGy.cm^2$) dinilai, dan aras rujukan diagnostic tempatan untuk ketiga-tiga pemeriksaan telah ditubuhkan. **Keputusan:** Taburan dos (P_{KA} dalam $mGy.cm^2$) menunjukkan nilai tertinggi DRL (Q3) adalah abdomen AP (17.26 $mGy.cm^2$) dan terendah adalah bagi pemeriksaan dada AP (6.79 $mGy.cm^2$). Julat rujukan bagi P_{KA} untuk pemeriksaan berikut adalah abdomen AP (1.98 – 140.98

mGy.cm^2), dada-abdomen (2.62 – 132.66 mGy.cm^2), dan dada AP (0.97 – 24.50 mGy.cm^2). **Kesimpulan:** Dapatan kajian ini mendapati bahawa nilai KAP meningkat secara berkadaran dengan kV, mAs dan FOV. DRL untuk neonatal berbeza bergantung pada kawasan yang diimbas untuk setiap pemeriksaan radiografi. Ringkasnya, kajian ini memberi sumbangan penting untuk meningkatkan keselamatan sinaran, penjagaan pesakit, dan membuat keputusan klinikal dalam pemeriksaan radiografi dalam kalangan neonatal. Secara keseluruhan, kajian ini bersetuju dengan kajian DRL lain yang telah dijalankan.

Kata kunci: ***Pemeriksaan Radiografi, Aras Rujukan Diagnostik, Neonatal***

ESTABLISHMENT OF LOCAL DIAGNOSTIC REFERENCE LEVEL (LDRLS) FOR DIGITAL MOBILE RADIOGRAPHY IN NEONATE POPULATION

ABSTRACT

Introduction: Radiology techniques such as chest AP, abdomen AP, and chest-abdomen X-rays are frequently performed on neonates to address various clinical conditions. However, a comprehensive Diagnostic Reference Level (DRL) that considers the specific needs and categories of neonates is currently lacking. Developing such DRLs is crucial for optimising radiation doses and ensuring safe imaging practises tailored to the delicate physiology of neonates. **Objectives:** This study aims to evaluate the dose distribution (Air Kerma-Area Product, P_{KA} in $mGy.cm^2$) for chest, abdomen, and chest-abdomen AP studies for mobile digital X-ray units among neonates and establish the local diagnostic reference levels (LDRLs) for these studies specifically for neonates. **Method:** In this study, a retrospective survey of X-ray data was conducted on 694 neonate samples, aged 1 to 28 days, who underwent chest AP, abdomen AP, or chest-abdomen X-ray examinations between January 2022 and December 2023 at Hospital Universiti Sains Malaysia (HUSM) using a mobile Samsung GM85 unit. The dose distributions (P_{KA} in $mGy.cm^2$) were evaluated, and the local diagnostic reference levels were established for these selected studies. **Results:** The dose distribution (P_{KA} in $mGy.cm^2$) revealed the highest DRL (Q3) value in the abdomen AP (17.26 $mGy.cm^2$) and the lowest in the chest AP (6.79 $mGy.cm^2$). The reference range of P_{KA} for the selected X-ray examinations are abdomen AP (1.98 – 140.98 $mGy.cm^2$), chest-abdomen (2.62 – 132.66 $mGy.cm^2$), and chest AP (0.97 – 24.50 $mGy.cm^2$). **Conclusion:** The findings of this study reveal that

KAP value proportionally increases with kV, mAs and FOV. The DRL for neonates varies depending on the area being scanned for each X-ray radiography examination. In summary, this study makes a significant contribution to enhancing radiation safety, patient care, and clinical decision-making in neonatal X-ray radiography. Generally, this study agrees with other conducted DRL studies.

Keywords: ***X-ray Radiography, Diagnostic Reference Level, Neonate***

CHAPTER 1

INTRODUCTION

1.1 Background of Study

A literature review was conducted to determine the norms for practise in neonates around the world, which will give the harmful risk (high cumulative dose) associated with radiation exposure at a very young age. The risk of radiation-induced harm later in life increases with every X-ray image taken especially for younger premature babies (Gislason-Lee, 2021). The greater the number of X-rays taken, the greater the neonate's cumulative exposure to radiation thus will particularly at the babies at risk of developing radiation-induced illness, such as cancer, later in life (Gislason-Lee, 2021). Recommended action should be taken to minimise the potential risk to the patient through justification concepts where the imaging benefits outweigh the patient's risk (Gislason-Lee, 2021). In most cases, increasing the radiation exposure to patients, especially infants, can lead to better image quality. But, on the other hand, this will lead to higher cumulative doses for the patients. It is crucial to balance this trade-off between the optimum image quality and dose reduction.

The diagnostic reference level was aimed at optimising the use of radiation in medicine. These levels serve the purpose of guiding and ensuring that radiation exposure is kept within reasonable limits, thus helping to prevent excessive radiation exposure during medical procedures (MOH, 2013). It also serves as a benchmark for local practise at the national or regional level. Due to the possible differences in imaging facilities and protocols among various centres in countries and regions, it is advisable to establish national or regional diagnostic reference levels (DRLs).

The concept of DRLs in medical imaging has been introduced as an indicator of the typical practise in a country or a region (Vassileva, 2015). It is not designated as a dose limit, nor does it signify a border between good and poor practise. Instead, it serves as a reference level to optimise radiation doses in medical imaging, promoting the achievement of high-quality diagnostic images with doses that are as low as reasonably achievable. It also assists in identifying any unusually high or low doses, where optimisation action needs to be applied. Currently, emphasis is placed on optimisation of practise in accordance with the principle of As Low as Reasonably Achievable (ALARA).

