A PROPOSAL FOR APPLICATION FOR THE CHESNEY-ISRRT RESEARCH FUND 2019

RESEARCH TOPIC

“DEVELOPMENT OF INDICATION-BASED DIAGNOSTIC REFERENCE LEVELS FOR COMPUTED TOMOGRAPHY EXAMINATIONS IN GHANA”

Main researcher: Benard Botwe,

Radiographer, Ghana and PhD student, University of Ghana (ID: 10600444; PhD. Radiation Protection).

Sirbenard13@gmail.com/ bebotwe@ug.edu.gh

Project supervisory Committee: Prof. C Schandorf, Dr. Stephen Inkoom, and Dr. Augustine Faanu

March, 2019
Structured abstract

**Background:** Diagnostic Reference level (DRL) is a numerically established radiation dose value for which, when standards and best practices as well as standard technical performances are adhered to, they are expected not to be exceeded. The concept of DRL has been introduced into medicine to offer standard dose parameters against which patients' dose estimates can be related to in order to assess practices with the overall aim of reducing radiation doses, including that of computed tomography (CT). However, there are no established National DRLs in Ghana, against which doses could be compared to ensure effective dose management. Previously established DRLs and in particular, those in the African sub-regional countries (which may have similarities in the socioeconomic conditions, health care structure, regulatory regimes, procedure protocols, and the anatomical structures) on which the country may probably adopt, have also focused mainly on specific anatomical regions, bracketing all indications for a particular anatomical region into one DRL. However, in medicine, the CT protocols are adapted to answer clinical questions and not just the scanning of an anatomical area. In addition, the image quality and dose requirements vary between the different indications for the anatomical region.

**General Aim:** To develop indication-based DRLs for common and prioritised indications for CT of the head, chest and abdominopelvic regions of the adult human body.

**Methodology:** A quantitative prospective cross-sectional study design will be used in this study. The study will be conducted at the certified CT facilities in the countries. Prior to the data collection, validation (reliability and validity) of the CT scanners will be assessed. Subsequently, CT images of patients which have been produced and declared diagnostic by radiographers and reporting radiologists will be retrieved from the CT scanners. Image quality analysis will be conducted with ImageJ software version 1.48. Once the images meet the standard technical properties of good or acceptable images, the dosimetric parameters such as the volume CT dose index (CTDIv,vol), and the dose length product (DLP) will be estimated for the common indications. This will be entered into a Microsoft Excel version 2013. Statistical Package for the Social Science (SPSS) version 23.0 will be used to analyse the dosimetric data. A 75 percentile rule will be used to develop the DRL for each indication.

**Expected outcome:** The study is expected to develop indication-based DRLs for CT head, chest and abdomino-pelvic regions of the adult and also propose an approach for dose optimisation in CT in Ghana.
INTRODUCTION

Background

Computed tomography (CT) is one of the imaging modalities that uses X-rays. It was invented by British engineer Godfrey Hounsfield, and South African-African born physicist Allan Cormack (Imaginis, 2017). The period between 1974 and 1976 saw the installations of the first clinical CT scanners (Imaginis, 2017). The CT imaging modality is considered a very useful diagnostic tool, which is applicable to an extensive range of clinical and research applications (Bosch de Basea, 2016). Some unique benefits of CT include fast scanning speed, isotropic spatial resolution, affordability compared to other modalities such as magnetic resonance imaging (MRI), applications in staging, treatment planning and follow up of cancer treatment (Gao et al, 2017).

However, the radiation exposures associated with CT are very high (Liang et al, 2017). According to the World Health Organization (WHO), the global CT imaging represented about 6% of all medical imaging procedures, but the associated radiation dose accounted for about 43% of the total dose resulting from imaging procedures (WHO, 2016). Storrs (2013) argued that a single CT scan subjects the human body to between 150 and 1,100 times the radiation of a conventional x-ray, or around a year’s worth of exposure to radiation from both natural and artificial sources in the environment. These high exposure levels can lead to health related adverse conditions and also induce cancer in patients (Liang et al, 2017). Some cancer predictive models in the USA have even suggested that CT examinations and their associated radiation doses could generate up to about 2% of future neoplasms among patients undergoing CT procedure (Brenner and Hall, 2007). Hence, there is the need for effective measures for optimisation of radiation exposures in CT imaging. These measures include the development of strategies to optimise, manage and reduce appropriately the existing levels of radiation exposure (Liang et al, 2017).

The International Commission on Radiological Protection (ICRP) introduced the concept of diagnostic reference levels (DRLs) for the first time in 1996 to optimise radiation doses. The ICRP defined DRLs as:

“a form of investigation level, applied to an easily measured quantity, usually the absorbed dose in air, or tissue-equivalent material at the surface of a simple phantom or a representative patient”

The current International Basic Safety Standard (BSS) [GSR Part 3, 2014, p, 387] also defines a DRL as:

“A level used in medical imaging to indicate whether, in routine conditions, the dose to the patient or the amount of radiopharmaceuticals administered in a specified radiological procedure for medical imaging is unusually high or unusually low for that procedure”
According to McCollough (2017), a DRL is not the suggested or ideal dose for a particular procedure or an absolute upper limit for dose. A DRL represents the dose level at which an investigation of the appropriateness of the dose should be initiated. It is a numerically established value which must not be exceeded following adherence to standards, best practices, and technical performances (Tsukamoto, 2017). According to Vassileva and Rehani (2015) and Liang et al (2017), the use of DRLs has been shown to reduce the range of radiation doses observed in clinical practice. In particular, the establishment of DRLs has led to an average exposure reduction of 22% for the volume CT dose index (CTDI\textsubscript{vol}), and 13% for dose length product (DLP) respectively from 2010 to 2013 in Canada (MacGregor et al, 2015).

