PUBLIC HEALTH IMPLICATIONS OF MEDICAL DIAGNOSTIC RADIATION EXPOSURE

by

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D E C L A R A T I O N

I declare that **PUBLIC HEALTH IMPLICATIONS OF MEDICAL DIAGNOSTIC RADIATION EXPOSURE** is my own work and that all the sources that I have used or quoted have been indicated and acknowledged by means of complete references and that this work had not been submitted before for any other degree at any other institution.

Jan Frank Gerstenmaier **21 February 2012**

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ABSTRACT

Radiation from Computed Tomography (CT) is now the major contributor to population radiation dose. Despite controversy around the dose-effect relationship of radiation from CT, the linear non-threshold (LNT) theory is endorsed by many authorities, and constitutes the basis of cancer risk estimates. The purpose of this study was (1) a literature review of radiobiological theories, and methods of dose saving stategies in CT; (2) to highlight the importance of dose saving in CT, and to demonstrate how dose can be saved in a radiology department: Following a 40% reduction in reference X-ray tube current for a CT of the urinary tract, the effecitve dose and estimated lifetime attributable risk of incident cancer due to this CT in a group (n=103) were reduced by 37% and 38% in an age and sex-matched group respectively. The literature review showed that the public health implications of CT radiation exposure remain uncertain.

KEY CONCEPTS

Radiation and cancer; computed tomography; radiation in medical diagnostic imaging; models of radiobiology; linear non-threshold theory; radiation hormesis; dose saving strategies; X-ray tube current reduction; cancer risk estimation.

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GLOSSARY OF TERMS AND LIST OF ABBREVIATIONS

ALARA Acronym for As Low As Reasonably Achievable. APARP (As Low As Reasonably Practicable) is used in the UK, and ALARA in the USA, Ireland and Canada. Both terms are interchangeable. An important principle in radiation exposure - the aim is to minimise the risk of exposure while accepting that some exposure may be necessary to achieve intended results.

BEIR Biological Effects of Ionizing Radiation. A series of reports commissioned by the United States Government and carried out by the National Research Council. The current report is the seventh in the series (BEIR VII). An example of how the data-based risk models developed in this report can be used to evaluate the risk of radiation exposure is illustrated in Figure 1.1

CT Computed Tomography. An X-ray-based medical imaging method where from series of two-dimensional images, a three-dimensional image is computed.

CTDI CT Dose index, a commonly used radiation dose index reported by manufacturers for each CT scan to radiography personnel. Can be used to calculate DLP.

CTKUB CT of kidneys, ureter and bladder. A CT test specifically carried out to look for calculi in the urinary tract.

DLP Dose-Length-Product. A measure of the dose of ionising radiation incident on a patient during a CT examination. This can be calculated from CTDI.

DRL Diagnostic Reference Levels. Radiation dose levels in medical radiodiagnostic practices for typical examination for groups of standard-sized patients or standard phantoms for broadly defined types of equipment. These levels are expected not to be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied.

ED Effective dose. This concept is used as an estimate of the stochastic effect that a non-uniform radiation dose has on a human. It is different from equivalent dose, which is a related but more general concept. In terms of whole-body radiation, the sum of effective doses to each body region adds up to the whole-body effective dose for the organism. In case only part of the body is exposed to radiation, then only the regions radiated are used to add up an "effective dose". This can be compared to organisms that receive a whole body "equivalent dose."

ETT Effective tube current

Gray (Gy) Gray is the SI unit of absorbed radiation dose of ionising radiation, and is defined as the absorption of one joule of ionising radiation by one kilogram of matter (e.g. human tissue).

kVp Peak kilovoltage. The maximum kilovoltage applied across an X-ray tube as also used in a CT scanner. One of the scan parameters and determinant of dose.

LAR Lifetime attributable risk. Difference in rate of a condition between an exposed population and an unexposed population, projected for the lifetime.

LNT Linear non-threshold model. A method for predicting long-term biological damage caused by ionising radiation. Based on the assumption that risk is directly proportional to dose at all levels.

LSS Life Span Study. The Life Span Study cohort consists of about 120,000 survivors of the atomic bombings in Hiroshima and Nagasaki, Japan, in 1945 who have been studied by the Radiation Effects Research Foundation (RERF) and its predecessor, the Atomic Bomb Casualty Commission.

mAs milli Ampère seconds. An X-ray tube parameter that controls the amount of X-ray photons produced.

RIS/PACS Radiology Information System/Picture Archiving and Communication System. An Integrated system in the radiology department that stores

images, image reports, patient data and imaging-related data such as radiation exposure parameters, and hence information about dose.

RPA Radiation Protection Advisor. The EURATOM Basic Safety Standards Directive (96/29/Euratom) requires ‘qualified experts’ to be involved in specified tasks relating to radiation protection.

Sievert (Sv) Sievert is the SI unit of *equivalent radiation dose*. A chest radiograph has a dose of 0.02 mSv. A CT of the chest and abdomen typically 6-18 mSv. 10 Vs. at once are certainly lethal. The unit of population dose is man-Sievert (individual doses multiplied by the size of the population.

CHAPTER 1
ORIENTATION TO THE STUDY

1.1 INTRODUCTION

Ionising radiation has been regarded as a potential public health problem for more than 50 years (Price 1958:197). The link between ionising radiation and cancer has long been recognised in the medical and scientific communities, and the general public alike. There is direct epidemiological evidence of a causative relationship not only between high-level radiation but also low dose levels of radiation and carcinogenesis (Wakeford 2004:6404-6405). No published data exists on the causality between medical diagnostic imaging-related ionising radiation and increased cancer risk.

Medical diagnostic imaging is an important source of exposure to ionising radiation and can result in high cumulative effective doses of radiation for individuals as well as in population terms (Fazel, Krumholz, Wang, Ross, Chen, Ting, Shah, Nasir, Einstein and Nallamothu 2009:849). In imaging, computed tomography (CT) is now the largest contributor to radiation dose delivered to patients. The number of CT examinations has grown exponentially over the last two decades, and so has the number of persons undergoing these examinations, thereby increasing radiation exposure in the population (Brenner and Hall 2007:2277).

Several authors express this new increased radiation exposure in cancer lifetime attributable risk (LAR) (Hall 2002:700-701; Berrington de Gonzalez and Darby 2004:345-347; Brenner and Elliston 2004:735-736; Hall and Brenner 2008:362-364; Berrington de Gonzalez, Mahesh, Kim, Bhargavan, Lewis, Mettler and Land 2009:2071-2072 & 2077; Griffey and Sodickson 2009:887-892; Sodickson, Baeyens, Andriole, Prevedello, Nawfel, Hanson and Khorasani 2009:175-184; Bartley, Metayer, Selvin, Ducore and Buffler 2010:1628-1637), usually using estimated cancer risk from atomic bomb-associated cancer mortality data.

This paradigm is based on the linear non-threshold model (LNT), a radiobiological concept that stipulates that radiation is always considered harmful with no safety threshold. Using the LNT model, it has been suggested that medical imaging radiation exposure might be responsible for 1-3% of all cancers worldwide (Berrington de Gonzalez and Darby 2004:345), also illustrated in Figure 1.1. This has prompted a strong drive in the radiology community (Johnson, Helft and Rex 2009:738) as well as from government bodies (FDA 2010:1-10) to reduce and limit unnecessary medical

radiation exposure in the light of potential public health problems. In addition, there is a growing public interest in the effect of medical radiation exposure.

How can dose reduction and limitation be achieved, and how effective would these measures be when considering current methods to translate medical radiation exposure to cancer risk? A practical example from within a radiology department of potential radiation dose savings in CT is investigated and is presented in the context of current knowledge on radiation and estimated cancer risk as relevant to medical diagnostic imaging.

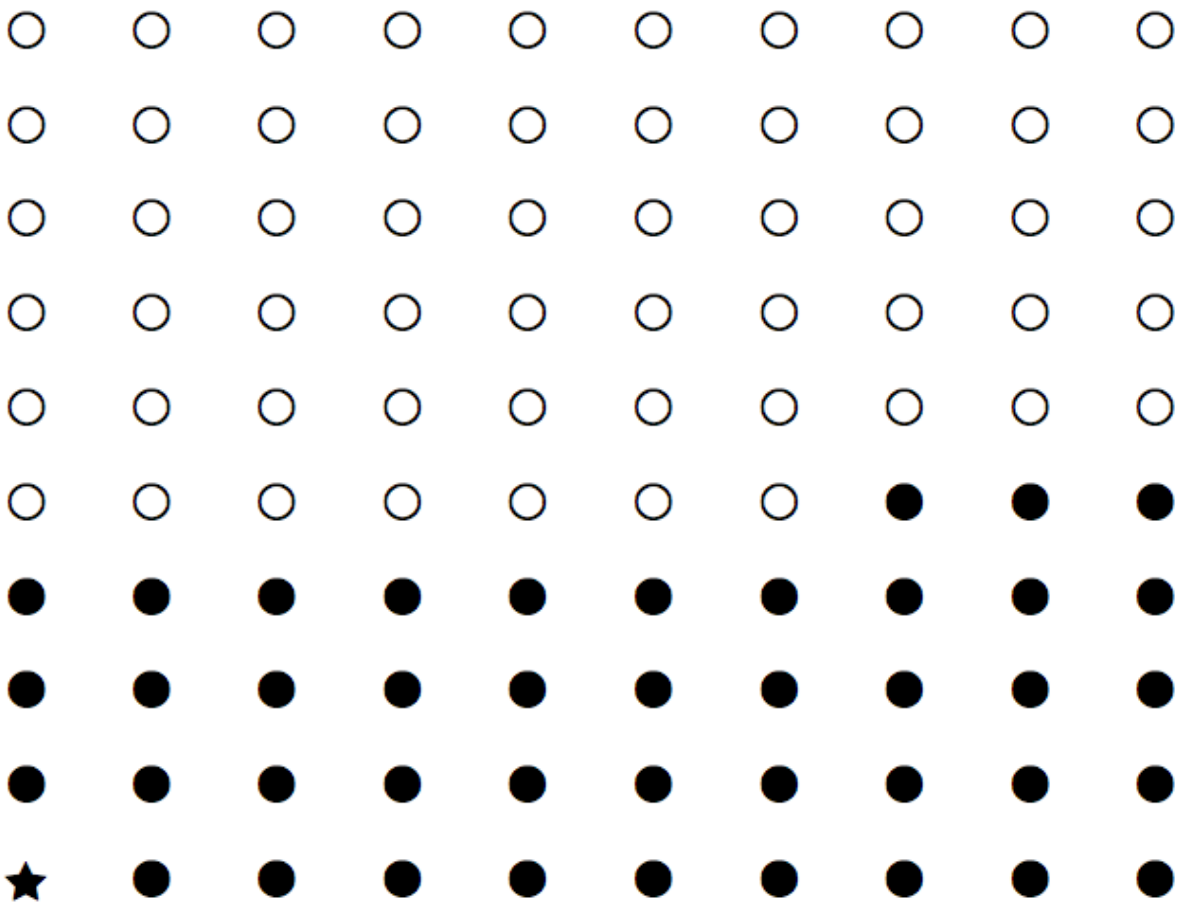


Figure 1.1 Additional cancer cases
In a lifetime, approximately 42 (solid circles) of 100 people will be diagnosed with cancer. Calculations in the BEIR-VII report suggest that approximately one cancer (star) per 100 people could result from a single exposure to 0.1 Sv of radiation above background. Adapted from the BEIR-VII report (NRC 2006:7).

1.2 BACKGROUND INFORMATION ABOUT THE RESEARCH PROBLEM

1.2.1 The source of the research problem

Notwithstanding the lack of a direct link between diagnostic radiation and cancer, in the setting of increasing population radiation dose load due to medical imaging, the principle of 'as low as reasonably achievable' (ALARA) remains valid and is practised throughout the radiology community. There are constant efforts to reduce radiation dose with a variety of strategies. These dose savings are part of everyday practice in a radiology department. Radiographers, radiologists, technicians, physicians and engineers are concerned with so-called dose savings.

In CT, dose savings can be achieved by optimising the CT scanner parameters so that radiation exposure is kept to a minimum whilst maintaining good image quality. Efforts are also being made to find alternative imaging methods where there is no radiation involved or less than the amount of radiation used in CT.

When using such dose saving strategies, while often the actual reduction of dose can be estimated, calculated or measured, little is known about what reduction of estimated LAR these dose savings can achieve. Further, any dose reduction in imaging expressed in dose units, may appear abstract and difficult to grasp for non-radiological healthcarers as well as patients.

1.2.2 Background to the research problem

1.2.2.1 Changes of contributing factors to population radiation dose

Ionising radiation exposure to the public has traditionally been largely determined by so-called natural sources. These are mainly radon, internal, terrestrial and cosmic radiation. Man-made radiation sources are considered exposures from medical applications (X-radiation, nuclear medicine) and consumer products (smoke detectors, camping gas lanterns etc.). A negligible contribution in public heath terms is made by occupational exposures, nuclear fallouts and nuclear fuel recycling (RPII 2008:4-7). Diagnostic X-rays are the largest man-made source of radiation exposure to the general population, contributing approximately 14% of the total annual exposure worldwide from all sources (Berrington de Gonzalez and Darby 2004:345-347). These proportions

applied in the mid-1980s, when medical radiation exposure consisted largely of radiography, with a small proportion of fluoroscopic methods. In 1982, the per-capita contribution by medical radiation to annual dose was 0.54 mSv, which increased by 600% to approximately 3.0 mSv in 2006 (Mettler, Thomadsen, Bhargavan, Gilley, Gray, Lipoti, McCrohan, Yoshizumi and Mahesh 2008(2):502-507).

Over the past three decades, Computed tomography (CT) has been introduced to diagnostic radiology. CT is an X-radiation-based imaging technique widely recognised as one of the great revolutions in diagnostic radiology. It can deliver speedy 'non-invasive' diagnosis and has helped to save innumerable lives. Its use has increased exponentially since its introduction. In the past, populations exposed to CT X-radiation largely consisted of the hospitalised and the sick. Nowadays, CT scanning is routinely used in emergency settings for minor and non-life threatening conditions (e.g. minor head injuries), and increasingly for asymptomatic persons as a screening test. In addition, paediatric radiology use of CT has dramatically increased.