A non-invasive medical test that aids in the diagnosis and treatment of medical disorders is an X-ray examination. An X-ray creates images of the inside of the body by using a tiny amount of ionising radiation. Infants, older children, and adults may all undergo X-ray examinations, which are essential for diagnosing various ailments and injuries. X-rays are often the first imaging modality used to identify sources of pain, evaluate severe injuries, and detect foreign bodies. They are utilised for imaging every part of the body, with chest X-rays being the most common test for assessing the chest area. They are particularly helpful in diagnosing and evaluating congenital abnormalities, inhaled foreign bodies, airway diseases, and other conditions. An abdominal X-ray is often the initial examination performed to determine the cause of acute pain in the lower back or abdomen. It is also useful for assessing unexplained nausea and vomiting, detecting ingested foreign objects, and identifying perforations in the stomach or intestines (Radiology (ACR), n.d.).

Digital mobile radiography is frequently used in emergency situations when patients are unable to visit the radiology clinic. It could be because of a medical problem that keeps them from being able to. Additionally, digital mobile X-ray examinations are frequently used for newborns who are still in the ward and require acute care, providing essential imaging capabilities at the bedside to promptly address urgent medical needs without the necessity of transporting vulnerable infants to the radiology department. For these patients, the digital mobile unit is the most effective imaging tool for diagnosis.

According to the International Atomic Agency (IAEA) Safety Standard: Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards (IAEA, 2011), the government should establish the Diagnostic Reference Level (DRL) for medical exposure incurred in medical imaging, including image-guided interventional procedures and diagnostic nuclear medicine (MOH, 2013). The concept of DRL has been introduced by ICRP, IAEA, BSS, and radiation protection of patients (RPOP), with the purpose of the optimisation of the patient dose together with adequate image quality (Krisanachinda, 2022). DRLs were determined through the 3rd quartile of the distribution of mean dosimetric values. Therefore, DRL is not a dose limit, but a guide for doing well. Local reviews should be undertaken whenever relevant DRLs are consistently exceeded, and appropriate corrective actions should be taken to improve practise and avoid unnecessary risks due to radiation health effects (Sharma, 2018).

The objective of DRL is to optimise the use of radiation in medicine and help avoid excessive radiation exposure. It can be accomplished by the comparison between the numerical value of the DRL derived from relevant regional, national, or local data and the mean or other appropriate value observed in practise from a suitable reference group of patients. A suitable reference group of patients is defined within a certain range of physical parameters such as height and weight (MOH, 2013). Based on a study by Krisanachinda et al (2022), a Malaysian representative proposed the survey of CT, General X-ray, Fluoroscopy, and Interventional Radiography regarding DRL at the World Congress on Medical Physics and Bio-Medical Engineering in 2000. The dose quantity of general X-rays is Air Kerma (mGy) and KAP (mGy.cm^2) (Krisanachinda, 2022).

This study aims to establish the local diagnostic reference levels for radiographic exams using a digital mobile unit, thus providing data for local reference which is an important tool for clinical practise especially in HUSM. Furthermore, this study assesses the diagnostic imaging techniques currently practised in the Radiology Department at HUSM, providing insights to optimise procedures specifically for neonates.

1.2 Problem Statement

Based on the literature review, national DRL had been established across European countries (Austria, Finland, France, Spain, Belgium, Ireland, UK and Germany) and local DRL for Non-European countries (Kenya) for chest/thorax and abdomen/pelvis region. Hence there is no DRL data related to the chest-abdomen region. The summary for each national DRL value for each country is presented in Table 2.2. Based on Table 2.2, the dose quantities used are IAK (mGy), ESD (mGy), ESAK (mGy), and KAP/DAP (mGy.cm^2). Regardless of the applied dose, national DRL studies used the third quartile of dose distribution while the mean value was used for the local DRLs. Patients were categorised according to age categories (Triantopoulou et al, 2020).

Moreover, the previously established DRL in radiography of neonatal chest AP examination conducted by Sharma et al was done based on gender and each mean organ dose was determined (µGy). A total number of 38 members of neonates (19 males and 19 females) were included in this study (Sharma et al, 2018). In addition, a recent study done by Gilley et al (2023) was done for a weight-based DRL for neonatal chest X-rays. The data collection was done on a total of 95 patients (17 neonates weighing <1000g, 28 neonates weighing 1000-2500 g, and 45 neonates weighing >2500 g) with the result of 3.3 $mGy.cm^2$ (<1000 g), 4.8 $mGy.cm^2$ (1000 g-2500 g) and 8 $mGy.cm^2$ (>2500 g). As of now, Malaysia has not established any national DRL specifically for neonatal radiography. Hence, this study aims to evaluate the dose distribution and establish the local diagnostic reference levels (LDRLs) for chest, abdomen, and chest-abdomen study for digital mobile radiography unit among neonates that will serve as a local benchmark for current practises in HUSM to emphasize the optimisation of the dose distribution thus following the principle of As Low As Reasonably Achievable (ALARA) among neonates.

1.3 Objectives of Study

1.3.1 General Objective:

This work aims to establish the local diagnostic reference levels (LDRLs) for chest, abdomen, and chest-abdomen study for mobile X-rays unit among neonates

1.3.2 Specific Objectives:

1. To evaluate the dose distribution (Air Kerma-Area Product, P_{KA} in $mGy.cm^2$) for chest, abdomen, and chest-abdomen study for mobile X-rays unit among neonates.
2. To study the correlation between scanning parameters (kV, mAs, FOV) and the dose distribution for chest, abdomen, and chest-abdomen study in the neonate population.
3. To establish the local diagnostic reference levels (LDRLs) for chest, abdomen, and chest-abdomen study for mobile X-rays unit among neonates

1.4 Significance of Study

The significance of this study is to evaluate the dose distribution (Air Kerma-Area Product, P_{KA} in $mGy.cm^2$) and thus establish the local diagnostic reference levels (LDRLs) for chest, abdomen, and chest-abdomen study for mobile x-rays unit among neonates. It provides a better understanding and awareness of dose optimisation strategies as the establishment of LDRL for chest, abdomen, and chest-abdomen study for mobile x-rays unit among neonates. During a radiography or fluoroscopic treatment, ionising radiation typically X-rays lays down the total energy in each area. This quantity is known as the Air Kerma-Area Product in radiology. It is defined as the integral of air kerma along the beam axis over the area of the irradiated field.