Due to the dose optimisation benefits of developing and establishing DRLs, member states of the International Atomic Energy Agency (IAEA) and affiliated to the ICRP (of which Ghana is a member) have been tasked to develop their national DRLs (NDRLs) (ICRP, 2007; IAEA, 2013). This is due to the variations in the socio-economic conditions, health care structure, regulatory regimes, procedure protocols and the anatomical structures of their people.

**Problem Statement**

It is well documented that the high doses associated with CT procedures are a major health worry in medicine globally (ICRP, 2007; IAEA, 2013; Yeh et al, 2016; WHO, 2016; Liang et al, 2017 Gao et al, 2017; Kanal et al, 2017). The doses account for about 43% of the total dose resulting from radiation procedures in medicine worldwide and can induce cancer in patients (WHO, 2016). The concept of DRL has been introduced into medicine to offer standard doses against which patients' dose estimates can be related to in order to assess practices with the overall aim of reducing radiation doses, including that of CT (Martin, 2016). It has been declared by the ICRP and the Commission of European Union as an important optimisation tool in medicine (Commission of European Union 1999; ICRP, 2007). The IAEA and the WHO have also included the establishment, use of, and regular update of diagnostic reference levels for radiological procedures in their Bonn call for action (IAEA, 2013). The new BSS [p. 74] further states that:

“The government shall ensure, as part of the responsibilities specified in para. 2.15, that as a result of consultation between the health authority, relevant professional bodies and the regulatory body, a set of diagnostic reference levels is established for medical exposures incurred in medical imaging, including image guided interventional procedures”.

The establishments and implementations of DRLs have been well utilised in Europe and United States and they have produced results across countries where they are available and in use (Brink and Miller, 2015). However, despite the utilisation of about 35 CT scanners in Ghana (Appendix 1), there are no established national DRLs in Ghana, against which dose parameters could be
compared to ensure effective dose management. Although some studies (Anim-Sampong et al, 2016; Addo, 2016; Akyea-Larbi, 2015; Hasford et al, 2015; Inkoom et al, 2014; Gedel, & Gablah, 2014) have attempted to assess CT doses on few scanners in the country, they are a paucity of adequate information on which a national DRL could be built. However, evidence from these studies, suggest that the radiation doses in some CT centres in Ghana are above the international reference levels. In particular, Anim-Sampong et al (2016) found the CTDI$_{vol}$ parameter for adult head CT examination to be 5.5 % higher than the ICRP’s standard reference dose (60 mGy). Additionally, Inkoom et al (2014) had also found the mean DLP [650 mGy.cm, 570 mGy.cm.] of the chest and pelvis to be above the European Commission’s DRLs (EUR 16262) by 2 and 6 % respectively. Consequently, both studies have recommended the development of a national DRL for Ghana, which to date has not been established.

Moreover, previously established DRLs, and in particular, those in the African sub-regional countries (which may have similarities in the socioeconomic conditions, health care structure, regulatory regimes, procedure protocols, and the anatomical structures) for which Ghana may probably adopt, have focused mainly on specific anatomical regions, bracketing all indications for a particular anatomical region into one DRL. For instance, currently an abdominal DRL as a benchmark dose is used for both the diagnosis of kidney stones and liver metastases in some establishments (Vock and Frija 2016). However, in medicine, the CT protocols are adapted to answer clinical questions and not just the scanning of an anatomical area and therefore it has been argued that national DRLs based on the anatomical region do not reflect clinical practice and might be reexamined using clinical indication (Vock and Frija 2016; Järvinen et al, 2015).

In addition, the image quality and dose requirements vary between the different indications for the anatomical region (Vock and Frija 2016; Lajunen, 2015). As a result, there have been recent calls for indication-based DRLs for CT by several international bodies such as the European Association of Nuclear Medicine [EANM], European Federation of Organizations for Medical Physics [EFOMP], European Federation of Radiographer Societies [EFRS], European Society of Radiology [ESR] and European Society for Radiotherapy and Oncology [ESTRO], 2017). Ghana continues to install more CT scanners across the country and so absence of such indication-specific DRLs as dose monitoring benchmarks could prevent effective optimisation in some clinical tasks that require different levels of exposures. This in turn could lead to overexposure of patients to radiation, which can induce cancer in these patients.

Significance of the study

I. New research area in Ghana

The development of indication-based DRLs in this research study will be the first study in Ghana and even Africa to characterise and benchmark the dose needed for specific indications for CT examinations of particular body parts. This development and subsequent implementation of the indication-based DRLs may further decrease the range of doses observed in clinical practice as
suggested by Lajunen (2015) and other international agencies such as the European Association of Nuclear Medicine et al (2017).

II. Policy implication

The use of radiation in medicine will require some binding policies and regulations. Although international organizations such as the ICRP, IAEA, WHO and other societies such as the American College of Radiology and the Commission of European Union have suggested the development or adoption and implementation of DRLs and recently indication-based DRLs in respective countries, Ghana, a Member State of these agencies is yet to accomplish this by the national regulatory authorities. It is believed that the lack of extensive research-based data to support the facilitation of this has been a drawback to this policy establishment, especially with the implementation of the indication-based DRLs. This study is timely and its outcome, it is anticipated, would offer a baseline data and information on which such policies and regulations could be built.

In addition, health authorities in collaboration with medical professional organisations are also responsible for setting up or approving DRLs and ensuring that as much as possible the doses should stay within the set levels (IAEA, 2014). This study’s outcome may also be a reliable basis on which such organisation may operate to further ensure patient safety.

III. Health implications

A report by Ridley (2016) have suggested that indication-based DRLs from seven CT facilities in Switzerland have proven to significantly lower doses to patients, independent of dose optimisation. Therefore, the establishments and implementation of indication-based DRLs can narrow down dose monitoring in CT examination and offer another level of accountability regarding the utilisation of ionising radiation in medicine. Studies (Liang et al, 2017; MacGregor et al, 2015; Vassileva & Rehani, 2015; Berrington de González et al, 2009) have proven cancer risks associated with exposure to CT scans. The DRLs proposed for development in Ghana could also be used to determine if a facility's dose index is unusually high and hence trigger corrective actions. This will in turn help to reduce radiation effects such as radiation-induced cancer in patients.

