Committee on Medical Aspects of Radiation in the Environment (COMARE)

SIXTEENTH REPORT

Patient radiation dose issues resulting from the use of CT in the UK

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CONTENTS

FOREWORD

i   The Committee on Medical Aspects of Radiation in the Environment (COMARE) was established in November 1985 in response to the final recommendation of the report of the Independent Advisory Group chaired by Sir Douglas Black (Black, 1984). The terms of reference for COMARE are:

> 'to assess and advise government and the devolved authorities on the health effects of natural and man-made radiation and to assess the adequacy of the available data and the need for further research'

ii   In the course of providing advice to government and the devolved authorities for over 28 years, COMARE has published to date 15 major reports and many other statements and documents mainly related to exposure to naturally occurring radionuclides, such as radon and its progeny, or to man-made radiation, usually emitted by major nuclear installations. The most recent COMARE report focused on the radium contamination in the area around Dalgety Bay.

iii   In August 2011, the Department of Health asked COMARE to produce a report on medical radiation dose issues with CT scanners. Issues to be considered in the report related to the increased use, justification and optimisation of CT exposures on patients. The report would focus on diagnostic CT applications, as well as including PET-CT, SPECT-CT and cone beam CT, but would not consider exposure of staff or asymptomatic individuals. A future report will investigate the use of CT in interventional radiology. COMARE reconstituted its Medical Practices Subcommittee, with a new membership consisting of committee members and external experts, to conduct this work. The subcommittee's terms of reference are:

> 'to advise COMARE on the health effects arising from medical and similar practices involving the use of ionising and non-ionising radiation through assessment of the available data and to inform COMARE of further research priorities'

The investigation of the increased use of CT, together with the potential risks associated with the radiation exposure from the examinations detailed in this report, lies within the remit of the subcommittee.

iv   The aim of this COMARE report has been to provide advice to the Department of Health on the increased use of diagnostic CT within the UK, with consideration of the potential dose reduction benefits of practical approaches and supporting initiatives.

v   When the subcommittee had finished its review, the report was presented to COMARE for consideration by the full committee, with the aim that the information would be presented to the Department of Health in due course. That information is contained in this, our sixteenth report.

CHAPTER 1

INTRODUCTION

1.1   Medical imaging is ranked within the top five recent medical developments in numerous surveys: for example, see the survey by the Royal College of Physicians of Edinburgh (RCPE, 2010). A variety of imaging modalities are currently available for clinical use, including radiography, fluoroscopy, computed tomography (CT), nuclear medicine (including hybrid imaging with CT), ultrasound and magnetic resonance imaging (MRI). Each has its advantages and disadvantages (see Appendix B for a comparison of CT, MRI and ultrasound).

1.2   The development of cross-sectional imaging (CT and MRI) has revolutionised the manner in which the body can be visualised to detect disease (eg cancer) and to inform treatment in a range of disease areas.

1.3   The principal advantages of CT are:

(a)   Rapid acquisition of images

(b)   Impressive spatial resolution

(c)   A wealth of clear and specific information answering a wide range of clinical questions

(d)   A view of a large portion of the body

(e)   The ability to discriminate between structures on the basis of density

No other imaging procedure combines these features into a single modality. In addition, as with most digital technologies, these developments have been achieved with a decrease in the real cost of equipment. The result has been increased patient throughput at lower cost per caput, which has consolidated CT as a major, first-line, diagnostic modality.

1.4   CT, originally known as computed axial tomography (CAT), uses specialised X-ray equipment to obtain image data from different angles around the body. Digital processing of this information results in detailed cross-sectional images of body tissues and organs in either two- or three-dimensional format. It was the first technique to produce such images and as the diagnostic advantages were immediately obvious, it rapidly became established as a valuable diagnostic tool.

1.5   The idea of CT was conceived in 1961 by W H Oldendorf (Oldendorf, 1961), although the first clinical application was envisaged in 1967 in England by G N Hounsfield at the Thorn EMI Central Research Laboratories, being publicly announced in 1972. The system was independently developed by A M Cormack at Tufts University and both he and Hounsfield shared the Nobel Prize for Medicine in 1979. The original test rig, developed in 1971, used americium as a gamma source, and took 160 parallel readings over 180 angles, each 1° apart. It took 9 days to collect sufficient information about the object being scanned and a further 2.5 hours to reconstruct the data into an image.

Later, the gamma source was replaced by a more powerful X-ray source, which reduced the scanning time (Hounsfield, 1973).

1.6   The first prototype clinical CT scanner (the forerunner of the commercial version known as the EMI scanner) was installed in Atkinson Morley's Hospital, Wimbledon. It was limited to making tomographic sections of the brain, and the first patient brain scan using the machine was obtained in 1971. To reduce the dynamic range of the radiation reaching the detectors, the machine required the use of a water-filled Perspex™ tank, with a pre-shaped rubber head cap enclosing the patient's head. The machine took between 4.5 and 20 minutes per 180° scan to acquire the image data, with 7 minutes required to process each image (Beckmann, 2006).