The patient's age and region of interest (chest, abdomen, chest-abdomen) will be the guidelines for each LDRLs value. Moreover, the technical parameter factors that are proportional to KAP value was able to be identified thus will guide the radiographer in selecting the correct technical parameters, especially the tube voltage (kV) and tube current product time (mAs) before exposing the radiation to neonates. The outcomes of this study will contribute to a greater comprehension of the diagnostic reference level for chest, abdomen, and chest-abdomen study for mobile X-rays unit among neonates whereas the LDRL value can be used during clinical practise to achieve the optimisation strategies following the principle of As Low as Reasonably Achievable (ALARA). Healthcare professionals can optimise imaging techniques to decrease patient radiation dose while maintaining diagnostic picture quality by monitoring KAP values throughout radiological procedures and comparing them to established diagnostic reference levels (DRLs). In radiology practise, this supports preserving radiation protection and patient safety. These results would therefore have important uses in clinical imaging.

CHAPTER 2

LITERATURE REVIEW

This chapter provides a comprehensive analysis of existing research on neonatal radiography, an overview of the application of diagnostic radiology for neonate's category, dose from X-ray radiography, and gaps in establishing Diagnostic Reference Levels (DRLs) for this demographic.

2.1 Applications of Diagnostic Radiology for Neonate's Category

Most of the performed diagnostic X-ray examinations during hospitalisation in the neonatal intensive care unit (NICU) comprise imaging of the respiratory and gastrointestinal systems, namely the chest and abdomen examinations (Bahreyni Toossi & Malekzadeh, 2012). According to the study of Sharma et al (2018), the chest X-ray is the most valuable modality in the assessment of neonatal respiratory disorder. A neonate is a baby who is 4 weeks old or younger (also called a newborn). The neonatal period is the first 4 weeks of a child's life. It is a time when changes are very rapid. Many critical events can occur in this period such as the risk for infections that may become more serious are higher as well as many birth or congenital defects are first noted (MedlinePlus, 2016). Several literature reports emphasise that the risk of cancer from exposure is inversely proportional to age, meaning that the radiosensitivity of a newborn is assumed to be greater than a mature child or adult (Armpilia et al, 2002; Datz et al, 2008 in Bahreyni Toossi & Malekzadeh, 2012). Therefore, the risk of radiation-induced malignancy is increased (Dougeni et al, 2007 in Bahreyni Toossi & Malekzadeh, 2012). In a study reported by Spitzer et al. (1993), routine screening chest radiographs were found to be significantly beneficial in one-third of the neonates, identifying, among other things, potential pulmonary problems before a patient's clinical status deteriorated (Spitzer et al, 1993 in Sharma, 2018). According to the research (Bahreyni Toossi & Malekzadeh, 2012), diagnostic radiology examinations need to be optimised so that the dose received by the patient is not higher than needed to obtain the required diagnostic image (Bahreyni Toossi & Malekzadeh, 2012). The International Commission on Radiological Protection (ICRP) has recommended the authorised bodies to set diagnostic reference levels that best meet their specific needs and are consistent for the regional, national or local area (Bahreyni Toossi & Malekzadeh, 2012).

2.2 Dose from X-ray Radiography

According to Vajuhudeen et al. (n.d.), the Dose Area Product (DAP) or Kerma Area Product (KAP) is a method of radiation dose monitoring used in radiographic and fluoroscopic studies. It provides one indication of the radiation dose received by a patient and also is the measurement used in dose audits (such as comparing the diagnostic reference levels) (Vajuhudeen et al., n.d.). A study by Magill et al. (2019) stated that KAP is a measure of the energy imparted to air by ionising radiation over an entire physical area of the X-ray field. It is the appropriate measurement for the total radiation incident on the patient's skin and is an indication of the total amount of radiation imparted during the examination (Magill et al., 2019). It is calculated as the product of dose and beam area ($Gy.cm^2$) and is measured using an ionisation chamber placed between the x-ray tube/collimator set up and the patient (which in theory is independent of its position in the beam). The dose area product can be divided by the area of exposure (in cm^2) to give the incident accumulated exposure (air kerma) at that site (Vajuhudeen et al., n.d.)

According to Huda (2014), KAP is simply the average of the air kerma (in Gy) multiplied by the corresponding x-ray beam cross-sectional area (in cm^2), the product of which is expressed as Gy·cm^2. This is depicted by the projection radiograph shown in Figure 2.1. The KAP is the appropriate way to measure the total amount of radiation incident on the patient. Importantly, KAP indicates the total amount of radiation used in an examination and is not a surrogate for patient doses. KAP is increasingly used to assess whether a given type of examination (e.g., chest x-ray) is being performed with the appropriate amount of radiation. This value, which is termed the "diagnostic reference level", is then used to identify high-dose facilities. That facility must review its techniques and protocols and either reduce its radiation values or justify the use of higher radiation values by a corresponding patient benefit in terms of improved diagnostic performance (Huda, 2014).