Moreover, currently, there is no indication-based DRL for which radiographers may use as a country-based guide to regulate and optimise their practices in Ghana. It is envisaged that the outcomes of this study will provide the required tool to address these inadequacies.

IV. Research implications

In Ghana, research activities on indication-based DRLs have just started with this research. It is believed that the outcome of this thesis will form the fundamentals on which future research studies could be based and other DRLs developed for other pathological cases. This will not only serve Ghana, but it will also serve as a model for other African countries that may like
to develop a research focus in this area. This is because, there is no such study in the African sub-region and this will ensure a collective and comprehensive patient dose reduction particularly in the sub-region as much as possible.

Aim
The main objectives of this study is to develop national indication-based (IB) DRLs for common and prioritised indications for CT of the head, chest and abdominopelvic regions of the adult human body for clinical application in Ghana.

Specific objectives

1. To obtain technical data on selected CT scanners in the country
2. To obtain CT scanner performance characteristics data on the selected CT scanners in the country
3. To obtain information on common indications for CT examinations of the head, chest and abdomino-pelvic regions
4. To evaluate patient dose and the image quality of the CT images of the indications prioritised for DRLs development.
5. To establish the national indication-based DRLs for the prioritised indications using the 75th percentile value of the dose distribution
6. To propose an approach for dose optimisation for the protection of patients in CT examinations in Ghana
7. Make appropriate recommendations from the findings

LITERATURE REVIEW

Computed Tomography
Computed tomography is a non-invasive specialised medical equipment that uses X-rays to produce cross-sectional images of the body. Every cross-sectional image characterises a “slice” of the patient being scanned. According to Imaginis (2017), the word “tomography” originated from the terms “tomos” and “graphia” which represented "section or slice" and "describing" respectively in a Greek dictionary. Computed Axial Tomography (CAT scanning) is also used in other jurisdictions to represent CT. It was invented in 1972 by a British engineer named Godfrey Hounsfield, and a South-African born physicist Allan Cormack (Imaginis, 2017). The period between 1974 and 1976 saw the installations of the first clinical CT scanners. Head imaging was the only scans that could be done until the “whole body” scanners that could image large body region of patients became available in the year 1976 (Imaginis, 2017).
The modality is considered as a very useful diagnostic tool, which is applicable for an extensive range of clinical and research applications (Bosch de Basea et al, 2016). Faster scanning speed, isotropic spatial resolution, affordability compared to other modalities such as MRI, applications in staging, treatment planning and follow up of cancer treatment are some of its unique benefits (Abdulkadir, Schandorf & Hasford, 2016; Yu et al, 2009). It is currently one of the most widely adopted medical imaging modalities in clinical applications and is increasingly used because of the technological advancements and improvements in medical infrastructure (Gao et al, 2017; Dauer & Hricak, 2014). In emergency departments alone, CT significantly impacts leading diagnosis, diagnostic confidence, and admission decisions (Pandharipande et al, 2016). The development of multi-detector-row technology (MDCT) with sub-second acquisition and CT fluoroscopy (enabling interventional radiological procedures to be undertaken), have advanced CT applications in medicine (Gedel and Gablah, 2014). Furthermore, the development of hybrid systems like single photon emission computed tomography-CT (SPECT-CT), positron emission tomography-CT (PET-CT), cone beam CT, cardiac CT and the use of a CT simulator in radiotherapy treatment planning among others is strengthening CT utilisation and applications in radiotherapy, nuclear medicine and other treatment planning (Sergieva et al, 2014) in healthcare.

Radiation dose associated with CT

Despite the enormous benefits of CT to patients, the radiation doses associated with such scanner are very high (Pyfferoen et al, 2017; Pearce et al, 2012). The doses in CT are comparatively, far higher than those utilised in conventional radiography (Pearce et al, 2012). A study (Bosch de Basea et al 2016) reported that although a small proportion of X-ray-related procedures are done with CT in the United Kingdom, the radiation doses from the CT scanners however, make up about 68% of the population’s collective dose. Similarly, in the United States of America, CT contributes half (50%) of the collective radiation dose from all medical examinations using X-rays even though CT scans represented only 12% of imaging procedures (Kanal et al, 2017). According to the WHO, the global CT usage, represented about 6% of all medical imaging procedures performed, but it accounted for about 43% of the total dose resulting from those procedures (WHO, 2016). Additionally, Storrs (2013) identified that a single CT scan subjects the human body to between 150 and 1,100 times the radiation of a conventional X-ray, or about a year's worth of exposure to radiation from both natural and artificial sources in the environment. Moreover, the ICRP (2007) indicated that the organ absorbed dose from CT scans can often reach or surpass that observed in atomic bomb survivors. These dose indicators make CT one of the highest contributors of radiation in medicine (Yeh et al, 2016).

Effect of CT radiation
CT associated radiations can lead to health related adverse conditions and also induce cancer in patients (Vassileva & Rehani, 2015; MacGregor et al, 2015; Liang et al, 2017). The mechanism leading to the risk of cancer induction by radiation is that, X-rays basically can cause cell apoptosis, or induce reproductive failure (Shah et al, 2012). This is due to the displacement of electrons from their orbits around a nucleus at the molecular level by X-ray photons (Goodman, 2018). This apoptosis can also cause genetic changes in cell growth regulation (Liang et al 2017; Shah et al., 2012). Other damages include DNA impairment and normal nuclear structure distortion and tumorigenesis (Shah et al, 2012). The resultant consequences of these diagnostic X-ray effects are normally stochastic responses such as cancer and hereditary effects. This also means that there are potential risks of hereditary distortions in future generations (Alkhorayef et al, 2017). Some cancer predictive models used in the United States of America have even suggested that CT examinations and their associated radiations could generate up to about 2% of future neoplasms among the people in that country (Brenner and Hall, 2007). It has also been argued that children could be worse off since they are radiosensitive and therefore more susceptible to radiation damage than adults (Bosch de Basea et al, 2016; Brenner and Hall, 2007).