With regards to radiation dose, CT is considered a 'high dose' modality. The amount of X-radiation used during a CT examination is up to several hundred-fold larger that that used during radiography of the same body part.

1.2.2.2 Reasons for sharp rise in CT examinations worldwide

An estimated 62 million CT scans are carried out in the United States each year (Brenner and Hall 2007:2277). These accounted for 15% of the total number procedures (excluding dental) and over half of the collective population dose (Mettler et al 2008(2):502).

One of the contributing factors to the steady increase in use of CT is its user friendliness for both health personnel and patients. Actual scan times for a CT of the abdomen have been reduced from up to 45 minutes in the 1980s, to less than one minute at present.

In addition, because of imaging providing rapid and accessible diagnosis of conditions that were previously diagnosed clinically, the clinical skills of doctors may vanish in certain areas, leading to a circle of ever increasing reliance on medical imaging in

patient management. The over-reliance on technology in general, including CT, has been illustrated in an editorial (Fred 2009:4-7).

The medical litigation crisis in many countries results in large proportions of doctors fearing a legal complaint (Birchard 2001:698). As a result, defensive medicine is now widespread in many countries including the USA and Ireland, with a major feature being unnecessary investigations (Catino 2011:5), including CT.

1.2.2.3 Population receiving CT exposure

The population receiving CT scans can be divided into groups depending on underlying conditions. Many chronic diseases require life-long follow-up and surveillance with CT. These diseases are often benign such as inflammatory bowel disease or cystic fibrosis, and patients are at particular risk of receiving high cumulative doses. Another group are cancer patients who receive regular, frequent CTs of the chest, abdomen and pelvis with or without CTs of the neck and brain. In deliberations about cancer risk associated with medical imaging, cancer patients are censored by some authors (Berrington de Gonzalez et al 2009:2072), as a key assumption in the estimation of lifetime radiation-related cancer risk is the life expectancy of persons receiving CT scans (Berrington de Gonzalez and Darby 2004:355). Patients without cancer or chronic illness form another group where CT scans are now much more frequent. While CT in severe trauma is of unquestionable benefit, and radiation becomes secondary of importance (McCollough, Guimaraes and Fletcher 2009(1):28-39), CT is now frequently used in less severe trauma. An example of a CT investigation that is non-trauma related, and used in normally well and often young patients, and chronically ill patients alike, is CTKUB. This type of test that has lent itself to the comparative survey on a dose saving strategy as discussed in this dissertation.

1.2.2.4 How CT radiation exposure is translated into cancer risk

The recent focus of attention towards radiation-induced carcinogenesis is a direct result from the increased utilization of CT. A widely recognised system (Higson 2005:324-325) of assessing cancer risk associated with medical radiation exposure are the findings of the BEIR VII Committee (Biological Effects of Ionizing Radiation) of the National

Academy of Sciences (NRC 2006:11-15), on which several publications on cancer risk due to CT are based (Brenner and Hall 2007:2277-2284; Berrington de Gonzalez et al 2009:2071-2077; Griffey and Sodickson 2009:887-892; Smith-Bindman, Lipson, Marcus, Kim, Mahesh, Gould, Berrington de Gonzalez and Miglioretti 2009:2078-2086; Sodickson et al 2009:175-184). This system of translating radiation exposure into cancer risk is based on the LTN model. An example of how the data-based risk models developed in this report can be used to evaluate the risk of radiation exposure is illustrated in Figure 1.1. There is much controversy around the LNT model with a growing body of evidence against it – recently reviewed by Tubinana et al (Tubiana, Feinendegen, Yang and Kaminski 2009) – and an increasing number of calls to reject it.

1.2.2.5 Clinicians' understanding of radiation dose

CT has now become ubiquitous and overused by clinicians and non-radiological healthcarers, who often display a marked lack of understanding of the severity of the potential problem of radiation induced cancer from medical diagnostic imaging. Clinicians do not undergo formal training in radiation protection, but they normally do have some level of understanding regarding different radiation doses for specific examinations. Without background knowledge of physics, many doctors are aware of the average dose received during a chest radiograph, the single most common imaging procedure; this typically is 0.02 mSv.

When it comes to higher dose examinations such as CT, radiation doses here are commonly conceptualised as multiples of chest radiographs (or transatlantic flights for that matter). For example, a CT of the chest typically represents the 350-fold dose of a chest radiograph. While this understanding holds true for isolated imaging procedures, there is little recognition among clinicians and patients about the relative latent cancer risks associated with repetitive exposure to ionising radiation.

1.3 RESEARCH PROBLEM

In the light of ongoing controversy around the LTN and alternative models, true dose-effect relationship might not be established for some time. The assumption that the additional LAR is not zero, therefore ALARA/ALARAP is being practised. At the local

level, within a radiology department, several methods of radiation saving can be identified (Gerstenmaier, Ridge and Murphy 2011), but not all are 'reasonably practicable', and some involve additional financial investment. Therefore, existing strategies to reduce radiation dose should reviewed and examined.

Previously, dose optimisation was assessed by changes in population dose (Crawley, Booth and Wainwright 2001:607-609), but not with estimated additional cancer LAR. Additional estimated LAR of cancer were made comparing different imaging methods (Richards, Summerfield, George, Hamid and Oakley 2008:347-351), but the imaging methods were chosen not on grounds of different radiation exposures.

To what extent estimated LAR of cancer can be achieved with dose reduction strategies that are employed as part of service evaluations and improvements in radiology departments is not clear.

With regards to choosing and alternative imaging method with less radiation, one study showed that an educational intervention brought about a reduction of radiation exposure in emergency department patients (Stein, Haramati, Chamarthy, Sprayregen, Davitt and Freeman 2010:392), but only equivalent dose was measured. What effect these measures had on estimated cancer LAR was not determined.

1.4 AIM OF THE STUDY

1.4.1 Research purpose

a) to review existing models of radiobiology and ways to translate radiation dose into cancer risk

b) to discuss methods to reduce radiation dose ('radiation dose saving') in CT procedures commonly conducted in tertiary hospitals

c) to investigate how population dose and cancer LAR can change with dose saving strategies employed as service evaluation/improvement in a radiology department

1.4.2 Research objectives

a) to discuss of current models of radiobiology, and radiation-associated cancer risk assessment.

b) to provide an overview and discussion of current strategies of radiation dose reduction.

c) to investigate how dose reduction and lifetime attributable cancer risk in CT can be achieved in a clinical setting, using a technological (change in imaging protocol parameters, i.e. CT radiation exposure factors) method as an example:

Primary question:

How will the effective mAs (milli Ampère seconds) and the effective radiation dose (ED) change following a reduction of CTKUB Quality Reference mAs?
How will the estimated LAR of incident cancer change following a reduction of CTKUB Quality Reference mAs?
Secondary Question:
Is there any significant image quality difference following a reduction of CTKUB Quality Reference mAs?

1.5 SIGNIFICANCE OF THE STUDY

The radiation dose burden on the population due to medical ionising radiation has increased almost exponentially (Brenner and Hall 2007:2277). Notwithstanding uncertain public health implications of increased cancer risk due to increased population radiation dose (no causal relationship demonstrated as yet), and the ongoing debate about the validity of the LNT model, the ALARA/ALARP principle remains a cornerstone of medical radiation protection. Radiation dose curtailment is therefore of paramount importance. It is hoped that this study will show that meaningful dose savings and reductions of estimated LAR of incident cancer can be achieved with practicable methods, and that these could be easily applied to other radiology departments without the need for additional financial investment or significant additional training of staff. In addition, changes in estimated cancer LAR due to imaging might become more palatable to referring physicians as well as patients. The ultimate beneficiaries would be individual patients as well as the patient populations.

1.6 DEFINITION OF TERMS

1.6.1 Biological effects of ionising radiation

These are considered in terms of effects on living cells. There are four principle outcomes: Desoxyribonucleic acid (DNA) damage can be detected and repaired; DNA damage cannot be repaired and the cell undergoes programmed cell death; a nonlethal DNA mutation that is passed on to subsequent generations of cells, possible contributing to the formation of cancer; irreparable DNA damage leading to transcriptional errors possibly leading to cancer (Princeton University 2012).

In addition, effects can be divided into two categories: deterministic and stochastic. *Deterministic effects* - Based on both experimental and theoretical studies, it was found that the severity of certain effects on human beings increases with increasing radiation doses (Bushberg 2002:814). For different effects, certain levels of radiation exposure exist. Below these levels, the 'thresholds', the effect will be absent. The severity of deterministic effects depends on dose. For example, cataract of the eye will only develop if the eye is exposed to a dose of 150 mSv per year; hence, the threshold dose for cataract is 150 mSv per year (RPII 2008:42).
Stochastic effects - The severity and event are independent of absorbed dose, and effects may or may not occur. There is no threshold dose, but the probability of effects occurring is dose dependent (Bushberg 2002:814). Examples are radiation-induced cancers and genetic defects. A cancer may develop after a single dose of 1 mSv only, whereas in other circumstances, no cancer may develop after a high exposure.

Some tissues or organs are more susceptible – radiosensitive – to ionising radiation than others. One of the principles behind this is the higher the inherent cellular turnover of an organ, i.e. cell renewal, the more radiosensitive that organ is. For example, stomach and breasts are organs with high cellular turnover and are therefore radiosensitive.

1.6.2 Ionising radiation in diagnostic medical imaging

Certain medical imaging methods utilise ionising radiation to generate images. These include radiography, CT, and nuclear medicine. CT is an X-ray based modality. X-rays are electromagnetic waves that on a spectrum of frequencies lie to the right of

ultraviolet light. X-ray sources include X-ray tubes as used in CT scanners, where high-velocity electrons collide with a metal target, producing X-rays.

By selecting current and voltage of the X-ray tube, the amount and energy of X-rays can be influenced, dependent on particular types of examinations. For example, imaging a hand will require a different amount of X-rays and a different energy of X-rays than imaging the liver. In imaging, radiation safety and image quality are tradeoffs. As a general rule, image quality improves with increased radiation exposure.

1.6.3 Principles of radiation protection

ALARA or ALARP are terms in safety-critical or safety-involved systems, such as radiation exposure in medicine. Both ALARA and ALARP terms are interchangeable, and tend to be used in North America and the UK respectively. ALARP (as low as reasonably *practicable)* recognises cost and logistics, and is a narrower term than 'physically possible'. APARP originates from UK legislation (Health and Safety at Work etc. Act 1974). ALARA is now used almost exclusively in radiation protection. Here, the aim is to minimise the risk of exposure to ionising radiation, while bearing in mind that a degree of exposure may be acceptable in order to fulfill a task, i.e. carry out an imaging procedure.

In radiology, the exposure is kept low enough to keep the statistical probability of cancer, i.e. stochastic effects, below an acceptable level, whilst achieving imaging of diagnostic quality. This practice is based on a principle that any amount of radiation exposure can lead to biological effects such as cancer, and on a principle where the probability of such effects occurring increases with cumulative doses of radiation. This is the basis of the LNT principle, which is now widely accepted (Little, Wakeford, Tawn, Bouffler and Berrington de Gonzalez 2009:6-12), although questioned by some (Tubiana 2005:317-319; Tubiana, Aurengo, Averbeck and Masse 2006:317-324; McCollough et al 2009(1):28-39; Tubiana et al 2009:13-22; HPS 2010), as it appears to be inconsistent with radiation biologic and experimental data.

There are four principle factors in radiation protection to reduce dose: Time (duration) of exposure, distance from the radiation source, shielding (e.g. by means of a lead apron), and amount and energy of ionising radiation.

In radiology, the concepts of justification, optimisation and limitation are practised. Justification means that every imaging test and hence every exposure must be justified against a clinical need. Optimisation refers to the balance between best possible qualities of imaging achievable with the least exposure.

1.6.4 Computed tomography

CT is a medical imaging method using an X-ray system rotating around the patient, thereby imaging from multiple angles during a 360 degrees rotation. Computer processing is used to generate three-dimensional images from the raw data of two-dimensional projections from different angles (Bushberg 2002:327).

1.6.5 Measuring and calculating radiation dose

Ionising radiation can be measured with a variety of instruments. With regards to CT, the radiation dose parameter is the CD Dose Index (CTDI), a mathematical integral under the dose profile of a single axial CT scan. It is a directly measurable and standardised quantity (McCollough 2008:507). Using the CTDI, the Dose Length Product (DLP) is calculated, estimating the total dose received over a specific scan length (McCollough 2008:508).

From the DLP, the effective dose can be estimated taking into account non-uniform exposure and different radiosensitivities of different organs (Huda, Ogden and Khorasani 2008:995).

1.6.6 Calculation of cancer risk associated with CT

Although no large-scale epidemiological studies of the cancer risk associated with CT have been reported, it is possible - assuming the validity of the LNT model - to estimate the cancer risk associated with any given CT scan by estimating the organ doses involved, and applying organ specific cancer incidence on cancer mortality data using atomic bomb-associated cancer indices. A scientific committee nominated by the National Research Council (USA) and organised by the National Academy of Sciences (USA) published their report on the Health Risks From Exposure to Low Levels of

Ionizing Radiation in 2006 (NRC 2006:1-406). This Biological Effects of Ionizing Radiation (BEIR VII-2) Phase 2 framework provides specific methodology to calculate lifetime attributable risk.

1.6.7 Dose reduction strategies

A wide range of options is available in order to reduce or limit radiation dose delivered to patients during imaging procedures. With regards to CT, strategies have been classified as technological and non-technological. Technological methods include changes to CT scanner parameters in terms of X-ray energy and X-ray amount. There are factory settings that might not be appropriate, for example in paediatric imaging. Non-technological methods include decision-making algorithms before the CT examination, to determine if the examination is necessary, if there is an alternative examination with less radiation, or if there is an examination without ionising radiation (e.g. ultrasound) that can answer the clinical question. An overview of current radiation dose saving strategies has been presented by this author (Gerstenmaier et al 2011).

1.7 FOUNDATIONS OF THE STUDY

The foundation of this study is based on a thorough literature review supported with the experience from the researcher's perspective gained from medical experience in radiology and medical radiation. Stakeholders of the topic include healthcare providers, patients, and the general population, i.e. the public.