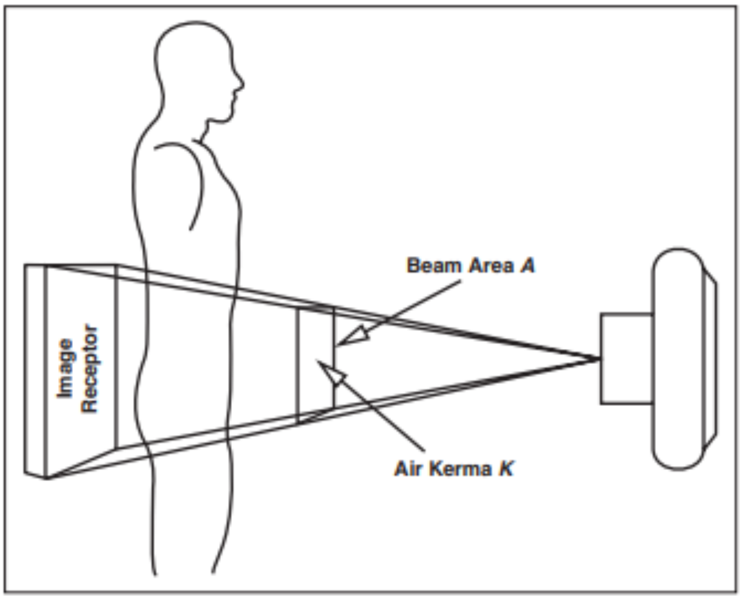

Figure 2.1. The figure shows the projection radiograph of Kerma Area Product (KAP) is calculated (Huda, 2014).

The total amount of radiation used to perform any single projection in radiography or fluoroscopy is the KAP, obtained as the product of the incident air kerma and the corresponding cross-sectional x-ray beam area (Huda, 2014). The total KAP for any patient examination is the sum of the KAP of all images obtained in the examination. Converting KAP into accurate patient dose estimates requires explicit information on the x-ray beam quality, the size and age of the exposed patient, and data on the body region exposed and exposure geometry (projections and field sizes) (Huda, 2014).

2.3 Previous Studies on Diagnostic Reference Levels (DRLs)

A worldwide review of literature on patient doses and DRLs for children of different age groups, or other distributions, and for different examinations was carried out with an emphasis on peer-reviewed papers, and reports from authoritative bodies, within Europe (European Commission, 2018). National paediatric DRLs are provided for some group of examination (radiography, fluoroscopy, or CT) in 17 countries. 9 countries have their DRLs that were established based on their patient dose surveys covering several radiology institutions. For national DRLs in radiography, fluoroscopy, and CT, there seems to be reasonable agreement on the examinations for which DRLs have been needed such as skull, chest, abdomen, and pelvis (European Commission, 2018). A reasonable agreement also prevails on the quantities used which is air kerma-area product (KAP) or dose area product (DAP), entrance-surface air kerma (ESAK), entrance surface dose (ESD) or incident air kerma (IAK) in radiography.

Table 2.1 The table shows the quantities used for DRLs and their symbols (European Commission, 2018).

Quantity	Symbol used in these guidelines	Other symbols used in literature	Closely similar quantity*
Incident air kerma	$K_{a,i}$	IAK	
Entrance-surface air kerma	$K_{a,e}$	ESAK	Entrance-surface dose (ESD)
Air kerma at the patient entrance reference point**	$K_{a,r}$	CAK	
Air kerma-area product	P_{KA}	KAP	Dose-area product (DAP)
Volume computed tomography dose index	$CTDI_{vol}$	C_{vol}	
Dose-length product	DLP	-	Air kerma-length product (P_{KL})

*Because "air kerma" and "dose in air" are numerically equal in diagnostic radiology energy range.

**Also names "cumulative dose", "reference air kerma" and "reference point air kerma" have been used in the literature

Hence, the physical quantity and the patient grouping (mainly by age) selected for the DRL settings have usually been reported exactly, and the background information on the patient dose calculation is often only briefly reported or not described at all. Published information is rarely available on the experiences of using paediatric DRLs and their feasibility in practise. Only about one-fifth of the countries have the existing DRLs based on their national patient dose survey. The patient dose surveys required for setting DRLs are resource-demanding and time-consuming. There is a lack of consistency in patient groupings (age, weight, or other group with a variety of options) (European Commission, 2018).

Based on a study by Gislason-Lee et al. (2021), the neonatal intensive care unit (NICU) hospitalises newborn babies with serious to life-threatening medical problems that demand close monitoring. X-ray imaging is crucial for the diagnosis and evaluation of these ill neonates. The number of chest and/or abdomen X-rays taken during a single NICU stay varies. The greater the number of X-rays taken, the greater the neonate's cumulative exposure to radiation from the NICU stay. Babies are at risk of developing radiation-induced illnesses, such as cancer. The younger the patient, the greater this X-ray risk is therefore, babies born pre-term are at the highest risk. The study aims to review published empirical studies on radiation dose from NICU X-ray imaging to gain insight into international norms for practise, mapping global patterns of radiological safety and As Low as Reasonably Achievable (ALARA) practises (Gislason-Lee, 2021).

A previous study by Sonawane et al. established DRL value for all radiographic examinations including paediatric, where DRL of chest anteroposterior of 5-year-old patients including males and females was obtained (Sharma et al, 2018). It can be said that evidence of an increased risk of mortality for all cancers, excluding leukaemia and lung cancer, has been reported with increasing radiation doses. Very young children are 3–4 times more sensitive to ionising radiation than adults. An increased susceptibility of children to radiation-induced cancer is biologically plausible because their tissues are still growing and therefore the dividing cells are more prone to somatic genetic damage. In addition, children have a longer life expectancy during which oncogenic effects may develop (Sharma et al, 2018). Based on a study done by Gislason-Lee (2021), there are 4 alternative ways have been proposed to minimise the risk of radiation to neonates and achieve greater consistency worldwide in NICU X-ray imaging which are setting specific DRL for NICU, use of standardised dosimetry methods, applying optimisation of settings for equipment and patient size, and using the standardised imaging protocol (Gislason-Lee, 2021).