**The need for Indication-Based Diagnostic Reference Levels**

According to Pyfferoen, et al (2017) the radiation doses used to perform similar CT studies of diagnostic quality across facilities have to stay within a relatively narrow range (Pyfferoen, et al, 2017). However, national and multinational surveys continue to indicate a very wide variety of dose levels across facilities and countries (Lajunen, 2015; Vassileva and Rehani, 2015; Liang et al 2017). In particular, dose parameter variations by a factor of 20 or more have been found in an anatomical region across certain CT facilities (Liang et al 2017). It is believed that indication-based DRLs establishments and implementation can narrow down dose monitoring in CT examination and offer another level of accountability regarding the use of radiation in medicine (EANM et al, 2017). This is because it focuses on benchmarking the doses that are used to answer specific clinical questions (Loose, 2017). Loose (2017) argues that setting up indication–based DRLs will involve more classification of patient conditions where different dose levels for one anatomical region are reasonable, but this will facilitate the reduction of overall dose to patients.

Moreover, currently, calls for indication-based DRLs establishments for CT have been made by several international bodies. These bodies include, but not limited to the IAEA (2013), EANM, EFOMP, EFRS, ESR, and ESTRO (EANM, 2017). In particular, the ESR through EuroSafe Imaging, have recently established a Workgroup with the charge to develop a set of clinical DRLs that will be based on indication rather than anatomical location with the intension of using the clinical DRLs to compliment the other existing DRLs (Bujila, Kelly and May, 2018). These calls further emphases the need for the indication-based DRLs in CT procedures.
Dosimetric parameters
In CT, the CTDI is most common parameter used to estimate and minimize patient dose (Bauhs et al, 2008). The CTDI is a volume-averaged measure that is used in situations where the CT table is incremented in conjunction with the tube rotation and the concept was first introduced by Shope et al, (1981). Since the introduction of the CTDI concept, attempts to better define the multiple scan average dose (MSAD) in CT have continued (Liang et al, 2017; Bauhs et al, 2008). Currently, the important parameter quantities used in establishing the DRLs in multi-detector computed tomography (MDCT) are the CTDI$_{vol}$, and the DLP (Liang et al, 2017).

METHODOLOGY

STUDY DESIGN
This study sought to use numerical data on the CT facilities across the country to develop indication-based diagnostic reference levels. As it is in line with the overall aim of the study, a cross sectional study design will be chosen for this study. Among the cross sectional study designs, a prospective cross-sectional study design will be used because it is very important that QC (validity and reliability) assessments of the CT scanners are assessed before data is collected. Hence, a quantitative cross-sectional study design will be used in this study. The decision to use this study design is also supported by literature, as all reviewed designs on DRLs (although mainly anatomical-based) have been based on this approach.

STUDY SITES
The study will be conducted at all the certified CT facilities in the countries. According to the Nuclear Regulatory Authority (NRA) of Ghana (Appendix 1) there are 35 CT scanners in Ghana. Out of the 10 regions in the country, seven of them have CT scanners. The facilities where the study will be conducted comprises public and private hospitals. In each hospital, the CT scanner (s) is located in the Radiology Department. Hence, the study site will be at the CT Units in the radiology departments of all hospitals that undertake CT examinations. The hospitals considered for this study include the Korle Bu Teaching Hospital, Okomfo Anokye Teaching Hospital, Cape Coast Teaching Hospital and Tamale Teaching Hospital. The non-teaching facilities include the Sunyani Regional Hospital, 37 Military Hospital, Koforidua Regional Hospital, Ridge Hospital and Effia Nkwanta Regional Hospital. Others are the Elmina Hospital, Spectra Hospital, GMIC Hospital, Sakumono Community Hospital, Lapaz Community Hospital, Lekma Hospital, C & J Hospital, Nyaho Medical Centre, Focus Orthopaedic Centre, the Sweden Ghana Medical Centre, the Sunshine Medical Centre, the Akai House, the Cocoa Clinic and the Trust Hospital. The CT scanners can also be found in diagnostics facilities which only provide imaging services such as Euracare Advanced Diagnostics, Paradise Diagnostic Centre, Quest Medical Imaging, the Diagnostic Centre,
Supreme Scan Specialists, and the MedLab-Ghana Ltd. Some of the centres have two CT scanners and as such both scanner centres or the units will all be used as study sites.

**STUDY POPULATION**

The study will involve the use of the CT scanners and the patients’ image folders which contain images and the CT dosimetric parameters. Hence, CT scanners and the patients’ image folders will form the two parameters under the study population. For the scanners, all certified CT scanners in the country will form part of the scanner population. With respect to the patients’ image folders, all those that will be generated during the course of the study will be forming part of the patient data population.

**INCLUSION CRITERIA**

Regarding the CT scanners, the study will include all certified, valid, reliable and functioning CTs that are available at the beginning of this study. Accordingly, patients’ image folders (containing images and the CT dosimetric parameters) which would be produced by these scanners will be included in the study. The imaging folders to use will consist of those folders whose images have been produced and declared as diagnostically acceptable by radiographers and reporting radiologists. These folders will involve both adult male and females as the study will be limited to adults because of easy availability of data and financial constraints.

**EXCLUSION CRITERIA**

All the following will be excluded.

- Uncertified CT scanners
- CT scanners that cannot display dosimetric parameters
- Centres that refuse permission for the study
- Faulty CT scanners
- Equipment which will fail QC assessments (validity and reliability tests)
- Patients’ image folders that will not be considered diagnostically acceptable by the scanning radiographers and reporting radiologists.
- Also patients’ image folders of children will be not be used as the study is focused on adults.