1.8 RESEARCH DESIGN AND METHOD

Following review of current literature on medical radiation exposure and associated estimated cancer risk, an attempt of radiation exposure limitation or reduction will be investigated with an explanatory study. Matching the research objective with the time dimension, an explanatory, retrospective study is appropriate (Johnson and Christensen 2012:361). A quantitative research paradigm lends itself for this, as radiation doses and cancer risks will be calculated.

The study is a quantitative, retrospective, explanatory study of two independent groups. The study is concerned with the radiation dose received during a CT of the kidneys, ureters and bladder (CTKUB). Two groups of patients (approximately 100 each) undergoing CTKUB before and after a change in imaging parameters are compared in terms of radiation dose received, and the resultant estimated cancer risk.

The change in imaging parameters occurred on a changeover date, where within the department of radiology, imaging parameters for CTKUB were changed in the context of service optimisation and service evaluation. This change occurred independently of this proposed survey, and on the recommendation of the department's Radiation Protection Advisor.

The imaging parameters, age and sex are independent variables. DLP, equivalent dose and cancer risk are dependent variables. Age and sex for Groups 1 & 2 will be controlled variables due to matching.

1.9 SCOPE OF THE STUDY

The study comprises a review of up-to-date literature on radiation as relevant to medical diagnostic imaging (CT), and a discussion of strategies of how radiation dose can be reduced. Using a modified CT radiation exposure parameter as an example, a comparative survey is used to illustrate how radiation dose savings can be achieved in a radiology department.

1.10 STRUCTURE OF THE DISSERTATION

There are five chapters to this dissertation including the current one. Chapter 2 contains a literature review. Chapters 3 and 4 are concerned with the conduction and results of the exploratory study on the reduction of radiation. Chapter 5 at the end of this dissertation concludes with remarks on the study's finding.

CHAPTER 2
LITERATURE REVIEW

2.1 INTRODUCTION

Over the last decade or so, there has been a significant increase in the amount of published literature on cancer risk associated with medical diagnostic radiation exposure, notably CT. The vast majority of these studies presume a LNT model. However, there is much controversy around this model as it is inconsistent with radiation biologic and experimental data (Tubiana et al 2009:13-15), and the theory that low doses of radiation are harmful at all. In the following, different models of radiobiology are explored, followed by a description of radiation measurement or estimation, and radiation dose reduction strategies as relevant to CT.

Recent media attention has focused on the potential danger of radiation exposure from CT, even though the potential benefit of a medically indicated CT far outweighs the potential risks. Examples are: “CT heart scans raise cancer risk” (ABC news 2011); “Raised cancer risk for children as soaring numbers are subjected to radioactive CT scans” (Daily Mail 2011). This publicity has prompted the radiological community to say that doses must be as low as reasonably achievable (ALARA) while maintaining diagnostic image quality. The use of CT must also be justified for the specific diagnostic task (McCollough, Primak, Braun, Kofler, Yu and Christner 2009(2):29).

In this literature review, the following topics were included: Biological effects of ionising radiation; principles of radiation protection; measuring and calculating radiation dose; calculating cancer risk associated with radiation; projected public health implication of diagnostic radiation exposure; radiation exposure in medical diagnostic imaging; and dose saving strategies in medical diagnostic imaging.

For primary literature, a Medline search was performed using the PubMed and Google Scholar™ search engines. Where relevant literature was found, a so-called ‘reverse citation trail’ (Gerstenmaier and Malone 2010:570) function in Google Scholar™ was utilised to identify further literature of relevance.

2.2 BIOLOGICAL EFFECTS OF IONISING RADIATION

2.2.1 Stochastic and deterministic effects

The biological effects of ionising radiaion on the human body can broadly be categorised into stochastic and deterministic effects. Deterministic effects are dose-dependent. Stochastic effects are not dose-dependent. At exposure to low doses as used in diagnostic imaging, deterministic effects are rarely relevant, whereas stochasitc effects can occur at any dose (Princeton University 2012).

Both stochastic and deterministic effects are considered in terms of their effects on living cells. Energy is transferred to atoms and molecules in the cellular structure. Ionising radiation results in atoms and molecules becoming ionised or excited. These excitations and ionisations can result in the production of free radicals, the breakup of chemical bonds, the production of new chemical bonds, as well as the cross-linkage between macromolecules.

2.2.2 Effects on deoxyribonucleic acid

When ionising radiation is incident on DNA, there is a spectrum of resultant biological outcomes of these excitations and ionisations. The most favourable result is that when cells experience DNA damage, they are able to detect and repair the damage. This occurs in most instances of exposure at low doses such as that received every day from background radiation. In some cases, cells experience DNA damage and are unable to repair the damage. These cells may go through the process of apoptosis (‘programmed cell death’). Therefore, any potential genetic damage is elimitated. If there is a non-lethal DNA mutation occurring that is passed on to subsequent cell divisions, this may contribute to the formation of a neoplasm. Cancer development is also thought to be possible of the cells experience damage to the DNA that is beyond the possibility of repair with transcriptional errors and replicational errors that initiate neoplasia. Much ground work on the biological effects of ionising radiation was conducted in the 1970s but concepts are still vaild to date, and are considered common knowlegde. Multiple publications are available that outline these concepts, for example the Unites States Nuclear Regulatory Commission fact sheet on Biological Effects of Radiation (USNRC 2011:1-3).

Cancer induction risks are difficult to estimate, as most of the radiation exposures that humans receive are very close to background levels. At such dose levels, the risk of radiation-induced cancers are very low, and if the risk actually exists, it is not readily distinguishable from normal levels of cancer occurrence.

At typical dose levels received during medical diagnostic imaging, the premise that radiation increases cancer incidence is controversial. The incidence of cancer due to non-radiation causative factors is much greater than any contribution from ionising radiation. For instance among a population of 100,000 people, about 25%, or 25,000 people, will eventually die of cancer. It is estimated that if that population was exposed to 0.01Sv of ionising radiation, about 4 to 8 additional cancer deaths would be calculated from high dose projections. At the same time, the variation is so large that any effect from radiation would not be distinguishable from natural incidence (Wright University 2011).

2.2.3 The LNT model

Worldwide, agencies regulating ionising radiation assume that high dose effects can be proportionately extrapolated to low doses (RPII 2008:10 & 52; USNRC 2011:2-3). This LNT model predicts the risk of cancer to be directly proportional to dose and the end point for biological effects is considered zero.

The LNT model has its basis in the theory that a single particle of radiation hitting a single DNA molecule in a nucleus of a single cell can induce cancer. The probability of cancer induction is proportional to the dose, and hence the risk is proportional to the dose. It is claimed that current scientific evidence is consistent with the hypothesis that there is such an LNT relationship between exposure to ionising radiation and the development of cancer in humans (NRC 2006:15).

However, several other models of risk from radiation exposure have been suggested:

The sub-linear model also assumes that the end point for biological effects is zero. The number of projected cancers still increases with dose, but at a much lower rate than the LNT model (Wright University 2011).

In the threshold model, the assumption is made that radiation has no effect below a certain dose. Above that dose, excess cancers from radiation exposure may be observed (Wright University 2011).

2.2.4 Controversy around radiation hormesis

Hormesis, from ancient Greek ὁρμάω = "to set in motion, impel, urge on" (Perseus 2011, sv ὁρμάω), is a term used originally by toxicologists to refer to a biphasic dose response to an environmental agent characterised by a low dose stimulation or beneficial effect and a high dose inhibitory or toxic effect. In medicine, hormesis is defined as an adaptive response of cells and organisms to a moderate, usually intermittent, stress (Mattson 2008:1). The radiation hormesis model assumes that radiation in high doses increases the incidence of cancer, whereas small doses are beneficial to the person.

In their critical discourse on radiation hormesis from a public health perspective, Thayer et al (Thayer, Melnick, Burns, Davis and Huff 2005:1274) referenced the BEIR-VII report in support of their opinion that hormesis should be ignored: “The assumption that any stimulatory hormetic effects from low doses of ionising radiation will have a significant health benefit to humans that exceeds potential detrimental effects from the radiation exposure is unwarranted” (NRC 2006:80 & 332). This reference was felt to be selective and misleading (Cook and Calabrese 2006:962; Cook and Calabrese 2007:1634).

Cook and Calabrese argue that the quotation by Thayer et al was incomplete. The sentence did not end with the word “unwarranted”, but with “unwarranted at this time.” (NRC 2006:352).

Further, in Thayer et al (Thayer et al 2005:1271-1276) it is not mentioned that among the 12 research needs recommended by the BEIR VII committee, two involved hormesis (NRC 2006:16-17; ANNEXURE 2).

Lastly, it is criticised that Thayer et al did not reference the report from the Académie Nationale de Médecine (Tubiana 2005:317-319; Tubiana and Aurengo 2005:317-319). Both the BEIR committee (NRC 2006) and the French committee (Tubiana 2005:317-319; Tubiana and Aurengo 2005:317-319) issued their reports concerning the health effects of ionising radiation at approximately the same time; therefore, both presumptively had access to the same literature. They both recommended research on hormesis, but the Académie Nationale de Médecine (Tubiana 2005:318; Tubiana and Aurengo 2005:318) went further in that they challenged the validity of the LNT model and stated, “the importance of hormesis should not be overlooked (Cook and Calabrese 2006:1633; Cook and Calabrese 2007:959).

In a further attempt to support the concept of hormesis, it has been proposed that radiation doses in the mGy range can cause two separate effects on the cellular genome (Feinendegen 2005:4-5). The first carries a relative low probability of damage per energy deposition event and increases proportionately to dose. At radiation exposures due to natural background radiation, this damage to the genome is felt to be much lower than that from endogenous sources, e.g. free radicals. A different effect at these low dose levels is adaptive protection against genome damage from several sources. Adaptive protection prevents genome damage, promotes genome repair and stimulates an immune response. This has been proven in a mouse model (Azzam, Raaphorst and Mitchel 1994:28) where error-free enhaced cell repair was observed following a radiation challenge. These effects appear to develop with a delay of hours, may last for days to months, decrease steadily at doses above about 100 mGy to 200 mGy and are not observed any more after acute exposures of more than about 500 mGy (Feinendegen 2005:5). The authors point out that radiation-induced apoptosis and terminal cell differentiation can occur at doses higher than commonly used in diagnostic imaging, and add to protection by reducing genomic instability and the number of mutated cells within tissues. However they also claim that at low doses, i.e. at those used in medical imaging, reduction of damage from endogenous sources by adaptive protection may be equal to or outweigh damage induction due to radiation.

2.2.5 Call to abandon the LNT hypothesis

Feinendegen et al argue that the LNT hypothesis “should be abandoned and be replaced by a hypothesis that is scientifically justified and causes less unreasonable fear and unnecessary expenditure” (Feinendegen 2005:6). This call by Feinendegen for abandonment of the LNT has been criticised on several accounts. Edwards and Bouffler (Edwards and Bouffler 2005:770) argue that there is evidence suggesting a continuously increasing response between cellular endpoints and radiation dose, and that there is continuing, significant uncertainty regarding the existence, mechanisms and basis of any adaptive responses (UNSCEAR 2000:75-157; NCRP 2001:18-20). In addition, a number of studies have shown that the induction of apoptosis is not only a high dose phenomenon, but also occurs at very low dose levels (Rothkamm and Lobrich 2003:5075; Enns, Bogen, Wizniak, Murtha and Weinfeld 2004:557). Edwards and Bouffler stress that in the absence of consistent radiobiological evidence it is prudent to somewhat overestimate health effects rather than underestimate them

(Edwards and Bouffler 2005:770). On a more general note on potential benefit from any type of exposure, when conducting risk assessments, the US Environmental Protection Agency (EPA) does not currently consider the beneficial effects below the so-called no observed adverse effect level (NOAEL) (DeSesso and Watson 2006:8).

2.2.6 The stance of the BEIR-VII committee

The BEIR-VII committee findings are that the epidemiologic data and the biological data are consistent with a linear model at doses where associations can be measured. The main studies establishing the health effects of ionising radiation are those analysing survivors of the Hiroshima and Nagasaki atomic bombings in 1945. Sixty-five percent of these survivors received a low dose of radiation, that is, low according to the definition used in this report (equal to or less than 100 mSv) (NRC 2006:6 & 10). The arguments for thresholds or beneficial health effects are not supported by these data. Other work in epidemiology also supports the view that the harmfulness of ionising radiation is a function of dose.

The suggestion that the LNT model exaggerates the health effects of low levels of ionising radiation is rejected by the BEIR VII committee. The committee found that reports claiming that at very low doses, ionising radiation does not harm human health or may even be beneficial were either based on ecological studies or cited findings not representative of the overall body of data.

The committee concludes that the “preponderance of information indicates that there will be some risk, even at low doses” (NRC 2006:10). When they considered the entire body of research on this question, a consensus view emerged - a view that the health risks of ionising radiation, although small at low doses, are a function of dose.

2.3 PRINCIPLES OF RADIATION PROTECTION

There are three prinicipal factors that control the dose of radiation received from a source, and an exposure can be managed by a combination of the three factors time, distance and shielding (Bushberg 2002:253).

Reducing the time of an exposure results in a linear, proportional reduction in the effective dose received by a person. Increasing the distance from the radiation source reduces the dose by the inverse square law, which states that a specified

physical quantity or strength is inversely proportional to the square of the distance from the source of that physical quantity. Shielding refers to a material that is capable fo absorbing radiation, and that is placed between the radiation source and the person. An example is a lead apron (Bushberg 2002:250-252). In addition to these basic principles, the International Commission on Radiological Protection (ICRP) has set further guidance with regard to the factors that influence radiation doses, and hence radiation risks (ICRP 2007:1-332):

Justification: No unnecessary use of radiation is permitted, which means that the advantages must outweigh the disadvantages.

Limitation: This involves setting upper limits on the dose that may be received by any member of the public from all man-made exposures other than medical exposures.

Optimization: Radiation doses should all be kept as low as reasonably achievable. This means that it is not enough to remain under the radiation dose limits.

The latest ICRP recommendations have been updated in 2007, and while maintaing the above principles of justification, limitation and optimization, the IRCP have now attempted to develop a more holistic approach to radiological protection covering different exposure situations: planned, existing and emergency (Wrixon 2008:161-168).

2.4 MEASURING AND CALCULATING RADIATION DOSE

The most important radiation dose parameter in CT is the CTDI, which is an integral under the radiation dose profile of a single axial scan normalized to the nominal X-ray beam width (HPS 2010:1).