Gender	Minimum	Mean	3rd quartile	Maximum
Male (n=19)	76	79.58±1.39	80.35	81.9
Female (n=19)	75.6	79.93±1.89	81.2	83

Figure 2.2 The figure shows the statistical summary of Entrance Surface Air Kerma (ESAK) (μGy) based on gender (Sharma et al, 2018)

Based on the DRL assessment done by Sharma et al (2018), the result for the institutional diagnostic reference level (DRL) is represented in Figure 2.2. According to the correlation analysis in this study, considerable significance was noted between the body mass index (BMI) and Entrance Surface Air Kerma (ESAK) of both male and female neonates. Nonetheless, there is no significant correlation identified between ESAK and other variables such as height, age, tube voltage, and mAs thus contributing to the fixed kV, mAs and field size used throughout this study (Sharma et al, 2018). On the other hand, Triantopoulou (2020) conducted a literature review of paediatric DRL in diagnostic and Interventional Radiology and Cardiology thus showing the summary of the findings in Table 2.2 which consists of the established paediatric DRL for European and Non-European countries.

Table 2.2 The table shows the European and Non-European DRL in paediatric (Triantopoulou, 2020)

Country	Type of DRL	Examination	Age	DRL quantity	DRL value
European DRL (3rd quartile) in paediatric radiography					
Austria, 2010	National	Abdomen	Newborn	KAP (mGy.cm^2)	60
				IAK (mGy)	0.2
		Chest AP/PA	Newborn	KAP (mGy.cm^2)	17
				IAK (mGy)	0.05

Table 2.2, continued

Finland, 2007	National	Chest	Curve ESD/DAP – patient thickness		
France, 2013	National	Chest AP	Newborn	DAP ($mGy.cm^2$)	10
				ESD (mGy)	0.08
Spain, 2015	National	Thorax PA	0 year	DAP ($mGy.cm^2$)	40
		Abdomen AP	0 year	DAP ($mGy.cm^2$)	150
Belgium assessed in 2019	National	Thorax simple (1 acquisition)	<1 year	DAP ($mGy.cm^2$)	15
		Abdomen	<1 year	DAP ($mGy.cm^2$)	40
Ireland, 2004	National	Chest AP/PA	1 year	ESD (mGy)	0.057
		Abdomen AP	1 year	ESD (mGy)	0.33
UK, 2004	National	Chest AP/PA	0 year	ESD (mGy)	0.07
		Pelvis AP	0 year	ESD (mGy)	0.21
Germany assessed in 2019	National	Thorax AP/PA	Newborn (0-3 months)	DAP ($mGy.cm^2$)	0.3
		Abdomen AP/PA	Newborn (0-3 months)	DAP ($mGy.cm^2$)	20
Non-European DRL in paediatric radiography					
Kenya, 2013	Local, mean value	Chest AP (non-grid)	< 1 month	ESAK (mGy)	0.05
		Abdomen AP (grid)	< 1 month	ESAK (mGy)	0.22

Recent research on DRLs in neonates by Gilley et al. (2023) indicates that DAP should be the metric recorded for neonatal radiography rather than Entrance Skin Dose (ESD) because it considers the area of the primary radiation beam. By way of example, a field increase of one or 2 centimetres may result in a several-fold increase in organ dose in premature infants (Minkels et al, 2017; Cherit et al, 2020 in Gilley et al, 2023). This study aimed to conduct a radiation dose survey for mobile chest X-rays (CXRs) in NICU to establish weight-based DRLs. The proposed DRLs will be made to radiographers to serve as a baseline for mobile CXR in the NICU and also will be recommended to national regulatory bodies so that it can be adapted for wider use (Gilley et al, 2023). The final DRL value for a weight-based study done by Gilley et al (2023) was stated in Figure 2.3 with the value on the 3rd quartile (75th percentiles) of DAP value ($mGy.cm^2$) considered as the DRL value for each weight category

	DAP value ($mGycm^2$)					
	25th percentile	Median	Mean	75th percentile	Min.	Max.
<1000 g (*n* = 17)	2.2	2.7	2.9	3.3	1.1	4.3
1000g to 2500 g (*n* = 28)	3.1	3.7	4.2	4.8	1.8	7.2
>2500 g (*n* = 45)	5.2	6.6	7	8	3	11.4

Figure 2.3 The figure shows the numerical summary of the collected DAP data by weight category (Gilley et al, 2023)

CHAPTER 3

METHODOLOGY

This chapter provides the methods used throughout this study which are the digital mobile radiography unit (Samsung GM85) and solid-state detector (Unfors Xi) for the experimental dose measurement, as well as the PACS system for the data collection. The workflow of how the experimental dose measurement was carried out was also explained in this chapter.

3.1 Research Tools

3.1.1 Digital Mobile Radiography Unit

This study included the dose quantity of Air Kerma Area Product performed using two Digital Mobile Radiography Units located at Hospital Universiti Sains Malaysia (HUSM, Kelantan). The mobile units are Samsung GM85 (Samsung Electronics Co., LTD, Korea, installed in 2022) labelled as mobile digital radiography 1 (MDR 1) and mobile digital radiography 2 (MDR 2). Each of these machines is usually placed in the Trauma and Emergency Department, and Radiology Oncall Services (ROSe) in the Radiology Department.