**SAMPLE SIZE**

The IAEA (2013) has suggested that NDRLs should be set on the basis of wide scale surveys of the doses representing typical practice for a patient group at a range of representative healthcare facilities. Vock and Frija (2016) have also indicated that a national survey of doses on which the NDRLs could be set should cover about 50% of the facilities and 30-50% of
facilities in small countries, while the local DRLs (LDRLs) should cover much of the local facilities in the population. In order to obtain data across the country, all the 35 scanners will be included in the study subject to the exclusion criteria.

With respect to the sample of patients’ image folders that will be selected, the sample size approach which suggests that a national data on indication-based DRL (IBDRL) should represent 10-20 patients per an indication for each CT centre will be used as recommended by the IAEA (2013), the UK Public Health (2014), and Vock and Frija (2016). It is therefore expected that 20 patients’ image folders will be randomly selected for each indication in a centre. Therefore, for each of the common CT indication, a sample size of 700 [20x 35 (if all the CT scanners qualify to be involved)] will be used. This number (700) will be multiplied by the number of indications that will be prioritised by the technical heads of all the CT centres in the country during the phase one study.

**SAMPLING TECHNIQUE**

A purposive sampling method will be used to select the CT scanners since the study will specifically select participants subject to the sampling criteria. For the selection of the patients’ image folders, a systematic random sampling will be used. In each common indication, 20 image folders containing the patients’ images and dosimetric parameters will be selected from all those that will be produced by each CT scanner.

**PROCEDURE TO BE USED**

i. **Data Collection Tools and Instruments**

The tools that will be used for the data generation collection and analysis include:

1. The CT scanners across the country (to generate patients’ image folders which contain images and dosimetric parameters)
2. CT scanners’ QC KITS (to validate the accuracy of the CT scanners’ output results)
3. A questionnaire (which will be designed and validated before being used to retrieve information on the functionalities of the CT scanners and the common CT indications across the CT centres in the country)
4. Microsoft-excel-designed dose collection booklet
5. Image J software (version 1.48) (to be used to test for the image quality of the CT images)

ii. **Procedure**

The procedure for the study will be in phases. Firstly, self-designed questionnaire tested for validity and reliability will be administered to all the 35 CT centres across the country through an online survey system (survey monkey) to retrieve information from the centres on which scanners are working within the country (Phase 1). It will also seek information on the common
CT indications for which CT head, chest and AP examinations are undertaken in the country. This would seek for information on which of the indications should be prioritised in this study. Next, QC of the CT scanners (to assess the validity and reliability) will be undertaken (Phase 2) and the principal investigator will travel to all the CT facilities to have this done. Scanners that will pass the QC assessments will be used for the study. Subsequently, patients’ image folders that will be generated by these scanners and declared diagnostically acceptable by the scanning radiographers and the reporting radiologists will be retrieved from the Picture Archiving and communication System (PACS) of the scanners. The image quality assessment will be undertaken (Phase 3). Once the images meet the standard technical properties of good or acceptable images, the dosimetric parameters such as the CTDI_{vol}, and DLP will be estimated for the common indications using the 75% percentile rule (Phase 4). The protocols for scanning audit will also be undertaken to identify areas for improvement (Phase 5). Subsequently, recommendations will be made. The detail of each phase of the procedure is as follows:

Phase 1: Identification of Common Indications
A questionnaire (Appendix 3) will be sent through online survey system (survey monkey) to the technical heads of the selected CT facilities to solicit for information on the common indications for which CT head, chest and abdomen are often undertaken. Based on the results, the common indications to be used for the study will be defined. Also, the state of the CT scanners will be inquired.

Phase 2: This phase will involve validation QC of the equipment (analytical tools) for the study. The analytical tools to be used for the dose survey are the CT scanners. The main dosimetric parameter needed in this study includes the CTDI_{vol} (mGy) and DLP (mGy.cm). The scanners are able to display these dose parameters on the console. To ensure the validity of the displayed parameters, an experimental analysis of the CT scanners will be conducted. The tools for Scanners’ QC (validation and reliability checks) include the following:
- A polymethylmethacrylate (PMMA) phantom for body (32-cm diameter).
- A PMMA phantom for head (16-cm diameter).
- A CT Dose Profiler or a 100 mm long pencil ionization chamber with an electrometer.
- Barracuda with Ocean Software interface (RTI Electronics, Sweden).
- Microsoft Excel spreadsheet version (2016).

The phantoms will be scanned with the Barracuda dose profiler in-situ. The displayed readings from the dose profiler and that on the CT console/monitor will be compared. The trueness of the values generated by the scanners would be determined from the equation below:

\[
\text{Trueness(\%)} = \frac{x}{\mu} \times 100
\]
where $\bar{X}$ = mean CT dose generated by the scanner’s dose software.

$\mu$ = CT dose value generated by the dose profiler

Poorly functioning CT’s will be excluded or correction factor will be applied where necessary. These assessments will be undertaken by the principal investigator who will travel to all the centres.

**Phase 3: IB image quality assessment**

The image quality of some of the images from each centre will be assessed to ensure quality before the DRLs are set. Image J software (version 1.48) will be used to assess the contrast noise ratio (CNR) and signal to noise ratio (SNR) while radiologists will be used to assess the images subjectively. Once the images meet the standard technical properties of good or acceptable images, the dosimetric parameters such as CT dose index (CTDI<sub>vol</sub>), and the dose length product (DLP) will be estimated for the common indications in **Phase 4**.

**Phase 4: IB Dose Survey**

A Microsoft-excel-designed dose collection booklet will be used to collect data at the study sites from the selected patients’ image folders. The content of the booklet will be based on the questionnaires of the UK Public Health (2014). (Appendix 4). According to the IAEA (2013), the UK Public Health (2014), and Vock and Frijia (2016), a national data on IB DRL should represent 10-20 patients per an indication for each CT centre. It is therefore expected that 20 patients will be randomly selected for each indication in a centre. The median of the dose distribution for each indication will be estimated. The IB DRL will be set at the 75% percentile.