1.7   CT scanners have gone through many phases of technological development, from single-slice static machines to single-slice spiral/helical machines, and in the last decade there have been further significant advances in CT technology (see Appendix C for a more detailed history). In particular, the continued development of multi-detector (often referred to as multi-slice) CT and developments in gantry technology have increased the speed of scanning and enabled high resolution reconstruction of images in all planes. Other recent developments allow consideration of volume CT acquisition. These improvements mean that more complex and extensive scans can be performed within timeframes tolerable to most patients. Large volumes of the chest can be scanned within a breath hold and cardiac examinations achieved within a single heart beat. An additional dimension has been provided by time-based exposures, which make it possible to investigate the perfusion characteristics of organs for a range of diseases.

1.8   Increased computing power and data processing capacity have contributed significantly to the expanded capability of CT systems and this is expected to continue. Software packages have been developed to make use of these benefits, with modern scanners being able to reconstruct a study yielding around 1000 images in less than 30 seconds. Multi-planar and three-dimensional imaging, created from the exposed volume, are now common techniques that have contributed to an increased demand for CT.

1.9   These developments have resulted in a dramatic increase in the number of clinical applications of CT. The first systems were designed only for examination of the brain. When body systems were first developed, they were restricted to selective examination of the trunk, largely in relation to the management of cancer. As the modality became more widely available, more accurate and more flexible, the number of applications in benign disease and in young people increased dramatically.

1.10   Today, there are many applications and benefits in the clinical use of CT, aiding more effective care management by:

(a)   Determining the necessity for surgery

(b)   Reducing the need for 'exploratory' surgery

(c)   Improving diagnosis, staging and treatment of cancer

(d)   Reducing the length of hospitalisations

(e)   Reducing the need for examination under sedation, especially in very young patients

(f)   Guiding the treatment of common conditions such as injury, cardiac disease and stroke

1.11   Of around 130 applications of CT recommended by the Royal College of Radiologists (RCR) in its guidelines 'iRefer', 70% now relate to benign or potentially benign conditions (RCR, 2012). In many conditions, which although benign can be life threatening, CT has been recommended as a standard investigation: for example, in the investigation of acute appendicitis (Raptopoulos et al, 2003; Saito et al, 2013).

1.12   CT has now replaced a large number of conventional examinations, such as barium studies and angiograms (Lederlin et al, 2011; Makayama et al, 2001). Additionally, CT can be used to obtain data from which virtual endoscopy can be created, obviating the need for invasive endoscopy (Summers, 2010; Vining, 1997). As a consequence, in many cases better diagnostic information has also been accompanied by a reduction in the radiation dose or the morbidity (and in some cases mortality) associated with traditional procedures. This is not always the case, however, as in some benign cases the use of CT in place of other investigations results in significantly higher radiation exposure, for example, in Crohn's disease (Jaffe et al, 2007). CT pulmonary angiography has in many places replaced nuclear medicine ventilation-perfusion lung scanning, but with increased breast radiation dose, especially for pregnant and lactating women (Anderson, 2007; Shahir et al, 2010).

1.13   Wider use of CT in benign disease and in younger patients, especially children, whose tissues have a greater radiosensitivity, highlights the need for conscientious radiation protection. Children have a longer predicted lifespan in which potential harmful effects of radiation exposure have more opportunity to emerge. The current success of treatments for a range of cancers and the increasing lifespan of the population as a whole means that radiation protection has become a matter of importance for all patients receiving CT scans.