Figure 3.1 The figure shows the Samsung GM85 digital mobile unit.

Referring to the Samsung GM85 User Manual, this unit was equipped with "Paediatric Exposure Management' as an advanced application which helps in providing more refined thoracic and abdominal imaging conditions for paediatric patients depending on the patient's size. It aims to assist the radiographer in reducing radiation dose for paediatric patients by guiding them to the imaging conditions optimised for each patient's body weight, age, and body part. Paediatric patients are more sensitive to radiation than adults and may experience higher radiation-induced risks as they have longer lifespans after undergoing the radiological examination. Paediatric Exposure Management is provided to help capture images under the optimised irradiation conditions that can reduce the radiation dose while maintaining the image quality. The details of the mobile unit used in this study are shown in Table 3.1. These mobile units were equipped with an S-DAP algorithm that has a similar function to a KAP metre. It is a software that helps to estimate the dose-area product (DAP) values at SID of 100 cm.

Table 3.1. The table shows the details of the Samsung GM85 mobile unit

Model	Column Type	Collimator Type	Tube	MDR	Department
GM85	Collapsible Type (C-Type)	SDR-OGCL40U	LUC-13LXRR-3332X	1	Emergency and ROSe
				2	

3.1.2 Solid State Detector (Unfors Xi)

The Unfors Xi Solid state detector (RaySafe, Sweeden) is a component of the RaySafe Xi system, which is a complete system for multiparameter measurements on all X-ray modalities. It includes a wide range of detectors for different applications, measuring everything from kVp and dose to HVL and waveforms (RaySafe Xi | RaySafe, n.d.). The RaySafe Xi solid-state technology offers many benefits, including durability, a smaller footprint, and enhanced sensitivity (RaySafe Xi online brochure, n.d.).

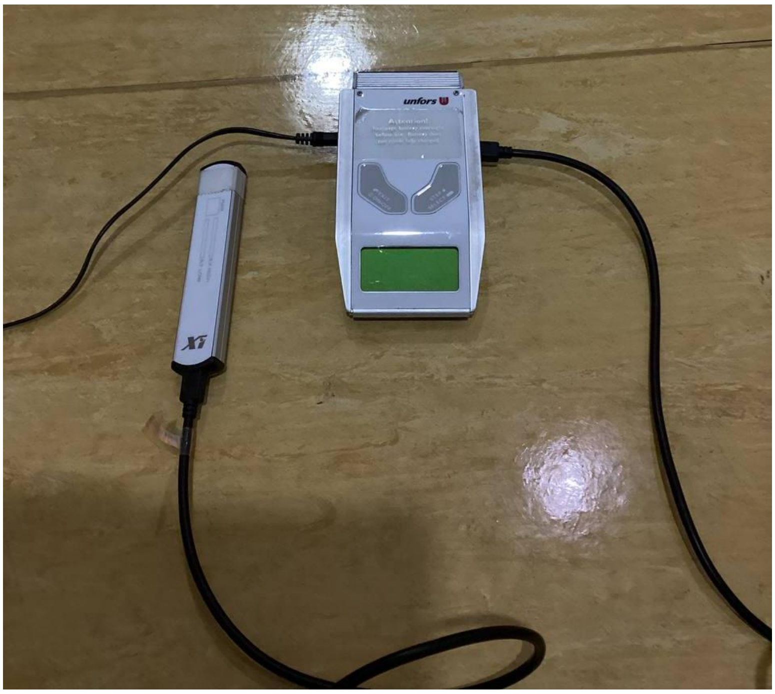

Figure 3.2 The figure shows the solid-state detector (Raysafe, Unfors Xi)

The RaySafe Xi R/F detector measures dose with a multi-segment sensor and the active compensation feature automatically corrects the displayed dose (and dose rate) for beam qualities with an HVL of 1 – 14 mm Al (RaySafe Xi online brochure, n.d.). During this study, the Raysafe Xi was placed on the square bolus to reduce the backscatter. The RaySafe Xi R/F detector will read the true input dose without the back scatter if placed directly against an object (RaySafe Xi online brochure, n.d.). The details information regarding the Unfors Xi used is shown in Table 3.2.

Table 3.2 The table shows the details of the solid-state detector, Unfors Xi

Xi version	Battery Type	Hours of operation	Charge Time	Sensor Menu
RaySafe Xi	7.4 V Li-ion	20-40 hours	4 hours	R/F high *Sensor for conventional high dose rate measurement higher than 1 mGy/s

3.1.3 Pictures Archiving and Communication System (PACS)

According to Charles (2018), the Pictures Archiving and Communicating System (PACS) is a medical imaging technology used primarily in healthcare organisations to securely store and digitally transmit electronic images and clinically relevant reports. PACS is used to store, retrieve, present, and share images produced by various medical hardware modalities such as X-ray machines, computed tomography (CT) scans, magnetic resonance imaging (MRI) scans, and ultrasound machines. PACS can handle many types of images from many different imaging devices and enable easy access to the image for diagnostic and medical decision-making purposes (Charles, 2018).

PACS allows various departments in HUSM to view medical images and retrieve the DICOM data. An advantage of using PACS for this study is that able to retrieve the data from previous procedures and it saves time. Since the data collection for this study will be taken starting from January 2022 until December 2023, the use of PACS to complete the data collection is more convenient. However, PACS only can be assessed by authorised people to protect the patient's confidentiality.

In this study, two types of PACS interfaces were used. PACS-Zero Footprint Client (PACSZFP Version 6.0) (GE Healthcare, USA) was used to collect the technical parameters (kV, mA, s, mAs, exposure time) and P_{KA} value ($mGy.cm^2$) while the PACS-Universal Viewers (PACSUV Version 6.0) (GE Healthcare, USA) was used to obtain information on the machine used (either MDR1 or MDR2). The collected PACS data is shown in Appendix D until Appendix I.