It is only an estimation of the average dose from a multiple-scan examination, however it is a directly measurable and standardised quantity. To measure the CTDI, the radiation dose from a single CT scan is collected by an ionisation chamber (10 cm long), and then the integrated dose is normalised to the width of the radiation beam (Bushberg 2002:364).

Based on the CTDI, the DLP is calculated. This provides a more accurate estimate of the total dose delivered over a specific scan length, therefore accounting for different patient sizes. Effective dose can be estimated and used to reflect the risk of a non-uniform exposure in terms of a whole-body exposure (McCollough 2008:508). To convert DLP into ED, conversion factors are used depending on the body region scanned.

ED is a concept that was introduced in the mid-1970s in an effort to quantify the effect of partial body irradiation, on the basis of data derived from whole body irradiation. The definiton of effective dose is the mean absorbed dose from a uniform whole-body irradiation, resulting in the same total radiation effect as from non-uniform partial body radiation concerned. The ED can be calculated as a weighted average of the mean absorbed dose to different body organs, whereas the weighting factor is the radiation effect on any given organ – from whole-body radiation – as a fraction of the total radiation effect.

There are several methods for calculating effective dose from radiographic, and hence CT exposure. First, it is necessary to estimate the radiation dose to individual organs. The Monte Carlo simulations of photon interactions within a simplified model of the human body is one way of forming a basis for calculating the equvalent dose, and therefore, the detriment associated with partial or organ-specific irradiations, as are common in diagnostic radiology, can be assessed (McCollough and Schueler 2000:828).

ED also allows comparison between different imaging techniques, and for a generic estimate of risk from a given procedure for a generic model of the human body. As such, this concept has inherent “uncertainties and oversimplifications” (McCollough, Christner and Kofler 2010:890).

2.5 CALCULATION OF CANCER RISK ASSOCIATED WITH RADIATION

Cancer risk due to diagnostic level radiation needs to be calculated based on certain models, as no direct epidemiological data is available at this time (Hoel 1987:105).

An important task of the BEIR VII committee was to develop “risk models” for estimating the relationship between exposure to low levels of low-LET ionising radiation and harmful health effects. The committee judged that the linear no-threshold model (LNT) provided the most reasonable description of the relation between low-dose exposure to ionising radiation and the incidence of solid cancers that are induced by ionising radiation.

The LNT model is the fundamental basis for calculating any risk at low levels of radiation exposure. However, there is an abundance of epidemiologic studies of persons exposed to ionising radiation, and these are the source of vast amounts of

information on cancer risks in humans. One such study is The Life Span Study (LSS) cohort of Japanese atomic bomb survivors (RERF 2007). This large cohort includes all ages and both sexes with a wide range of well-characterised doses. It is the primary resource for estimating carcinogenic risks from so-called low linear energy transfer external exposure, the range of exposure medical diagnostic radiation would fall into. These type of epidemiologic studies provide the necessary data for quantifying cancer risks as a function of radiation (Gilbert 2009:467). When analysing atomic bomb survivors morbidity and mortality, it was found that the cohort in the LSS was a heterogenous group, as there were both bomb-related and unrelated injuries. As such, significant differences between survivors with and without multiple injuries exist.

Some studies have suggested that certain low-dose exposed atomic bomb survivors live longer than their peers (Anderson 1973:643). In a cohort of survivors of the atomic bombings of Hiroshima and Nagasaki (Japan), the effect of radiation on life expectancy has been re-examined (Cologne and Preston 2000:303). In this prospective cohort study of 120,321 survivors, 45 years of mortality follow-up with radiation-dose estimates available for most cohort members were analysed. The relative mortality rates and survival distribution were calculated using internal comparison (cohort-based estimation of background mortality). The authors found that median life expectancy decreased with increasing radiation dose at a rate of approximately 1-3 years per Gy, and declined more rapidly at high doses. At estimated doses below 1 Gy, median loss of life among cohort members was about 2 months. The authors did not find that survivors exposed to low doses of radiation live longer than comparable unexposed individuals.

A group of radiologists have launched the website xrayrisk.com with the aim of “promoting responsible imaging through patient and provider education” (www.xrayrisk.com 2012) that allows the calculation of cancer risk for a variety of examinations. The methodoloy used on the website is based on the BEIR-VII report (NRC 2006:11-15). The authors have used estimates of numbers of additional cancer cases attributable to a single dose of 100 mSv, for different age groups and both sexes. The data are based on the incidence of all cancer types. The authors then plotted and extrapolated the data to achieve a formula which allows the calculation of cancer risk for any equivalent dose eceived, and any age and sex. They also adapted a table from Mettler et al that lists average adult doses for various medical imaging studies (Mettler, Huda, Yoshizumi and Mahesh 2008:254), for the purpose of comparison. Conversion

factors used for calculation of effective dose from DLP were 0.0022 mSv/mGy·cm for Head CT; 0.0054 mSv/mGy·cm for Neck CT; and 0.0180 mSv/mGy·cm for Body CT (Huda et al 2008:999).

2.6 PROJECTED PUBLIC HEALTH IMPLICATIONS OF MEDICAL DIAGNOSTIC RADIATION EXPOSURE

Overall little literature and data exist on the projected public health implications of radiation exposure. Prolific authors in this field have suggested that medical imaging radiation exposure might be responsible for 1-3% of all cancers worldwide (Berrington de Gonzalez and Darby 2004:345). The results of their research show that in the United Kingdom, approximately 0.6% of the cumulative risk of cancer to age 75 years could be attributable to diagnostic X-rays, which translated to an additional incidence of 700 cases of cancer per year. In other industrialised countries, point estimates of LAR ranged from 0.6% - 1.8%, with the risk being highest in Japan at more than 3%.

Brenner and Elliston (Brenner and Elliston 2004:735-738) estimate both radiation dose and risks from CT: a single full-body CT scan results in a mean effective radiation dose of 12 mSv - “To put this (dose) in perspective, a typical mammogram…has an effective dose of 0.13 mSv – a factor of almost 100 times less.” According to Brenner and Elliston’s calculations, “a 45-year- old adult who plans to undergo 30 annual full-body CT examinations would potentially accrue an estimated lifetime cancer mortality risk of 1.9% (almost 1 in 50)…Correspondingly, a 60-year-old who plans to undergo 15 annual full-body CT examinations would potentially accrue an estimated lifetime cancer mortality risk of one in 220” (Brenner and Elliston 2004:736).

Berrington de Gonzales et al also estimated that approximately 29,000 (95% uncertainty limits: 15,000-45,000) future cancers could be related to CT examinations performed in the United States in 2007. One-third of the projected cancers were due to scans performed at the ages of 35 to 54 years compared with 15% due to scans performed at ages younger than 18 years, and 66% were in females. In this study, the largest contributions were from scans of the abdomen and pelvis (n=14,000) (95% uncertainty limits: 6900-25000) (Berrington de Gonzalez et al 2009:2072).

Other studies have focused on certain subgoups of patients at risk of frequent or repeat scanning. Cumulative radiation exposure and LAR of radiation-induced cancer from CT

scanning of adult patients at a tertiary care academic medical center has been estimated in Sodickson et al (Sodickson et al 2009:175). This group used cumulative CT radiation exposure as a sum of typical CT effective doses. The BEIR-VII methodology was used to estimate LAR on the basis of sex and age at each exposure. In their cohort of 31,462 patients who had a CT in 2007, and had a total of 190,712 CTs since 1985, one third of cases had five or more CT examinations. 5% of cases had between 22 and 132 examinations over the 22 year period. There was a significant proportion of 15% of cases who received cumulative effective doses of more than 100 mSv. A minority (less than 4%) received cumulative high doses of up to 1.375 Sv. The calculated associated LAR for cancer incidence had mean and maximum values of 0.3% and 12%, and for cancer mortality mean and maximum values of 0.2% and 6.8%. This translated into 0.7% of total expected baseline cancer incidence and 1% of total cancer mortality due to CT radiation exposure. The researchers found that cumulative CT radiation exposure did add incrementally to the cohort's baseline cancer risk. Sodickson et al conclude that a subgroup is potentially at high risk due to recurrent CT imaging, although most patients accrue low radiation-induced cancer risks (Sodickson et al 2009:180).

Griffey and Sodickson (Griffey and Sodickson 2009:887-892) sought to define a conservative estimate of the number of patients in an emergency department undergoing repeat or multiple emergency department CT studies, and to quantify their cumulative CT radiation doses and LAR of incident cancer. Their cohort included patients who attended the emergency department on at least three occasions within a year, and underwent whole body CT. They found that among 130 emergency department patients over an almost 8-year period, mean cumulative dose was 122 mSv with a maximum of 579 mSv. The authors estimated LAR with a simplified formula derived from BEIR-VII methodology of one cancer per 1,000 patients receiving a 10 mSv dose. The mean LAR of cancer was 0.012 with a maximum of 0.056. The authors also found that a proportion of 1.9% of emergency department patients undergoing whole body CT of the have high cumulative rates of multiple or repeat imaging. This subgroup of patient may have a heightened risk of developing cancer from cumulative CT radiation exposure (Griffey and Sodickson 2009:182).

Although it is known that CT is associated with substantially higher radiation exposure than conventional radiography, typical dose levels are not normally known. Smith-

Bindmann et al (Smith-Bindman et al 2009:2078-2086) conducted a retrospective cross-sectional study describing radiation dose associated with the 11 most common types of diagnostic CT studies performed on 1119 consecutive adult patients at 4 separate institutions in the USA (Smith-Bindman et al 2009:2079). Using BEIR-VII methodology (NRC 2006), they estimate lifetime attributable risks of cancer by study type from these measured doses. The authors find that there was great variation in radiation doses between the different types of CT studies, and across institutions. The median effective doses ranged from 2 mSv for a routine head CT scan to 31 mSv for a multiphase abdomen and pelvis CT scan. Within each type of CT study, effective dose varied significantly within and across institutions, with a mean 13-fold variation between the highest and lowest dose for each study type. The estimated number of CT scans that will lead to the development of a cancer varied widely depending on the specific type of CT examination and the patient's age and sex (Smith-Bindman et al 2009:2080). The authors estimate that 1 in 270 women who underwent CT coronary angiography at the age 40 years will develop cancer from that CT scan (1 in 600 men), compared with an estimated 1 in 8,100 women who had a routine head CT scan at the same age (1 in 11,080 men). For 20-year-old patients, the risks were approximately doubled, and for 60-year-old patients, they were approximately 50% lower. The authors conclude that “radiation doses from commonly performed diagnostic CT examinations are higher and more variable than generally quoted, highlighting the need for greater standardization across institutions” (Smith-Bindman et al 2009:2083-2084).

In Richards et al (Richards et al 2008:347), the radiation dose of cervical spine and body CT in a cohort of unconscious, major trauma patients for three different scan protocols are compared. They sought to quantify the radiation exposure effect of the protocols on the lifetime cancer risk. With regards to CT of the whole cervical spine, they found that this may be justified in the unconscious, severely injured patient. However, in conscious trauma patients, the additional lifetime risk may not justify CT of the whole cervical spine as a routine practice (Richards et al 2008:347).

In addition to cancer, radiation exposure has been demonstrated to increase the risk of other diseases, particularly cardiovascular disease, in persons exposed to high therapeutic doses and also in atomic bomb survivors exposed to more modest doses. However, there is no direct evidence of increased risk of non-cancer diseases at low doses, and data are inadequate to quantify this risk if it exists. Radiation exposure has

also been shown to increase risks of some benign tumors, but again data are inadequate to quantify this risk (NRC 2006:8).

2.7 RADIATION EXPOSURE IN MEDICAL DIAGNOSTIC IMAGING

Over the past two decades, the capabilities of CT imaging have markedly increased with improved temporal and spatial resolution, thinner slices and shorter examination times. Despite this, the average dose per exam has decreased by a factor of two or more over the same time period (McCollough 2008:510). This is an argument in favour of relaying to patients that the benefits of justified CT outweigh the potential risks with radiation.

Data in the United States from 1996 through 2007 reveals a steep rise in the use of CT to diagnose illnesses in emergency departments. The rate of CT use grew 11 times faster than the rate of emergency department visits during the study period. Only 3.2 percent of emergency patients received CT scans in 1996, while in 2007, 13.9 percent of emergency patients underwent CT (Kocher, Meurer, Fazel, Scott, Krumholz and Nallamothu 2011:452).

CT contributed approximately 20% to the collective effective dose to the United Kingdom population from medical X-rays in 1990, but this rose to an estimated 40% in 1999. What is more is that much of the collective dose reduction achieved through advances in other areas had been offset by a corresponding increase in the collective dose from CT. In Crawley et al (Crawley et al 2001:607-614) effect optimization of image quality and patient dose is investigated in relation to the annual collective dose of the study's patient population. Over a 2 year period, they achieved a 33% reduction in annual collective ED (16.5 manSv to 11 manSv). Yet the annual collective ED has almost increased threefold since 9 years prior to they study, almost entirely a direct result of the increased use of CT (Crawley et al 2001:610).

Outside the emergency department, the frequency of diagnostic radiologic examinations has had increased, almost 10-fold, between the years 1950 and 2006. The United States per-capita annual effective dose from medical procedures has had increased approximately six fold, from 0.5 mSv in 1980 to 3.0 mSv in 2006. Worldwide, the

average annual per-capita effective dose from medicine (about 0.6 mSv of the total 3.0 mSv received from all sources) has approximately doubled in the past 10–15 years. (Mettler, Bhargavan, Faulkner, Gilley, Gray, Ibbott, Lipoti, Mahesh, McCrohan, Stabin, Thomadsen and Yoshizumi 2009:520).

French figures indicate that in medical diagnostic imaging, conventional radiology accounts for 90% of the total number of procedures but only 37% of the collective dose, whereas CT examinations make up only 8% of total examinations but 39% of the collective dose (Scanff, Donadieu, Pirard and Aubert 2008:204).

This marked increase of radiation exposure, primarily brought about by CT, places the cumulative medical exposures en par with natural background radiation exposure in the United States and other countries with comparable health systems (Schauer and Linton 2009:293).