**Phase 5: Protocol Audit**

The scanning protocols used at the facilities will be reviewed. An observational checklist tool will be used to collect data across the centres. Recommendations for dose optimisation will then be proposed.

**Data Handling**

In order to prevent linkage of information pertaining to patients, the CT centres will be coded. Similarly, all the patients’ image folders that will be used will be coded. The data will be stored on the personal computer of the researcher and protected with a password. The data will be available for five years from the date of the analysis and it will be archived for future research projects if necessary.

**Data Analysis**

Microsoft Excel version 2016 and Statistical Package for the Social Science (SPSS) version 23 will be used to analyse the data. The data will first be entered into an excel sheet and organised appropriately. This will then be transferred into SPSS where descriptive statistics
such as frequency and associations will be assessed. Inferential statistics such as the mean and median of the CT dose parameters will be estimated. The 75% percentile of the median dose parameters such as CTDvol and DLP for each indication will be determined.

Data from different centres will also be compared. A histogram analysis of the variables will first be analysed and based on the normal distribution of the data, the correct statistical tool will be used to compare the variables. A *p*-value of less than 0.05 will be interpreted as significant.

**Dissemination of results**

The data will be used for my thesis write-up. In addition, the data will be published in a peer-review journal. Feedback in the form of a summary of the research will be made available to participants through emails. The results will also be presented at workshops, seminars and conferences. Upon request a copy of the summary of the research will also be provided to the hospitals where the study will take place.

**Ethical issues**

Ethical clearance will be sought from the following:

- The Protocol and Ethical Review Committee of College of Basic and Applied Sciences
- The Protocol and Ethical Review Committee of School of Biomedical and Allied Sciences
- The Protocol and Ethical Review Committee of the Ghana Health Service.
- The Research and Ethical Review Committee of the various Teaching Hospitals
- The Research and Ethical Review Committee of Nuclear Regulatory Authority (NRA) of Ghana.
- The Research and Ethical Review Committee of the hospitals that may require approval. An example is the Korle Bu Teaching Hospital.

Permission will also be sought from the facility heads of the CT centres (where the dosimetric data and images will be retrieved).

Information sheet (Appendix 1) will be jointly administered with the questionnaire to the technical heads. It will be used to explain the purpose of the study. They will be made aware that the questionnaire carries very limited or negligible risks. They will also be informed that although participation in the research study is voluntary and not beneficial individually, their participation will however, help to establish an IB DRL in CT in Ghana. The participants will also be informed that the questionnaire will take 20 minutes to complete and that they may decline or withdraw from the research without providing an explanation at any time until the work is completed. They will also be informed that their details will not be required during the completion of the questionnaire and that their responses will be coded. Finally, the consent of the participants to participate would be confirmed by signing a consent form.
With respect to the patients’ image folders required for the data analysis, the identities of patients will be safeguarded by blocking the names during the data collection. The confidentiality of information peculiar to the patients shall also be ensured by keeping the data collected under password protection. Also, The CT centres will also be coded to prevent linkage of information pertaining to patients. All data generated will also be used for research purposes only and nothing else.

**Personnel of the study team**

This project is a student thesis and as such the student and the supervisory committee members (Prof. C Schandorf, Dr. Stephen Inkoom, and Dr. Augustine Faanu) will form the study team. The radiographers in the CT facilities have agreed to assist in the data collection.

**Table 1: Work Schedule**

<table>
<thead>
<tr>
<th>PROJECT ACTIVITY</th>
<th>DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethical clearance</td>
<td>APRIL, 2018- JUNE, 2018</td>
</tr>
<tr>
<td>Data collection</td>
<td>JULY, 2018- MAY, 2019</td>
</tr>
<tr>
<td>Progress report</td>
<td>MAY, 2018</td>
</tr>
<tr>
<td>Progress report</td>
<td>NOV, 2018</td>
</tr>
<tr>
<td>Seminar</td>
<td>FEB, 2019</td>
</tr>
<tr>
<td>Data Analysis</td>
<td>JUL, 2019</td>
</tr>
<tr>
<td>Progress report</td>
<td>NOV, 2019</td>
</tr>
<tr>
<td>First Dissertation draft</td>
<td>FEB, 2020</td>
</tr>
<tr>
<td>Finishing &amp; Submission</td>
<td>JUN, 2020</td>
</tr>
</tbody>
</table>

**Table 2: BUDGET & LOGISTICS**

<table>
<thead>
<tr>
<th>Printing Materials</th>
<th>Cost (GH₵)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stationery</td>
<td>5,000</td>
</tr>
<tr>
<td>Image analyses Software</td>
<td>10,000</td>
</tr>
<tr>
<td>Transportation</td>
<td>5,000</td>
</tr>
<tr>
<td>Communication</td>
<td>1,500</td>
</tr>
<tr>
<td>Software for data tracking &amp; Management</td>
<td>10,000</td>
</tr>
</tbody>
</table>
Funding
Self

Conflict of interest
None

References


Appendix 1
The Head of Department
Department of Nuclear Safety & Security
School of Nuclear & Allied Sciences
University of Ghana
Atomic Campus

Dear Sir,

RE: REQUEST FOR OFFICIAL INFORMATION ON THE NUMBER OF COMPUTED TOMOGRAPHY (CT) SCANNERS IN THE COUNTRY

Your letter No. DNSAS/SNAS/ADM/3/17 dated 14th December 2017 on the above refers.

Please find attached the number of computed tomography (CT) scanners in the country as requested for your necessary action.

Thank you.