Figure 3.3 The figure shows the interface of PACSZFP.

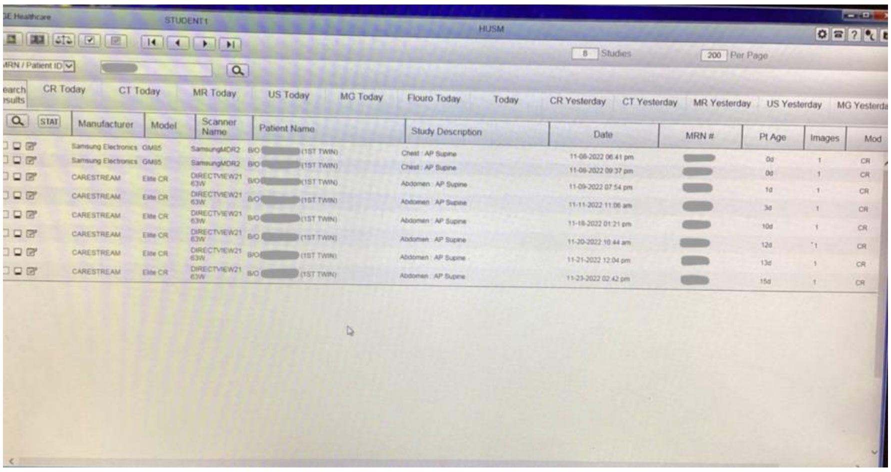

Figure 3.4 The figure shows the interface of PACSUV

3.1.4 Windows Excel Software

As part of the study, Microsoft Excel (Version 2404) was used to record the data more conveniently. The software's spreadsheet and data manipulation features helped in organising the collected data for the past 2 years (January 2022 to December 2023). The variables of interest such as age, sex, and types of exams, were organised and formatted within the Microsoft Excel workbook. The data of technical parameters (kV, mA, s, and mAs) and P_{KA} value (mGy.cm^2) were added manually from PACS. With Microsoft Excel, data can be organised and structured in a convenient tabular form. Besides, each parameter was assigned to its column, making the identification, and accessing specific data points easy. Once the statistical analysis of the patient is complete, the statistical values of minimum, first quartile (Q1), second quartile (Q2), third quartile (Q3), and maximum value of dose distribution will be obtained using Microsoft Excel which will be used to establish the local diagnostic reference levels (LDRLs). Figure 3.5, Figure 3.6, and Figure 3.7 shows the template in Microsoft Excel for data collection.