2.8 DOSE SAVING STRATEGIES IN MEDICAL DIAGNOSTIC IMAGING

In 2010, a United States Food and Drug Administration White Paper outlined the goal that "each patient should get the right imaging exam, at the right time, with the right radiation dose" and detailed how this could be achieved (FDA 2010).
The basic concepts of justification, optimisation and limitation can also be applied to CT. In order to achieve dose savings, one can reduce the dose by performing a CT study employing a reduced dose technique. An alternative test can be performed by selecting a different test using less or no ionising radiation. Alternatively, the test may not be performed at all if the study is not justified. Dose savings can occur before, during and after the CT examination (Gerstenmaier et al 2011).

2.8.1 Dose saving before the examination

Clinical decision rules can help overcome factors that result in CT studies being performed when they are not justifiable or unhelpful on clinical grounds. Decision making algorithms can help to decide whether an alternative test is equally suitable or better. An example is a ventilation/perfusion scan instead of CT pulmonary angiogram in the setting of a normal chest radiograph. Educational intervention using an

emergency department chest pain algorithm has been shown to reduce radiation dose in patients with suspected pulmonary embolism (Stein et al 2010:392, due to selection of an appropriate imaging modality.

Another example of dose reduction is the diagnostic strategy in the workup of subarachnoid haemorrhage where structured imaging guidelines designed to direct the clinician in selecting the appropriate type of exam (i.e. CT angiogram, CT perfusion) and timing, have been proven to reduce cumulative radiation exposure by 12% (Loftus, Minkowitz, Tsiouris, Min and Sanelli 2010:176).

A number of resources are available for physicians to determine the most appropriate test. One such example is the American College of Radiology Appropriateness Criteria® evidence-based guidelines which help guide appropriate imaging decisions (ACR 2012). The guidelines are also available for a variety of mobile device platforms. In the United Kingdom, 'iRefer' by the Royal College of Radiologists (RCR 2012) contributes to the reduction of unnecessary radiation exposures.

2.8.2 Dose saving during the examination

The most efficient way to reduce radiation dose when a CT is clinically appropriate is through adaptation of the scan parameters according to the anatomy of the patient (Siemens 2012). Due to increased utilization of CT and therefore increased individual as well as population doses, the manufacturers of CT systems have developed several options to appropriately manage or reduce the radiation dose from CT. The principle mechanisms for dose reduction during a CT examination are listed X-ray tube current modulation, kVp optimisation, X-ray beam filtration, X-ray beam filtration, and noise reduction algorithms.

2.8.2.1 Tube current modulation

Tube current modulation is actually a major contributor to dose (McCollough, Bruesewitz and Kofler 2006:503) It has been reported that dose reductions of 20% - 50% are possible using tube current modulation techniques (McCollough 2008:509). The tube current can be modulated according to patient attenuation, or a sinusoidal-type function (McCollough et al 2006:503).

Feedback mechanisms exist in CT systems where the X-ray tube output is directed by the incident amount of radiation in a detector on the other side of the patient's body. For example, a large person will absorb more radiation, therefore there will be less incident radiation at the detector, which results in increased output from the X-ray tube to maintain adequate levels of radiation for image quality.

2.8.2.2 AEC at St. Vincent's University Hospital

The automatic exposure control in the CT systems of the Department of Radiology at St. Vincent's University Hospital, Dublin/Ireland requires a reference level from which to adjust the mAs for individual patients. This must be defined by the operator, and in SIEMENS systems this is called "Quality Reference mAs" (Siemens 2007).

The noise target (standard deviation of CT numbers) is varied on the basis of patient size by using an empirical algorithm; thus, image noise is not kept constant for all patients but is adjusted according to an empirical impression of image quality. Following the topogram, the "effective mAs" is adjusted for patient attenuation. The effective mAs is a SIEMENS concept (Primak, McCollough, Bruesewitz, Zhang and Fletcher 2006:1785). and is the tube mA multiplied by rotation time and divided by pitch. This will yield the desired image quality, given individual patients' size and anatomy. An online feedback system fine-tunes the actual tube current values during scanning to precisely match the patient-specific attenuation values at all angles. The default setting for Quality Reference mAs in CTKUB is 100 mAs. In an attempt to make radiation dose savings, this reference value has been lowered to 60 mAs.

2.8.2.3 Other techniques

Radiation shielding using a variety of materials has been used to shield radiosensitive organs, such as eyes during head and neck examinatins, or breasts during chest examinations. The use of bismuth breast shields together with a lower kVp and automatic tube current modulation has been shown to reduce the absorbed radiation dose to the breast and lungs without degradation of image quality to the organs of the thorax during CT chest (Hurwitz, Yoshizumi, Goodman, Nelson, Toncheva, Nguyen, Lowry and Anderson-Evans 2009:244).

X-ray tube current modulation is carried out by automatic exposure control (AEC). Care should be taken when radiation shielding is used as AEC can theoretically increase the

tube current to compensate for the shield (Paterson and Frush 2007:507). In addition, bismuth shields may compromise image quality.
A more recent development is breast displacement with a reported reduction of organ dose by 90% during abdominal CT (Swaney 2011). Additional parameters that can be manipulated to lower dose include gantry rotation time, table speed and detector configuration.

In paediatric radiology, optimising CT protocols involves the avoidance of multiphase examinations where possible. Image Wisely™ (imagewisely 2010) and its paediatric counterpart Image Gently Campaign (imagegently 2011) are valuable resources for information on low-dose techniques. Nievenstein et al. recently reviewed dose reduction strategies in paediatric cardiology (Nievelstein, van Dam and van der Molen 2010:1324).

New technical developments are made by various manufacturers. For cardiac or thoracic imaging, these include adaptive electrocardiogram (ECG) pulsing and ECG dose modulation.

Dual Energy CT systems (DECT) may be able to reduce radtiation dose by cutting the number of phase examinations, i.e. tests where a non-enhanced CT is followed by one or several phases (scans) of intravenous contrast-enhanced CT. This can be achieved by calculating a virtual non-enhanced (noncontrast) image from the image obtained during contrast enhancement.
An American group showed that substantial radiation dose savings are possible with DECT imaging if virtual noncontrast imaging reconstruction replaces precontrast imaging (Ho, Yoshizumi, Hurwitz, Nelson, Marin, Toncheva and Schindera 2009:1400). However, radiation doses with DECT were higher using the CT scanner manufacturer's proprietary image reconstruction software. For electrocardiographically gated coronary CT angiography, image noise equivalent to that of multi–detector row CT can be achieved with DECT at doses comparable to or up to a factor of two lower than the doses at multi–detector row CT, depending on heart rate of the patient (McCollough, Primak, Saba, Bruder, Stierstorfer, Raupach, Suess, Schmidt, Ohnesorge and Flohr 2007:775).
In additon, DECT allows the generation of virtual non-contrast images from a contrast examination. For example, urinary stones can be detected with virtual non-enhanced

images from a contrast-enhanced abdominal CT (Stolzmann, Scheffel, Frauenfelder, Schertler, Desbiolles, Leschka, Marincek and Alkadhi 2007). This could reduce the number of phases when a multiphase CT is planned.

Other techniques include organ-based dose modulation, and automated dose modulation involving variable kV (in addition to conventional current modulation).
Information technology tools will be critical in helping reduce radiation exposure from medical imaging (Prevedello, Sodickson, Andriole and Khorasani 2009:125). Advanced reconstruction techniques (e.g. iterative reconstruction in space, and sinogram-affirmed iterative reconstruction) allow for decoupling of spatial resolution and image noise
With regards to multidetector CT (MDCT), initial data on dose reduction in 320 MDCT suggests the potential for dose reduction but more work is needed to confirm this (Bauknecht, Siebert, Dannenberg, Bohner, Jach, Diekmann, Scheurig and Klingebiel 2010:199; Kroft, Roelofs and Geleijns 2010:294).

2.8.2.4 WHO's Global Initiative on Radiation Safety in Health Care Settings

Some of the World Health Organization's (WHO) responsibilities include the recommendation of "evidence-based public health policy to protect health and reduce radiation risks"; and the provision of "technical support and capacity building on radiation protection and health" (WHO 2008). The WHO has now launched the Global Initiative on Radiation Safety in Health Care Settings, which aims to bring together key stakeholders for combined action, and aims to complement the International Action Plan for the Radiological Protection of Patients (IAEA 2002).

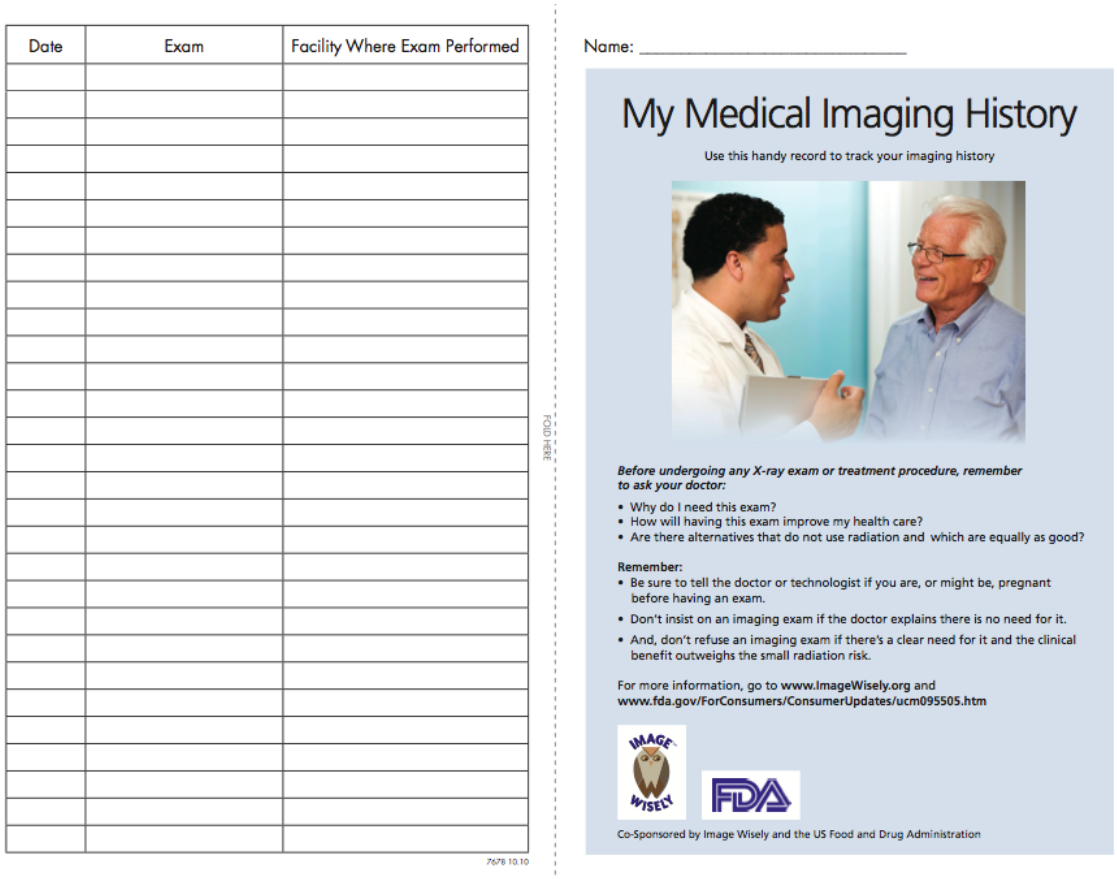
As radiation is used so widely in medicine, a public health approach to controlling and minimizing health risks, while maximizing the benefits has been stipulated. Within this framework, particular consideration is given to the evaluation of possible health hazards related to the use of radiation. Based on scientific evidence, the WHO hopes to raise awareness by promoting radiation safety in medicine especially by preventing unnecessary medical radiation exposures. The initiative aims to devlelop a referral tool in order to justify medical radiation exposures (WHO 2008).

2.8.3 Dose saving after the examination

Subgroups of patients where radiation curtailment is of particular importance are those with chronic conditions requiring serial imaging. Examples are patients with inflammatory bowel disease, cystic fibrosis and chronic liver disease. Accurate records of radiation exposure help maintaining awareness of a patient's cumulative dose.

The American College of Radiology (ACR) and the International Atomic Energy Agency (IAEA) both recommend that hospitals monitor radiation exposure. Radiation dose entry into the health record enables physicians to see dose accumulations, thereby creating a "Radiation account". Important considerations on the way to widespread implementation have been discussed (Sodickson and Khorasani 2010:752-754). It may take time and investment before all hospitals have the ability to track individual exposure.

Empowering patients to keep a record of, and also query repeat examinations if there is doubt regarding duplicate tests, as well as patient awareness is part of the FDA strategy (FDA 2010). FDA, ACR and RSNA have teamed up to disseminate a Patient Medical Imaging Record, and example of such a "Radiation passport" is shown in Figure 2.1.



Date	Exam	Facility Where Exam Performed

7678 10.10

FOLD HERE

Name: _____

My Medical Imaging History

Use this handy record to track your imaging history

Before undergoing any X-ray exam or treatment procedure, remember to ask your doctor:

- Why do I need this exam?
- How will having this exam improve my health care?
- Are there alternatives that do not use radiation and which are equally as good?

Remember:

- Be sure to tell the doctor or technologist if you are, or might be, pregnant before having an exam.
- Don't insist on an imaging exam if the doctor explains there is no need for it.
- And, don't refuse an imaging exam if there's a clear need for it and the clinical benefit outweighs the small radiation risk.

For more information, go to **www.ImageWisely.org** and **www.fda.gov/ForConsumers/ConsumerUpdates/ucm095505.htm**

Co-Sponsored by Image Wisely and the US Food and Drug Administration

(http://www.radiologyinfo.org/en/safety/ImageWisely/7678_Medical%20Imaging%20History.pdf)

Figure 2.1 My Medical Imaging History

The use of low-dose chest examinations is becoming established, but image quality may be subobtimal. Post-processing with a software filter providing context-controlled restoration of digital images promises to improve diagnostic performance in these types of examination (Martinsen, Saether, Olsen, Wolff and Skaane 2010:3242).

2.9 CONCLUSION

In this chapter, following review and discussion of radiobiological models, radiation exposures in medical diagnostic imaging, and projected public health implications, several methods of dose savings have been outlined.

Many of these methods require the acquisition of new software or hardware, with significant financial implications. On the other hand, several ways of achieving dose savings exist that do not need new financial commitments, and that are easy to apply with existing systems.

Despite the challenges associated with understanding the health effects of low doses of radiation, current knowledge allows several conclusions.