Yours faithfully,

PROF. FELMI REYNOLDS
AG. DIRECTOR GENERAL

Encl.:
<table>
<thead>
<tr>
<th>No.</th>
<th>REGION</th>
<th>NUMBER</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Greater Accra</td>
<td>20</td>
</tr>
<tr>
<td>2</td>
<td>Ashanti</td>
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</tr>
<tr>
<td>3</td>
<td>Northern</td>
<td>3</td>
</tr>
<tr>
<td>4</td>
<td>Western</td>
<td>1</td>
</tr>
<tr>
<td>5</td>
<td>Central</td>
<td>1</td>
</tr>
<tr>
<td>6</td>
<td>Eastern</td>
<td>1</td>
</tr>
<tr>
<td>7</td>
<td>Brong Ahafo</td>
<td>1</td>
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<tr>
<td></td>
<td>TOTAL</td>
<td>35</td>
</tr>
</tbody>
</table>
INFORMATION SHEET AND CONSENT FORM

Researcher:

My name is Benard Botwe and a PhD candidate in the Department of Nuclear Safety and Security, School of Nuclear and Allied Sciences, University of Ghana.

Project Title: Development of indication-based diagnostic reference levels for computed tomography examinations in Ghana

General Outline of the Project:

- **Description and Methodology:**Computed tomography (CT) examination subjects patients to high levels of radiation. Diagnostic reference level (DRL) has been found to help in dose optimisation. CT scan protocols and parameters are chosen based on the clinical indication. However, previous DRLs for CT examinations have focused mainly on specific anatomical regions. There are numerous calls by international bodies, for each country to develop its own indication-based DRls. Hence, this study aims at developing common indication-based diagnostic reference levels for computed tomography examinations in Ghana to be used as a benchmark for dose monitoring and optimisation practices.

- **Participants:** The current phase of the study involves administering questionnaires to the technical heads of the CT facilities to gather information on the type of CT, equipment functionality, quality management systems, available personal, nature of cases and cost, and the commonest indications for which CT scans are requested. Therefore, all the technical heads of the CT facilities will be administered with a questionnaire.
• **Use of Data and Feedback:** The data will be used for my dissertation write-up. In addition, the data will be published in a peer-review journal. Feedback in the form of a summary of the research will be made available to participants through emails.

• **Project Funding:** This research is self-funded.

**Participant Involvement:**

• **Voluntary Participation & Withdrawal:**
  Your participation in this research is voluntary, and you may decline to take part or to withdraw from the research without providing an explanation at any time until the work is completed. Within the research, you may also decline to answer any question. If you withdraw, the data you have provided prior to withdrawal will be destroyed and not used.

• **What does participation in the research entail?**
  You are invited to take part in a questionnaire survey and with your consent I will provide you with a questionnaire to fill. (Please fill the consent form attached if you agreed to participate in the study).

• **Location and Duration:**
  The completion of the questionnaire is expected to last about 20 minutes, and will be done at a place of your choosing.
  • **Risks:** The research carries very negligible risk.
  **Benefits:** It is unlikely that you will personally benefit from participation in this research. However, the work will help to develop indication-based diagnostic reference levels for computed tomography examinations in Ghana. This could also provide some information on which some policy decisions and directions can be built.
  • **Compensation:** No monetary compensation will be provided for participating in the study, however, when necessary a certificate may be provided for taking part in the study.

**Exclusion criteria:**

• **Participant Limitation:** Excluded will be those who will not consent to participate or those who will voluntarily withdraw from the study.

**Confidentiality:**

• **Confidentiality:** Confidentiality will be protected as far as the law allows. No participant details will be linked with his or her responses.

**Data Storage:**

• **Where:** The data will be stored on the hardrive of the researcher’s computer. This will be secured with a password.
• **How long:** The data will be available for five years from the date of the analysis and it will be archived for future research projects if necessary.

**Queries and Concerns:**

• **Contact Details for More Information:** Should you have any concerns, you may contact me the principal investigator on: 0244029365, email: sirbenard13@gmail; bebotwe@ug.edu.gh. You may also contact the IRB Administrator (Victor Nortey) at the IRB office of the Korle Bu Teaching Hospital on: R&D unit, Medical Directorate, Central Admin Block, Korle Bu Teaching Hospital, P. O. Box, 77 Accra, Ghana, e-mail: rdo@kbth.gov.gh Phone: +233-302739510.

• Please fill the appropriate portions of the consent form below if you you agreed to participate in the study.

---

**CONSENT FORM**

I confirm that I have been briefed on the nature of the research and my role as a participant. I understand that the researcher is a student in the Department of Nuclear Safety and Security, School of Nuclear and Allied Sciences, University of Ghana School and this research is the student’s dissertation.

I therefore freely give my consent for the use of my data in this research, with the knowledge that I have the right to withdraw from this research at any point in time without explanations.

…………………………………………………. ……………………..

Participant’s Signature Date

…………………………………………………. ……………………..

Researcher’s Signature Date
APPENDIX 3

QUESTIONNAIRE

1. Name of centre: ........................................................................................................

2. Ownership: Private ☐ Public ☐ Quasi-government ☐

3. Location........................................................................................................................

4. CT Type/Model: ...........................................(Serial Number).................................

5. Manufacturer & Year of manufacture: ........................................................................

6. Year of installation: ....................................................................................................

7. Number of CT Slices: ................. Scanning Mode:.................................

8. Equipment working status: ........................................................................................

9. Number of CT scanners in your facility: .................................................................

10. Is your equipment having an automatic exposure control/tube current modulation system? Yes ☐ No ☐

11. Number of CT operating radiographers. ............Full time ........ Part-time .............

12. How many of the radiographers have post-graduate training in CT?........................

13. Number of CT attending radiologists: ............Full time ........ Part-time .............

14. Number of medical physicists: ............Full time........ Part-time ........................

15. Are data on the following dose descriptors recorded from the control console

(i) CTDIvol Yes ☐ No ☐

(ii) DLP Yes ☐ No ☐

16. Do you have any established quality management systems (QMS) in place? Yes ☐ No ☐

17. Is there Departmental Quality Assurance (QA) or Quality Control (QC) or (QMS) Committee in place? Yes ☐ No ☐

18. Do you have in your facility a written/laid down protocol for CT scanning? Yes ☐ No ☐

19. Are quality assessments done post major repairs of faulty equipment? Yes ☐ No ☐

20. Are routine QC checks done at regular intervals? Yes ☐ No ☐

21. If yes to question 20, please indicate the frequency.................................................
22. Is there any established acceptance testing procedure or record for your installed CT machines? .................................................................