1.14   Comparing data from the USA between 1980 and 2006 shows a significant increase in both the average annual effective dose to the US population and the contribution from medical radiation sources (Figure 1.1). The data for the UK population in 2003 show a similar distribution to that of the 1980s US population; however, more recent data suggest that the UK is following a similar trend to the USA, with an increasing contribution from medical exposures.
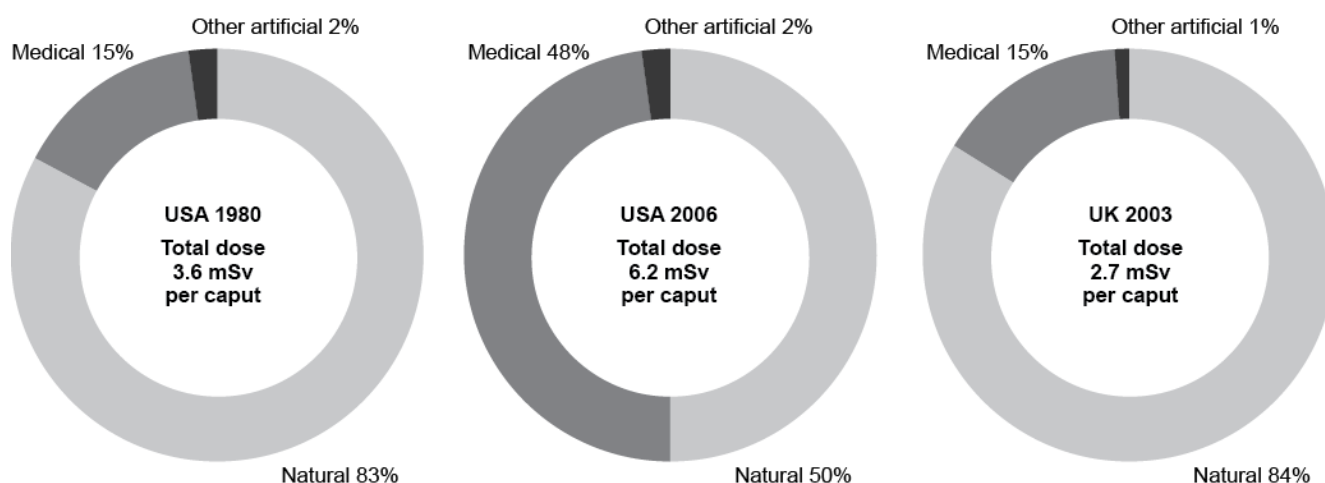

Figure 1.1   Average annual effective radiation dose to the US and UK populations from all sources (Mettler et al, 2009; Watson et al, 2005)

1.15   For the UK population, the annual per caput effective radiation dose from all diagnostic X-rays has increased from 0.33 millisievert (mSv) in 1997 to 0.4 mSv in 2008 (Hart et al, 2010). For some time, medical X-rays have been the largest single artificial source of radiation exposure for the UK population. In 2008, they contributed 15% of the average annual effective dose to the population from ionising radiation[*]. It has been recognised that CT makes a disproportionate contribution to the radiation exposure of patients compared with other radiation-based imaging techniques. The then National Radiological Protection Board (NRPB)[†] noted in 1989 that while CT comprised around 2.5% of all examinations, it contributed around 25% of the collective dose to the population from imaging (Shrimpton et al, 1991). By 2008, CT accounted for around 7% of all medical and dental X-ray examinations, but produced 68% of the collective dose (Hart et al, 2010).

1.16   According to statistics from the NHS[‡], the number of CT scans conducted in hospitals in England each year for the period 1996/97 to 2012/13 steadily increased from just over 1 million to almost 5 million, with no sign of reaching a plateau (see Figure 1.2).

1.17   The increasingly extensive examinations and more widespread use of CT are major contributors to the observation that diagnostic uses of radiation have almost doubled the average radiation exposure to the population in some 20 years, as has been shown for the USA (Hricak et al, 2011).
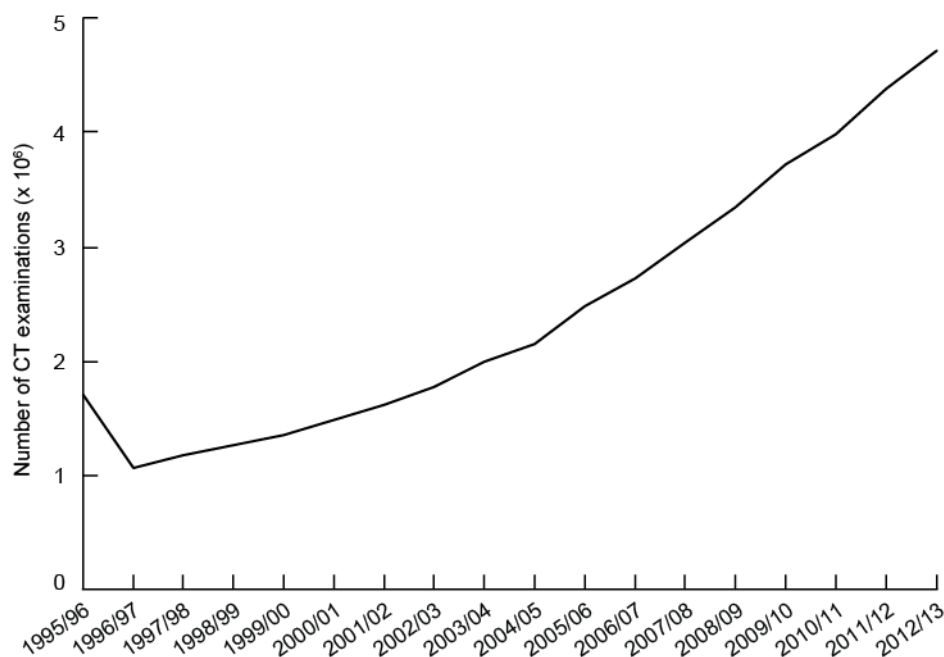
Figure 1.2   Number of NHS CT examinations performed from 1995/96 to 2012/13 in England

*   The average annual effective dose from natural and artificial sources of ionising radiation is estimated at 2.7 mSv for the UK, with the majority of this attributed to natural radiation (2.2 mSv) (Watson et al, 2005).