The BEIR-VII committee concludes that current scientific evidence is consistent with the hypothesis that there is a linear dose response relationship between exposure to ionising radiation and the development of radiation-induced solid cancers in humans. The committee further judges it unlikely that a threshold exists for the induction of cancers but notes that the occurrence of radiation-induced cancers at low doses will be small. The committee maintains that other health effects (such as cardiac disease and cerebrovascular accidents) occur at high radiation doses, but additional data must be gathered before an assessment can be made of any possible connection between low doses of radiation as seen in diagnostic imaging and non-cancer health effects. Additionally, the committee concludes that although adverse health effects in children of exposed parents (attributable to radiation-induced mutations) have not been found, there are extensive data on radiation-induced transmissible mutations in mice and other organisms. There is no reason to believe that humans would be immune to this sort of harm.

CHAPTER 3
RESEARCH DESIGN AND METHOD

3.1 INTRODUCTION

In this chapter, the study design and method of an analysis of a dose saving intervention in the radiology department are described; a method without the need for new soft- or hardware, and that can be implemented by the radiography technician without the need of an engineer. The intervention is a change in the CT X-ray tube current parameter. This was part of the Department of Radiology at St Vincent's University Hospital, Dublin (the Department) service evaluation and improvement programme.

3.2 RESEARCH DESIGN

An explanatory retrospective design is chosen (Johnson and Christensen 2012:361). Therefore this is a retrospective comparative analysis of radiation exposure among two independent groups (Group 1 and Group 2) undergoing CTKUB. The Quality Reference mAs for CTKUB was lowered ffrom 100 mAs to 60 mAs. Group 1 consisted of consecutive patients receiving the test with the imaging parameter used after a changeover date for the new imaging protocol (Quality Reference mAs of 60 mAs).
This changeover took place in early 2011. Group 2 consisted of patients that are age and sex matched against Group 1 and who had been referred for a CTKUB before the changeover date for the new imaging parameters. No patients receive extra radiation because of this study.
Within the Department, the imaging parameters were altered (independent of this study) so that the test remained diagnostic, but radiation dose may be reduced. Only after this change was this research designed and carried out.

3.3 RESEARCH METHOD

3.3.1 Sampling

The research setting was St. Vincent's University Hospital, a large teaching hospital in Dublin/Ireland. The average number of CTKUB per year is approximately 420. The sampling frame was three months, i.e. approximately 100 cases per three months. The sample consisted of two independent groups of patients who were referred to radiology for a CTKUB.

Reverese consecutive sampling from RIS/PACS of all patients undergoing CTKUB at SVUH from 30/8/2011 to 30/5/2011 (Quality Reference mAs = 60 mAs) was conducted. There were no exclusion criteria. The RIS/PACS system was interrogated with a syntax consisting of this timeframe (30/05/2011-30/08/2011), and the relevant procedure code (anf_code="CT.CTKUB"). This generated a list of all CTKUB examinations. Subsequently, age and sex matching of all cases was made with with CTKUB examinations carried out in 2009 (Quality Reference mAs = 100 mAs). The cases from 2009 were retrieved from RIS/PACS in the same manner, i.e. with a search syntax consisting of the relevant timeframe and the procedure code for CTKUB.

3.3.2 Data collection

A Case Record Form (CRF) was completed for each case of Groups 1 and 2 (Annexure 1). All data were obtained from the Department's RIS/PACS system (Siemens, Erlangen/Germany). The following variables were obtained for each case and recorded on the CRF: unique, anonymous identifier (Study ID); age; sex; reference mAs; effective mAs; CTDI; DLP. The study was retrospective. At the time of data collection, all data already existed on RIS/PACS, but had to be manually sourced and retrieved. A Microsoft® Excel® 2008 for Mac Version 12.2.9 (Microsoft Corporation, Redmond WA/USA) spreadsheet was prepared with columns headed by the following variables: Study ID; age; sex; Dose report obtained from RIS/PACS: reference mAs; effective mAs; CTDI; DLP. The Excel® cells were filled with the raw data obtained from the CRF.

For the nested audit of image quality, every 5th matched pair was blinded and randomised, which resulted in a list of Study IDs (without study date or any other information attached). The imaging of this sub-sample of 20% of the matched pairs of

studies was presented blindly to two independent reviewers (reviewer A and reviewer B) who rated the image quality on a 5-point quality scale. The values on the 5-point image quality scale assigned were: 1= Excellent 2=Good; 3=Fair; 4=Poor; 5=Nondiagnostic. Quality scales with five points or similar have been used extensively in radiological research, e.g. by Ganten et al (Ganten, Radeleff, Kampschulte, Daniels, Kauffmann and Hansmann 2003:171-176), and were felt appropriate for the purpose of this study.

3.3.3 Data analysis

Following data entry into Microsoft® Excel® 2008 for Mac Version 12.2.9 (Microsoft Corporation, Redmond WA/USA), means of age, effective mAs, CTDI, DLP were calculated. ED (in mSv) was calculated using a conversion factor of 0.0190 mSv/mGy·cm which is suitable for an examination such as CTKUB wich involves irradiation of the abdomen and pelvis (Huda et al 2008:999).

Using BEIR-VII methodology (NRC 2006:14), the estimated LAR for incident cancer was calculated for each case based on age and sex, expressed in cases per 100,000 per the respective ED. A table was adapted from the BEIR-VII Phase 2 report (Table 3.1).

Table 3.1 Lifetime Attributable Risk of Cancer Incidence
Number of cases per 100,000 persons exposed to a single dose of 0.1 Gy. Estimates based on relative and absolute risk transport (adapted from BEIR-VII Phase 2 report, page 311).

	Age at exposure (years)										
	0	5	10	15	20	30	40	50	60	70	80
males											
all cancers	2563	1816	1445	1182	977	686	648	591	489	343	174
females											
all cancers	4777	3377	2611	2064	1646	1065	886	740	586	409	214

The table is a summary of estimates of the number of additional cases of cancer (all cancer types) attributable to a single dose of 100 mGy, for both sexes and different age groups. The data from the table were plotted, and a trendline generated based on regression formulae (Figue 3.1) with age being the independent variable, and number of incident cancer being the dependent variable. This enabled the calculation of the number of additional cases of cancer for any age. Trendline and formula are functions

of Excel® 2008. The formula derived for males was number of incident cancer (y) as a function of age (x): $y = 1997.6e^{-0.027x}$; and for females number of incident cancer (y) as a function of age (x): $y = 3757.8e^{-0.034x}$. Power equations appeared to have the best fit. These formulae were applied to cases within both groups, and then the number of additional cancer cases per single dose of 100 mGy were converted to the number of additional cancer cases per ED respective to the cases in both groups. The unpaired (two-sample) two-tailed *t*-test was used to test for differences in effective tube current, ED and estimated LAR bewteen the two groups, and within the two groups bewteen males and females.

For the nested image quality audit, the null hypothesis H_0 = *the distribution of image quality scores is the same in the 60 mAs and the 100 mAs group* was tested against the alternative hypothesis H_1 = *the distribution of image quality scores is not the same in the 60 mAs and the 100 mAs group* with the Mann-Whitney-U test, for each reviewers A and B.

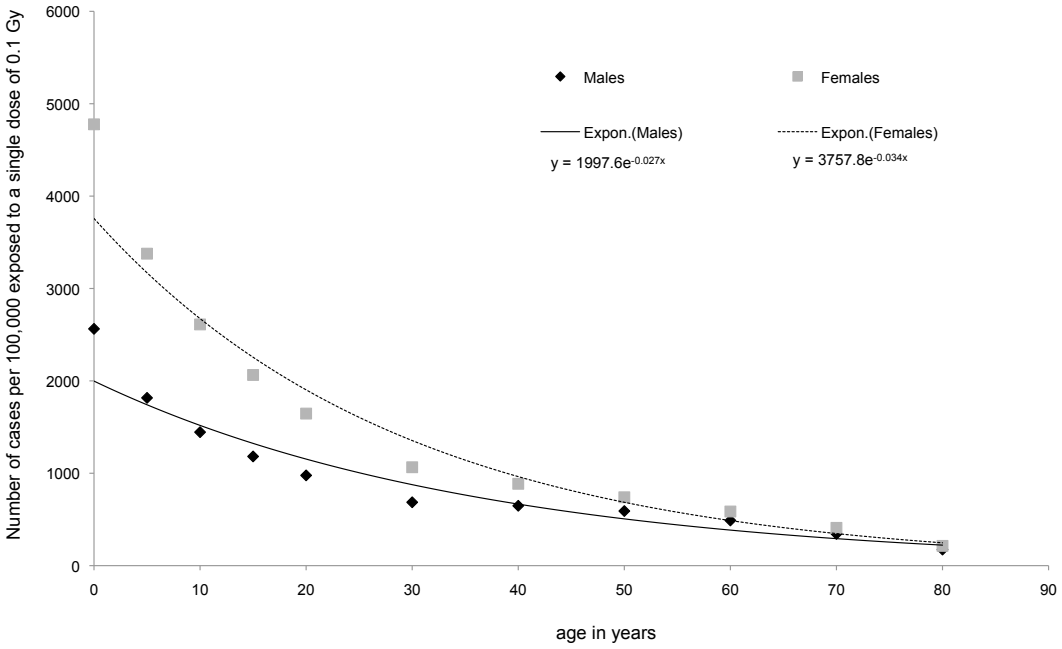


Figure 3.1 Trend lines and formulae from data points of Table 3.1

3.4 INTERNAL AND EXTERNAL VALIDITY OF THE STUDY

The study was of a descriptive quantitative nature, and pre- and post intervention measurements are made. This particular setting had the character of clinical audit (Ashmore and Ruthven 2008:18-22), and should not be regarded as experimental.

The radiation indices that were used for dose calculations were recorded and provided by the CT scanning system (Somatom Sensation 64 Cardiac, Siemens, Erlangen/Germany) and this is subject to rigorous and regular quality control. In Europe, imaging systems are similar nowadays in terms of exposure control.

External validity of the sampling design: The accessible population included patients undergoing CTKUB, and was representative of the population of hospital patients, as both normally well, chronically ill, and acutely ill patients typically undergo these tests. Consecutive sampling was employed, which is considered the best of non-probability sampling methods. However, this may have posed a threat to external validity. Approximately 100 CTKUB each are carried out over a three-month period in the Department, therefore choosing a timeframe of three months was considered to maintain external validity in terms of sampling.

The use of CTDI to calculate the ED is an established and widely accepted process (Huda 2008:995-1003). The estimation of LAR of incident cancer follows the BEIR-VII methodology, and therefore has the backing of an international committee on experts. However it should be noted that this methodology has the LNT theory as a basis, and a fundamental question persists whether this theory is appropriate for dose levels typically delivered at CT.

3.5 ETHICAL CONSIDERATIONS

The UNISA Ethical Clearance Certificate is included in Annexure 5.

a) Anonymity - The study was conducted on a local population basis. All gathered information was anonymous. As a unique identifier, the Study ID was used, which is a numeric code attributed to an individual examination. This Study ID cannot be used by the Hospital Information System or elsewhere to draw conclusions about individuals'

identity. Information on individual CT examinations was limited to the date of the examination, body parts examined and radiation exposure factors.

b) Character of the study - This was a retrospective observational study where the investigator was not involved in patient management.

c) Patient permission – this was a retrospective study and service evaluation, for which review by the Hospital Audit Committee was required at St. Vincent's University Hospital. An application in this regard was been made to the Committee (Annexure 3), and a formal decision was granted (Annexure 4). Obtaining the data had no impact on diagnosis and management of patients. The requirement for informed consent was waived, and direct patient permission was not sought.

d) Patient protection - in the unlikely event that patients were found to have received a radiation exposure outwith DRL, the Radiation Protection Adviser (RPA) or the Radiation Protection Board of the Hospital would have been notified who would have take appropriate and necessary measures. Any untoward excess exposure would have normally been recognised by radiography staff at the time of examination, and reported to the RPA. The respective roles of the RPA or the Radiation Protection Board are explained in the Glossary of Terms. An image quality control audit was carried out to ensure that there was no significant difference in image quality between the two groups.

e) Duty to disseminate results – results will be presented to the Radiation Protection Board of the Department of Radiology, St. Vincent's University Hospital Dublin/Ireland with suggestions for potential changes in practice. It will also be presented to the Audit Committee in the form of an audit report. It may be presented as a poster during the Hospital's Study Day depending on the findings.

f) Benefit to others – findings are hoped to benefit future patients in receiving a lower radiation dose.

g) Special considerations regarding the use of information technology (IT) – all data were obtained from the Department's RIS/PACS system, which is embedded in the hospital's IT networks. Therefore the hospital's IT policy was adhered to. In addition, the principles of Good Medical Practice including confidentiality were maintained.

3.6 CONCLUSION

In this chapter, study design and method of an analysis of a dose saving intervention in the radiology department are described, and ethical considerations of this evaluation highlighted.

CHAPTER 4

ANALYSIS, PRESENTATION AND DESCRIPTION OF THE RESEARCH FINDINGS

4.1 INTRODUCTION

A description of data handling and data analysis of the study is reported. Prior to the outcome of the nested image quality audit, the outcome of the comparative study is presented.

4.2 DATA MANAGEMENT AND ANALYSIS

Data were managed and analysed with Microsoft® Excel® 2008 for Mac Version 12.2.9 (Microsoft Corporation, Redmond WA/USA). Data were obtained from the RIS/PACS system, and manually entered into Excel®, as described in the previous chapter. Excel® formulae AVERAGE, STDEV and arithmetic were used to calculate ED, LAR, means and standard deviations. For the nested image quality audit, the Mann-Whitney-U test was applied using an online tool from the Virginia Commonwealth University (VCU 2012). Graphs were produced using Excel®.

4.3 RESEARCH RESULTS

4.3.1 Results of the comparative survey

The primary questions were:

How will the effective mAs and ED change following a reduction of CTKUB Quality Reference mAs?

How will the estimated LAR of incident cancer change following a reduction of CTKUB Quality Reference mAs?

The study population comprised of all patients who have undergone CTKUB since electronic records began. Between 7/7/2006 and 30/8/2011, 1667 CTKUB were carried out at St Vincent's University Hospital.