23. Do you have an effective maintenance system in place?  
   Yes ☐  No ☐

24. How long does it normally take to repair your equipment when it is broken down?

25. Overall average number of CT cases per a year: ......................................................

26. Average number of CT cases per a year for the following:

   Head: ..............................................................................................................
   Chest: ............................................................................................................
   Abdomen: .....................................................................................................
   Pelvis .............................................................................................................
   Abdominopelvic ..............................................................................................
   Lumbar spine .................................................................................................
   Others ............................................................................................................

27. How much does it cost to do the following non-contrast examinations?

   Head: ..............................................................................................................
   Chest: ............................................................................................................
   Abdomen: .....................................................................................................
   Pelvis .............................................................................................................
   Abdominopelvic ..............................................................................................
   Lumbar spine .................................................................................................
   Others, please specify: ..................................................................................

28. How much does it cost to do the following contrast-based examinations?

   Head: ..............................................................................................................
   Chest: ............................................................................................................
   Abdomen: .....................................................................................................
   Pelvis .............................................................................................................
   Abdominopelvic ..............................................................................................
   Others, please specify: ..................................................................................

.................................................................
29. Indicate the commonest indications and the average frequency (example, 2 a day or 100 a year) for which adult patients come for Head CT examinations [You may select more than one(1) but not more than three (4)]

<table>
<thead>
<tr>
<th>Indication</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. CVA/Stroke</td>
<td></td>
</tr>
<tr>
<td>II. Head injury/trauma</td>
<td></td>
</tr>
<tr>
<td>III. Tumour/Metastasis/cancers</td>
<td></td>
</tr>
<tr>
<td>IV. Headaches</td>
<td></td>
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<tr>
<td>V. Sinusitis</td>
<td></td>
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<tr>
<td>VI. Facial bone injuries/trauma</td>
<td></td>
</tr>
<tr>
<td>VII. Blurred vision</td>
<td></td>
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<tr>
<td>VIII. Others please specify</td>
<td></td>
</tr>
</tbody>
</table>

30. Indicate the commonest indications and the average frequency (example, 2 a day or 100 a year) for which adult patients come for Chest CT examinations [You may select more than one(1) but not more than three (3)]

<table>
<thead>
<tr>
<th>Indication</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. Chest tumour/cancer/metastasis/abscess</td>
<td></td>
</tr>
<tr>
<td>II. Chest injury/trauma</td>
<td></td>
</tr>
<tr>
<td>III. Plural effusion/Airway assessment</td>
<td></td>
</tr>
<tr>
<td>IV. Interstitial lung diseases</td>
<td></td>
</tr>
<tr>
<td>V. Pulmonary embolism</td>
<td></td>
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<tr>
<td>VI. Recurrent cough</td>
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</tbody>
</table>

Others please specify

31. Indicate the commonest indications and the average frequency (example, 2 a day or 100 a year) for which adult patients come for abdomen/abdominopelvic CT examinations [You may select more than one(1) but not more than three (3)]

<table>
<thead>
<tr>
<th>Indication</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. Liver metastases</td>
<td></td>
</tr>
</tbody>
</table>
II. Kidney stone/colic ☐ Frequency ………………………………………….……

III. Abdominopelvic abscess/tumour/cancer ☐ Frequency ……………………

IV. Chrohn’s disease ☐ Frequency …………………………………………………

V. Others, please specify

………………………………………………………………………………………………………

………………………………………………………………………………………………………

………………………………………………………………………………………………………

32. Indicate the specialised procedures (with their related indications) and their average frequencies that are undertaken in your CT?

i. CT IVU (for kidney tumour/stone) ☐ Frequency…………………………………

ii. Multiphase liver (for metastases) ☐ Frequency……………………………………

iii. CT Colonoscopy (for Polys/tumour) ☐ Frequency………………………………

iv. Enterocolysis (for Chrohn’s disease) ☐ Frequency………………………………

v. High resolution CT (HRCT) (for interstitial lung disease) ☐ Frequency…………

vi. Pulmonary Angiogram (for pulmonary embolism) ☐ Frequency…………………

vii. Cerebral angiogram (aneurysms/vessel blockages) ☐ Frequency………………..

viii. Renal angiogram (Renal vessel blockage) ☐ Frequency…………………..

ix. Cardiac Angiogram (heart disease) ☐ Frequency……………………………………

x. Thoracic and abdominal aorta (aneurysms) ☐ Frequency………………………….

xi. Others, please specify ……………………………………………………………………
APPENDIX 4
CT DOSE PARAMETERS DATA SHEET

Name of Institution

Indication:

<table>
<thead>
<tr>
<th>Patient ID</th>
<th>Age</th>
<th>Sex</th>
<th>Wt</th>
<th>kVp</th>
<th>mAs</th>
<th>Total DLP (Gy.cm)</th>
<th>CTDIvol (mGy) per 1SE</th>
<th>SE</th>
<th>P</th>
<th>RT</th>
<th>No. of slices</th>
<th>Slice thickness (cm)</th>
<th>SCAN COVERAGE</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>

Key: Wt = weight, kVp = tube potential, mAs = milliampere second, SE = number of sequence, P = pitch, RT = rotation time, DAUT = distance above upper target, DBLT = distance below lower target.