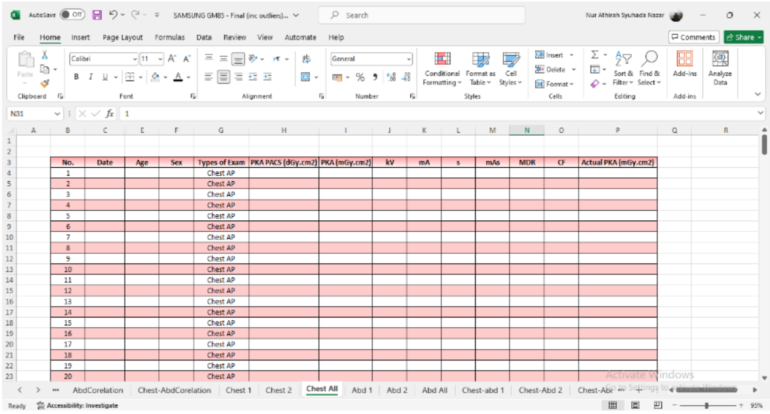

Figure 3.5 The figure shows the Microsoft Excel template for Chest AP exam

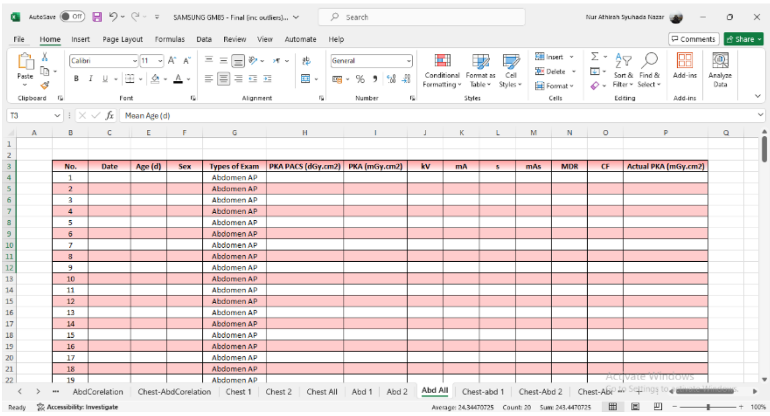

Figure 3.6 The figure shows the Microsoft Excel template for Abdomen AP exam

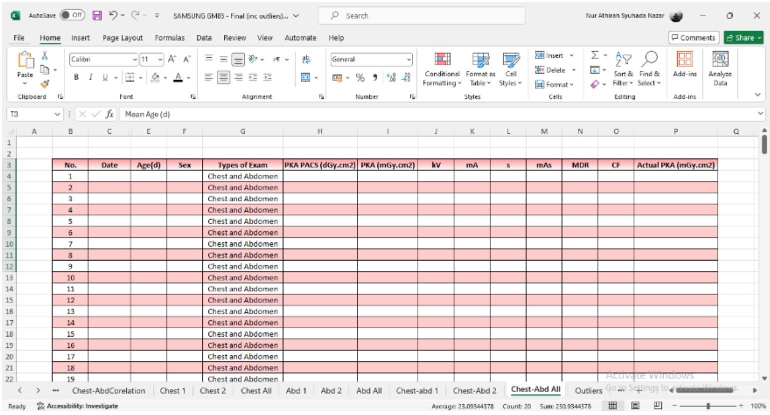

Figure 3.7 The figure shows the Microsoft Excel template for Chest-Abdomen exam

3.2 Research Methodology

3.2.1 Study Design

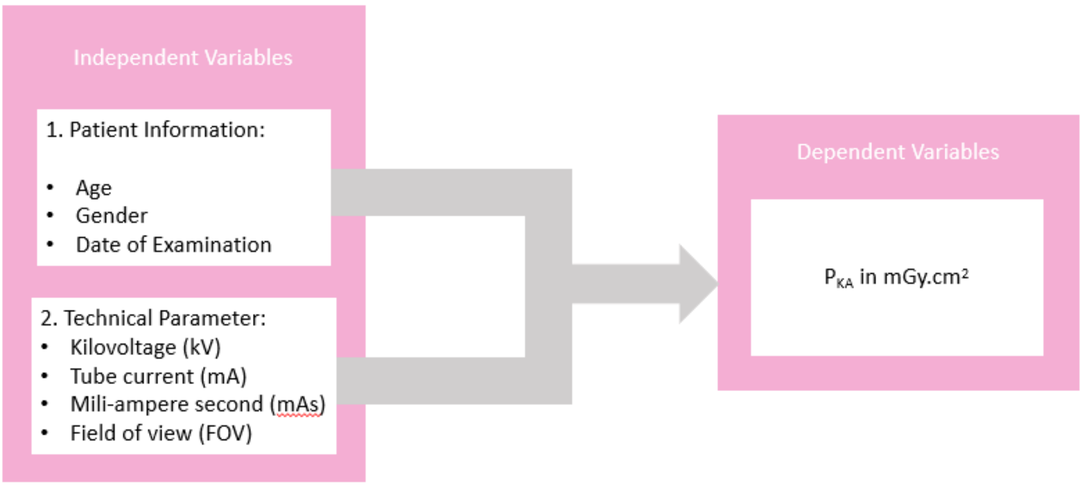

Figure 3.8 The figure shows the diagrammatic illustration of the conceptual research framework.

This study design is a retrospective observational study where we quantify the phenomenon and does not involve the use of intervention. Retrospective study was done where the patient data was collected via PACS system according to the purpose of the study. In this study, the data collection has been done in terms of Air Kerma-Area Product, P_{KA} in mGy.cm^2 of neonates who had undergone general x-ray for chest, abdomen, and chest-abdomen body part by using the mobile unit, Samsung GM85 at Radiology Department in Hospital Universiti Sains Malaysia (HUSM). From this study, the determination of DRL for neonate's category can be determined for each chest, abdomen, and chest-abdomen body part.

3.2.2 Study Flowchart

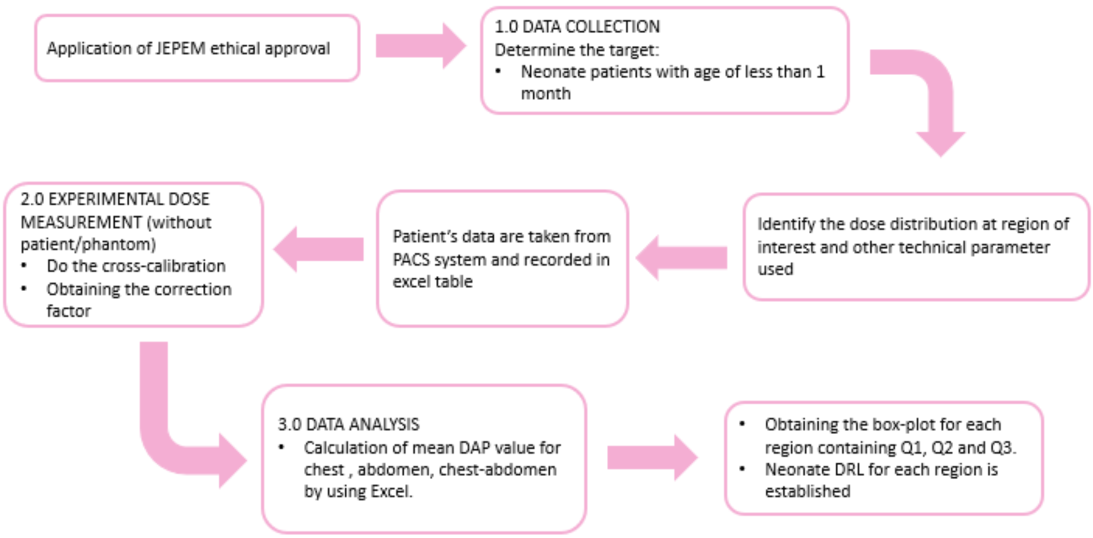

Figure 3.9 The flowchart of research methodology showing the steps of research work.

3.2.3 Study Population

In this study, the study population will involve neonate patients (aged < 1 month old) who undergo x-ray examinations (for chest, abdomen, and chest-abdomen regions) using a digital mobile radiography unit (Samsung GM85). The data was collected from the Radiology Department at Hospital Universiti Sains Malaysia (HUSM), Kubang Kerian, Malaysia using PACS system from January 2022 to December 2023.

The sampling method used is purposive sampling where the samples will be selected based on the inclusion and exclusion criteria. The related patient's data such as patient's age, gender, types of exams, Air Kerma-Area Product, P_{KA} in mGy.cm^2, and exposure parameters such as tube voltage (kV), tube current (mA), field of view