During the sampling timeframe bewteen 30/5/2011 and 30/8/2011, 118 CTKUB were carried out. These were matched with 118 CTKUB from the year 2009, when the Quality Reference mAs was set at 100 mAs.

Of those 336 examinations, 30 were censored: Ten cases in the 60 mAs group due to Quality Reference mAs adjustment at the radiographer's discretion; four cases in the 100mAs group due to Quality Reference mAs adjustment at the radiographer's discretion; one case in the 100mAs group due to non-availability of either a dose report on PACS or MPPS data on RIS/PACS. The reasons for Quality Reference mAs adjustment were severe obesity, or severe cachexia.

The Quality Reference mAs adjustments at the discretion of the radiographer in the 100 mAs group ranged between 75 mAs and 250 mAs. The Quality Reference mAs adjustments in the 60 mAs group ranged between 30 mAs and 180 mAs. These ranges are for excluded patients.

Left for analysis were 103 pairs of cases that underwent CTKUB. Figure 4.1 gives an overview of the survey.

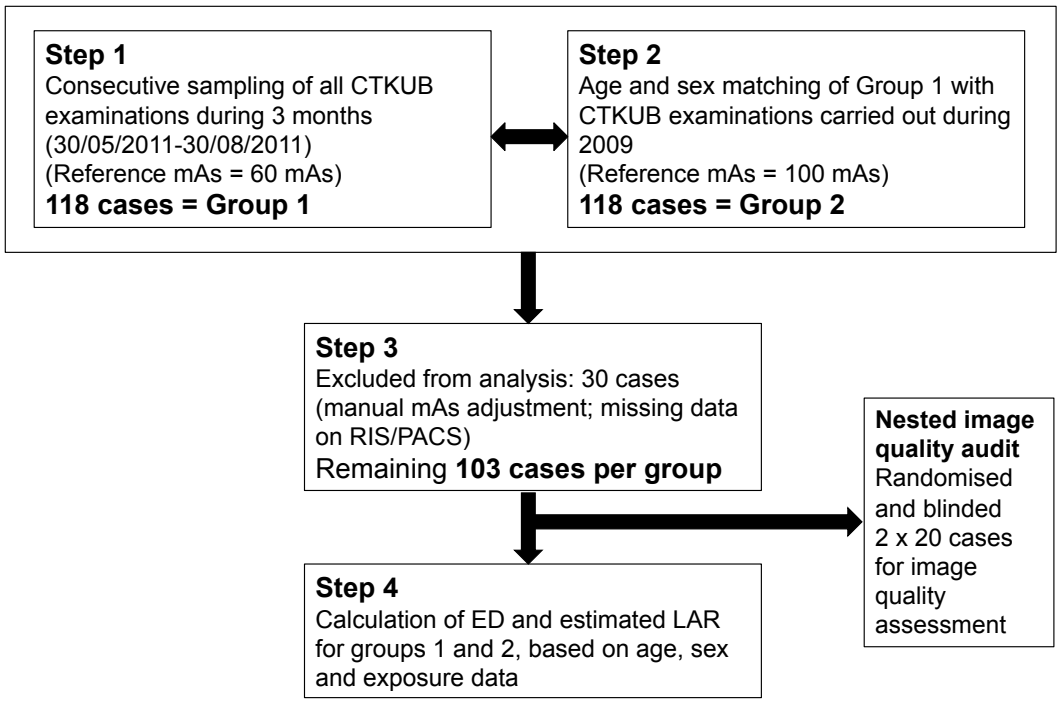


Figure 4.1 Flowchart of the Survey

In each of the two groups, there were 45 female and 58 male cases. The mean age was 47.3 ± 15.4 years (range 19-82 years). The age distribution was normal with a confidence of 30.33%, the age distribution among males was normal with a confidence of 54.51%, and the age distribution among females was normal with a confidence of 50.82% (Anderson-Darlington normality test). The age distribution is illustrated in Figure 4.2. The results for both groups, and for males and females within each group, are listed in tables 4.1 and 4.2 respectively. In the 60 mAs group, mean effective tube current was 46.14 ± 10.04 mAs, mean DLP 152.79 ± 39.31 mGy • cm, and mean effective dose 2.9 ± 0.7 mSv. In the 100 mAs group, mean effective tube current was 72.97 ± 15.8 mAs, mean DLP 243.45 ± 57.74 mGy • cm, and mean effective dose 4.6 ± 1.1 mSv.

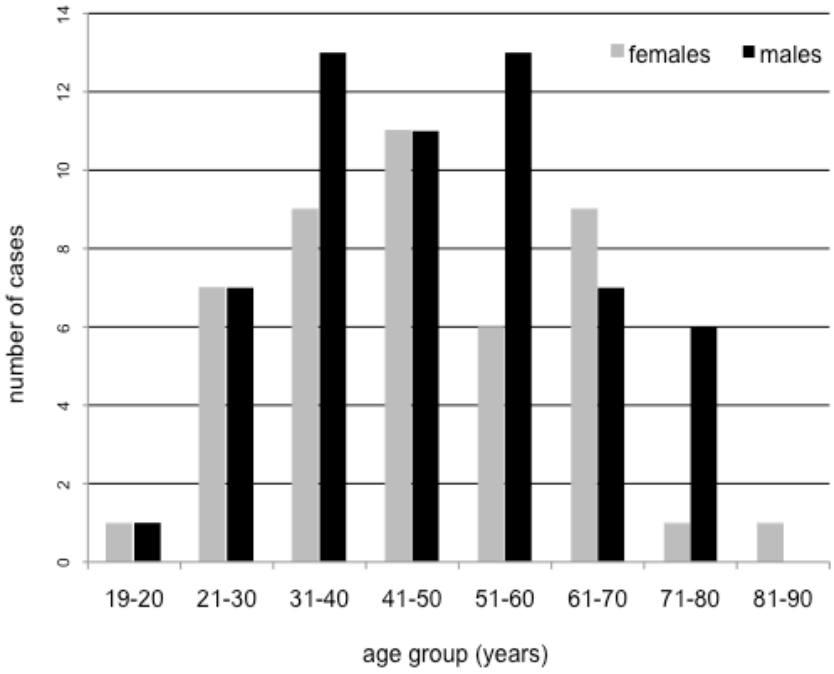


Figure 4.2 Age (group) distribution

Using BEIR-VII methodology, the estimated LAR expressed as mean number of cases per respective ED per 100,000 population was 19.92 ± 10.03 for Group 1, and 32.16 ± 15.17 for Group 2. This means that using a conservative estimation method, the estimated number of incident cancers per 100,000 population using the mean ED with the new protocol (60 mAs) has reduced to just under 20, compared with just over 32 cases using the old protocol (100 mAs).

Among the two groups, there was a significant difference bewteen estimated LAR for males and females, an expected finding given the differences in radiobiology bewteen males and females. Contributing to the difference in estimated LAR, there was a significant difference bewteen males and females in terms of DLP, and therefore ED.

Table 4.1 Results for Groups 1 and 2

	Group 1	Group 2	
n	all cases 103 mean (SD)	all cases 103 mean (SD)	P*
ETC (mAs)	46.14 (10.04)	72.91 (15.8)	**<0.0001**
DLP (mGy•cm)	152.79 (39.31)	243.45 (57.74)	**<0.0001**
ED (mSv)	2.91 (0.74)	4.63 (1.09)	**<0.0001**
LAR	19.92 (10.30)	32.16 (15.17)	**<0.0001**

* unpaired (two-sample) two-tailed *t*-test

Table 4.2 Results for Groups 1 and 2 by males and females

	Group 1			Group 2		
n	males 58 mean (SD)	females 45 mean (SD)	p	males 58 mean (SD)	females 45 mean (SD)	P*
ETC (mAs)	46.60 (9.56)	45.53 (10.72)	0.594	75.37 (15.15)	69.86 (16.15)	0.078
DLP (mGy•cm)	158.29 (37.95)	145.71 (40.29)	0.107	259.93 (56.35)	222.22 (52.62)	**<0.005**
ED (mSv)	3.01 (0.72)	2.76 (0.76)	0.091	4.93 (1.07)	4.22 (0.99)	**<0.005**
LAR	17.51 (7.65)	23.04 (12.35)	**<0.005**	28.73 (12.05)	36.58 (17.59)	**<0.005**

* unpaired (two-sample) two-tailed *t*-test

4.3.2 Results of nested image quality audit

The secondary research question was:

Is there any significant image quality difference following a reduction of CTKUB Quality Reference mAs?

For both observers A and B, there was no difference in distribution of values on the image quality scale from 1 to 5. The range of values for the 60 mAs group was 1-4 for observer A, and 2-4 for observer B, and for the 100 mAs group values were 1-5 for observer A, and 2-4 for observer B. No statistical significant difference in image quality was detected between the two groups (2 reviewers: Median 2 and 2.5; p=0.62 and p=0.91). The null hypothesis was accepted: *The distribution of image quality scores is the same in the 60 mAs and the 100 mAs group.* Therefore, there was no significant difference in image quality between the two protocols. This was a test of overall image quality, and image noise – by definition increased with decreased tube current – was not formally assessed.

Table 4.3 Nested image quality audit
Values: 1=excellent; 2=good; 3=fair; 4=poor; 5=non-diagnostic.

Observer A:

	100 mAs (Group 2)	60 mAs (Group 1)	P*
Values	1,1,1,1,1,1,1,1,1,2,2,2,2,3,3,3,4,4,5,5	1,1,1,1,1,1,1,1,1,2,2,2,2,2,2,3,3,3,3,4	
$P_{(Normality)}$	0.07% (Anderson-Darling normality test)	0.05% (Anderson-Darling normality test)	0.6202
Median	2	2	

*Mann-Whitney-U Test (2-tailed)

Observer B:

	100 mAs (Group 2)	60 mAs (Group 1)	P*
Values	2,2,2,2,2,2,2,2,2,3,3,3,3,3,3,3,3,4	2,2,2,2,2,2,2,2,2,3,3,3,3,3,3,3,4,4	
$P_{(Normality)}$	0% (Anderson-Darling normality test)	0% (Anderson-Darling normality test)	0.9058
Median	2.5	2.5	

*Mann-Whitney-U Test (2-tailed)

4.4 OVERVIEW OF RESEARCH FINDINGS

The image quality audit showed that there was no significant difference in image quality between the two groups. A 40% reduction in quality reference tube current resulted in a 36.7% reduction in effective mAs, and a 37.1% reduction in effective dose. Using BEIR-VII methodology, the estimated LAR of cancer incidence was reduced by 38.1%. There is a near-proportional relationship between Quality Reference mAs, and resultant effective tube current and effective dose without significant image compromise in CTKUB.

4.5 CONCLUSION

Reducing the exposure factors (Quality Reference mAs), as set by the CT system's manufacturer, for this particular type of examination (CTKUB) can achieve significant dose saving without significant image quality compromise.

CHAPTER 5
CONCLUSION AND RECOMMENDATIONS

5.1 INTRODUCTION

In the previous two chapters, the assessment of an effective and apparently safe method of radiation dose reduction was described. In this chapter, the findings are put into the context of the debate around medical radiation exposure.

5.2 SUMMARY AND INTERPRETATION OF THE RESEARCH FINDINGS

The literature review highlighted the controversy around different models of radiobiology. The LNT model is used as the basis of the vast majority of LAR estimation in all recent publications on the topic. The ICRP and the BEIR VII reports do recognise that there are biological arguments against the LNT model. However it is felt that there are not sufficient biological proofs against it to change current risk assessment methodology and subsequently regulatory policy. The main opponents of the LNT are the French Academies of Science and Medicine, and the Health Physics society.

It is common practice to aim for radiation dose savings in radiology - whatever “camp” of radiobiological model one belongs to. Therefore the ALARA/ALARP principle is followed. In chapter 2.7, a variety of dose saving strategies are reviewed. Many are costly or cumbersome. Variation in ED across different hospitals within the same health system has been shown. There is scope to employ simple technological and non-technological interventions to reduce dose. The results of this study showed that reducing the Quality Reference mAs in our CT systems can save nearly 40% of ED delivered to our population, without significant image quality compromise.

As both dose and risk reductions were in the region of 40%, i.e. the same percentage of reduction bewteen Quality Reference mAs, it would appear that the effect of the tube current setting on total dose could be calculated or predicted. These similar percentages are likely incidental. In a previous study on the effect of altering Quality Reference mAs on dose, image quality and diagnostic efficacy, there was no linear relationship between the reduction in Quality Reference mAs and the resultant CTDI. In

the same CT system as in the present study, a reduction in Quality Reference mAs from 260 mAs to 220 mAs resulted in a reduction of the CTDI from 15.72 to 11.42 mGy (Allen, Baker, Einstein, Remer, Herts, Achkar, Davros, Novak and Obuchowski 2010:89-100). Therefore, a 15% reduction of Quality Reference mAs resluted in a 28% reduction in CTDI.

5.3 LIMITATIONS OF THE STUDY

This study had several limitations. The retrospective nature is suboptimal, and a prospective, experimental, randomised study would be a stronger design. However, this would carry multiple ethical and logistical implications, which would be beyond the scope of this work. In addition, the power of the study could have been improved e.g. by age and sex matching four historic controls to each person at the new dose.

There was a significant difference between males and females in Group 2 for DLP, ED and estimated LAR. In Group 1, the difference between males and females was only significant for estimated LAR. The most obvious explanation for the difference in DLP, and hence ED is natural size differences between males and females: taller or larger persons will have a greater scan length, and a greater effective tube current, and therefore a greater DLP. Estimated LAR depends on age and sex, therefore the difference between males and females in both groups is accentuated further. For the purpose of estimating LAR, the male:female ratio ideally should have been 1:1, but an approximation was achieved. On the other hand, age and sex profile of the two groups appeared to be representative of our patient population, and reflects the slightly higher incidence of urinary tract calculi in males. The age distribution was normal, and similar to the age distribution of estimated number of all CT scans in the USA in 2007 (Berrington de Gonzalez et al 2009:2073).

In addition, the determination of equivalent dose received during CT by means of using exposure data from the CT scanner for each exam, age and sex is only a very good approximation, but not an actual measurement. Using ionisation chambers to measure CTDI for each examination would be complex and involved.

Directly translating population CT exposure to cancer risk is problematic in several ways: The time thought for a cancer develops is several years, therefore CT

examinations performed in the last years of life are not relevant contributors to cancer risk. Populations already affected by cancer, and those who develop cancer shortly following exposure (average time to develop radiation induced cancer is considered 5 years) should be censored, too. However, for the purpose of this study, estimated cancer LAR is considered to be relevant for every individual patient. The LNT principle has been criticised (Cohen 2008:7; McCollough et al 2009(1):28-30; HPS 2010), and effective dose should not be used for epidemiologic studies or for estimating population risks (McCollough et al 2010:894). As discussed, other models of radiation biology exist – some even postulate beneficial effects of low dose radiation (Feinendegen 2005:3-5).
Estimated LAR is for all types of cancer, and based on whole body ED. The CTKUB examination involves however irradiation of the lower torso only. While some of the most radiosensitive organs are involved (e.g. stomach, gonads, hips), others (e.g. thyroid, breast) are outside the field of radiation, although there will be a dose to those organs due to scatter radiation.

Relevant BEIR-VII figures were translated into an age-risk curve and a formula derived. This is only an approximation, and therefore not entirely accurate. A similar system of estimating LAR has been used by a group of radiologists at xrayrisk.com.
Image quality assessment between the two groups was crude but one purpose was to safeguard patient welfare. Had there been a stark discrepancy in image quality between the two groups, this spot check method would have been expected to detect this. However, results cannot be used to make inferences on true image qualities of the respective scan protocols.

5.4 RECOMMENDATIONS

The CTKUB Quality Reference mAs level of 60 mAs should continue to be used, as there is a significant dose saving in a relatively young patient population, without apparent overall image quality compromise. Increase in noise is permissible if the study remains diagnostic.

Other CT protocols such as CT abdomen should be examined with a view to reduce Quality Reference mAs, while aiming to maintain adequate image quality. Patient weight-based quality reference mAs has been shown to substantially reduce the dose in

Crohn disease patients undergoing MDCT enterography (Allen et al 2010:89) and could be considered at this hospital for this group of young patients who are prone to frequent CT examinations and therefore high cumulative doses.

Estimated LAR of incident cancer are good for illustrative purposes, but should not be used in any official audit report

5.5 CONCLUDING REMARKS

This work is a review of medical radiation dose to the population and a discussion of the associated cancer risk and hence public health implications. Radiation dose reduction and saving remain cornerstones of radiological practice. It is hoped that this study as an example can demonstrate how this can be achieved. Further, this work should promote knowledge about radiation safety among health care providers who refer patients to medical imaging; and advocate radiation safety.

The BEIR VII committee does recommend that in the interest of radiological protection, there should be follow-up studies of cohorts of persons receiving CT scans, especially children. Further, the committee recommends studies of infants who experience diagnostic radiation exposure related to cardiac catheterisation, and of premature infants who receive frequent repeat radiographs for the monitoring of pulmonary development (NRC 2006:5). In addition, the BEIR-VII committee has identified twelve areas of research need (see ANNEXURE 2).

ANNEXURE 1 Case record form

CASE RECORD FORM (CTKUB)

OLD CT SCAN PROTOCOL ☐ NEW CT SCAN PROTOCOL ☐

DATE OF EXAM ☐☐☐☐☐☐

EXAM ID ☐☐☐☐☐☐☐

AGE ☐☐

SEX ☐

kVp ☐☐☐

mAs ☐☐☐

DLP ☐☐☐ mGy·cm

ANNEXURE 2 Summary of recommended research needs by the BEIR-VII committee (NRC 2006:15-18)

Research Need 1: Determination of the level of various molecular markers of DNA damage as a function of low-dose ionising radiation

Currently identified molecular markers of DNA damage and other biomarkers that can be identified in the future should be used to quantify low levels of DNA damage and to identify the chemical nature and repair characteristics of the damage to the DNA molecule.

Research Need 2: Determination of DNA repair fidelity, especially with regard to double and multiple strand breaks at low doses, and whether repair capacity is inde- pendent of dose

Repair capacity at low levels of damage should be inves- tigated, especially in light of conflicting evidence for stimulation of repair at low doses. In these studies the accuracy of DNA sequences rejoined by these pathways must be determined, and the mechanisms of error-prone repair of radiation lesions have to be elucidated.

Research Need 3: Evaluation of the relevance of adaptation, low-dose hypersensitivity, bystander effect, hormesis, and genomic instability for radiation carcinogenesis

Mechanistic data are needed to establish the relevance of these processes to low-dose radiation exposure (i.e., <100 mGy). Relevant end points should include not only chromosomal aberrations and mutations but also genomic instability and induction of cancer. *In vitro* and *in vivo* data are needed for delivery of low doses over several weeks or months at very low dose rates or with fractionated exposures. The cumulative effect of multiple low doses of less than 10 mGy delivered over extended periods has to be explored further. The development of *in vitro* transformation assays utilizing nontransformed human diploid cells is judged to be of special importance.

Research Need 4: Identification of molecular mechanisms for postulated hormetic effects at low doses

Definitive experiments that identify molecular mechanisms are necessary to establish whether hormetic effects exist for radiation-induced carcinogenesis.

Research Need 5: Tumorigenic mechanisms

Further cytogenetic and molecular genetic studies are necessary to reduce current uncertainties about the specific role of radiation in multistage radiation tumorigenesis.

Research Need 6: Genetic factors in radiation cancer risk

Further work is needed in humans and mice on gene mu- tations and functional polymorphisms that influence radiation response and cancer risk.

Research Need 7: Heritable genetic effects of radiation

Further work should be done to establish (1) the potential roles of DNA double-strand break repair processes in the origin of deletions in irradiated stem cell spermatogonia and oocytes (the germ cell stages of importance in risk estimation) in mice and humans and (2) the extent to which large radiation-induced deletions in mice are associated with multisystem development defects. In humans, the problem can be explored using genomic databases and knowledge of mechanisms of origin of radiation-induced deletions to predict regions that may be particularly prone to radiation-inducible deletions.

With respect to epidemiology, studies on the genetic effects of radiotherapy for childhood cancer should be encouraged, especially when they can be coupled with modern molecular techniques (such as array-based comparative genomic hybridization).

Research Need 8: Future medical radiation studies

Most studies of medical radiation should rely on exposure information collected prospectively, including cohort studies as well as nested case-control studies. Future studies should continue to include individual dose estimation for the site of interest, as well as an evaluation of the uncertainty in dose estimation.

Studies of populations with high- and moderate-dose medical exposures are particularly important for the study of modifiers of radiation risks. Because of the high level of radiation exposure in these populations, they are also ideally suited to study the effects of gene-radiation interactions, which may render particular subsets of the population more sensitive to radiation-induced cancer. Genes of particular interest include BRCA1, BRCA2, ATM, CHEK2, NBS1, XRCC1, and XRCC3.

Of concern for radiological protection is the increasing use of computed tomography (CT) scans and diagnostic X-rays. Epidemiologic studies of the following exposed popu-

lations, if feasible, would be particularly useful: (1) follow- up studies of persons receiving CT scans, especially children; and (2) studies of infants who experience diagnostic expo- sures related to cardiac catheterization, those who have re- current exposures to follow their clinical status, and premature babies monitored for pulmonary development with repeated X-rays.

There is a need to organize worldwide consortia that would use similar methods in data collection and follow-up. These consortia should record delivered doses and technical data from all X-ray or isotope-based imaging approaches including CT, positron emission tomography, and single photon emission computed tomography.

Research Need 9: Future occupational radiation studies

Studies of occupational radiation exposures, in particular among nuclear industry workers, including nuclear power plant workers, are well suited for direct assessment of the carcinogenic effects of long-term, low-level radiation exposure in humans. Ideally, studies of occupational radiation should be prospective in nature and rely on individual real- time estimates of radiation doses. Where possible, national registries of radiation exposure of workers should be estab- lished and updated as additional radiation exposure is accumulated and as workers change employers. These registries should include at least annual estimates of whole-body radiation dose from external photon exposure. These exposure registries should be linked with mortality registries and, where they exist, national tumor (and other disease) registries. It is also important to continue follow-up of workers exposed to relatively high doses, that is, workers at the Mayak nuclear facility and workers involved in the Chernobyl cleanup.

Research Need 10: Future environmental radiation studies

In general, additional ecological studies of persons ex- posed to low levels of radiation from environmental sources are not recommended. However, if there are disasters in which a local population is exposed to unusually high levels of radiation, it is important that there be a rapid response not only for the prevention of further exposure but also for scientific evaluation of possible effects of the exposure. The data collected should include basic demographic informa- tion on individuals, estimates of acute and possible continu- ing exposure, the nature of the ionising radiation, and the means of following these individuals for many years. The possibility of enrolling a comparable nonexposed population should be considered. Studies of persons exposed environmentally as a

result of the Chernobyl disaster or as a result of releases from the Mayak nuclear facility should continue.

Research Need 11: Japanese atomic bomb survivor studies

The LSS cohort of Japanese A-bomb survivors has played a central role in BEIR VII and in past risk assessments. It is important that follow-up for mortality and cancer incidence continue for the 45% of the cohort who remained alive at the end of 2000.

In the near future, an uncertainty evaluation of the DS02 dosimetry system is expected to become available. Dose-response analyses that make use of this evaluation should thus be conducted to account for dosimetry uncertainties.

Development and application of analytic methods that allow more reliable estimation of site-specific estimates is also needed. Specifically, methods that draw on both data for the specific site and data for broader cancer categories could be useful.

Research Need 12: Epidemiologic studies in general

Data from the LSS cohort of A-bomb survivors should be supplemented with data on populations exposed to low doses and/or dose rates, especially those with large enough doses to allow risks to be estimated with reasonable precision. Studies of nuclear industry workers and careful studies of persons exposed in countries of the former Soviet Union are particularly important in this regard.

ANNEXURE 3 Audit Proforma for Hospital Audit Committee

Clinical Audit Submission

Name	Jan Frank Gerstenmaier	Dept	Radiology
Title	Specialist Registrar	Contact details	0851393183 j.gerstenmaier@svuh.ie

Audit title
Radiation dose savings in CTKUB. Potential radiation dose savings in PE workup.

Why are you proposing to conduct this audit? Why was this topic chosen?
As part of our radiation dose saving strategy, we have changed CT exposure settings for CTKUB. As a service evaluation, we aim to investigte what effect this change has on radiation dose received and on estimated lifetime attributable cancer risk.

What **standards** will you be auditing against?	Remember to attach a copy of the relevant standard(s) to the submission
For CTKUB, the standard is the mAs reference level prior to the change to a lower level.	
Describe the audit **tool** you intend to use?	Please attach a copy of the audit tool to the submission
Case record forms include exposure factors, age, sex. Interrogation of RIS/PACS system	

Please tick additional reasons (if any) for carrying out this audit

Patient centeredness	☒	Professional development	☒
High volume activity	☒	Service improvement	☒
High risk activity	☐	Re-audit	☐
High cost activity	☐	Risk management	☐

Each audit should satisfy all of the following

- It should aim to improve patient care
- It should be multidisciplinary where possible
- It should have support within your department, including a willingness to implement changes
- Data Protection legislation

Have all the potential stakeholders been identified? Yes ☒ No ☐

List relevant stakeholders by name	Are these stakeholders aware of this audit?	
Professor Jonathan Dodd (Consultant Radiologist, Professor UCD)	Yes ☒	No ☐
Dr Michael Casey (Chief Physicist and Radiation Protection Advisor)	Yes ☒	No ☐
Mrs Susan Collins (CT clinical specialist radiographer)	Yes ☒	No ☐
	Yes ☐	No ☐

Has a literature search been undertaken?	Yes ☒	No ☐
Sample size	100/100	
Timescale / length of time to audit	1 months	
Target completion date	September / / 2011	

Please submit a completed proforma to the clinical audit department (clinicalaudit@svuh.ie) along with supporting documentation and **a hard copy signed by you and your head of department**. Contact Clinical Audit for any further assistance by ringing #3329 or #3426

Signed _____ Signed _____

Audit lead Audit sponsor

Received Discussed

ANNEXURE 4 Permission Letter from Hospital Audit Committee

Elm Park
Dublin 4
Tel: +353 1 221 4000
Fax: +353 1 221 4001
Web: www.st-vincents.ie

St. Vincent's University Hospital

IC/NE

Dr Jan Frank Gerstenmaier,
SpR Radiology,
SVUH

14th September 2011

Dear Dr Gerstenmaier,

Re: Audit titled – Radiation dose savings in CTKUB. Potential radiation dose savings in PE workup

Your audit submission proforma has now been approved by the Clinical Audit Committee with Chairman's approval. We would be obliged if you would keep the Clinical Audit Department informed of your progress while carrying out this audit. Should you need any assistance in developing an audit tool, data collection, measuring or analysis we are happy to help.

On completion of the audit, we require a Clinical Audit report outlining the Aims, Objectives, Methodology and Results of the audit. More importantly we will require recommendations for improvement out of the audit to complete the audit cycle.

If you have concerns around any of these requirements the Clinical Audit Department will be more than happy to assist, so do please make contact with us.

Please quote audit no **478** on the top of your audit report when you are submitting same.

Yours Sincerely,

pp Ian Callanan MB, FRCSI, MBA
Group Clinical Audit Facilitator
St Vincent's Healthcare Group

Cc Prof Jonathon Dodd – Audit Sponsor

ANNEXURE 5 UNISA Ethical Clearance Certificate

UNISA university of south africa

UNIVERSITY OF SOUTH AFRICA
Health Studies Higher Degrees Committee
College of Human Sciences
ETHICAL CLEARANCE CERTIFICATE

HSHDC/2/2012

Date of meeting: 26 January 2012 Student No: 4338-916-3

Project Title: Public Health Implications of Medical Diagostic Radiation Exposure.

Researcher: Jan Frank Gerstenmaier

Degree: Masters in Public Health Code: DIS4986

Supervisor: Prof SP Human
Qualification: D Cur
Joint Supervisor: Dr C Seebregts

DECISION OF COMMITTEE

Approved [√] **Conditionally Approved** [ ]

Prof E Potgieter
CHAIRPERSON: HEALTH STUDIES HIGHER DEGREES COMMITTEE

Dr MM Moleki
ACTING ACADEMIC CHAIRPERSON: DEPARTMENT OF HEALTH STUDIES

PLEASE QUOTE THE PROJECT NUMBER IN ALL ENQUIRES

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