†   The NRPB was subsequently incorporated into the Health Protection Agency (HPA). On 1 April 2013 the HPA was abolished and its functions transferred to Public Health England.

‡   www.england.nhs.uk/statistics/statistical-work-areas/diagnostics-waiting-times-and-activity/imaging-and-radiodiagnostics-annual-data/

1.18   Documented average exposures to the population in reality reflect even higher exposure of a smaller number of people, namely patients. The role of CT in the clinical management of some diseases may result in a patient receiving a large number of scans in the course of one illness (Katz et al, 2006; Meeson et al, 2009; Sodickson et al, 2009). Restricting doses in CT is, therefore, widely perceived as an important objective in the practice of the technique and is held by some authors to be medicine's major current challenge in radiation protection (Golding, 2005).

1.19   The rising use of CT, the radiation exposure used in the examination and the potential risks associated with it are described in this report. These circumstances indicate that there is potential benefit in recommending steps to reduce population exposure due to CT. These are considered in detail in the following chapters.

CHAPTER 2

APPLICATIONS AND BENEFITS OF CT SCANNING

2.1   CT is a powerful, highly flexible clinical tool, capable of making radical changes to the management of patients. On the basis of the current state of alternative technologies, it is possibly the most important cross-sectional imaging modality in the diagnosis and management of a broad array of conditions. There is a strong evidence base which demonstrates that CT changes patient management in a wide range of applications and disease states (RCR, 2012). In some conditions it may be the only investigation the patient requires.

2.2   As is common to all investigations in medicine, the correct application of CT is based on weighing the potential benefit of reliable investigation against the inherent risk. While this principle supports the widespread use of CT, active measures to achieve greater dose constraint are required in view of the current position of CT as a major source of patient irradiation.

Principles of radiation protection relevant to CT and regulation

2.3   The governance of CT adheres to the established radiation protection principles of the International Commission on Radiological Protection (ICRP). Three key principles of radiation protection were reaffirmed in 1990 (ICRP, 1991):

> *Justification* – exposure to radiation must produce sufficient benefit to the exposed individuals, or to society, to offset the potential radiation detriment

> *Optimisation* – implementing procedures and techniques to keep exposures as low as reasonably practicable, economic and social factors being taken into account

> *Dose limitation* – keeping radiation doses received within specified limits

2.4   The ICRP issued new recommendations on radiation protection in 2007 (ICRP, 2007), which formally replaced its 1990 recommendations (ICRP, 1991).

2.5   Only justification and optimisation apply in the context of medical radiation exposures for patients, whereas all three key principles apply to the occupational exposure of medical staff. Occupational exposure is not considered further in this report; rather it focuses on patient exposure. The concept of diagnostic reference levels (DRLs) has been introduced to support the control and periodic reduction of radiation doses from diagnostic procedures. These are based on dose data for a range of commonly requested procedures in the UK and are regularly updated.

2.6   In the UK, legislation has been put in place implementing key European Council Directives, to address the hazards associated with ionising radiation. For CT scanning there are three sets of regulations of particular importance:

> The Justification of Practices Involving Ionising Radiation Regulations 2004, which address justification of practices at the highest level

The Ionising Radiations Regulations 1999, which address protection of workers and the public[*]

The Ionising Radiation (Medical Exposure) Regulations 2000, which address protection of patients and others

2.7   The guidance on the application and administration of the Justification of Practices Involving Ionising Radiation Regulations 2004 includes medical exposures using CT for diagnosis as an existing type of practice. The Ionising Radiation Regulations 1999 require employers to establish a framework to ensure exposures arising from work activities are kept as low as reasonably practicable and below dose limits.

2.8   The Ionising Radiation (Medical Exposure) Regulations 2000 (IR(ME)R 2000) (Department of Health, 2000) continue these themes at the individual patient level and require that all individual medical exposures are referred, justified and optimised. Both the referrer and the practitioner must be registered healthcare professionals.

2.9   IR(ME)R 2000 require an identified person, known as the 'practitioner' in the UK, to take legal responsibility for deciding whether an individual medical exposure is justified. Such a person must be adequately trained to carry out the task of justification and be entitled to do so by their employer. Justification of exposures must take into account medical information about the individual provided by a referrer and should be based on the available scientific evidence. Justification cannot be retrospective. The practitioner's decision as to whether an individual medical exposure is justified must be made prior to the exposure, and must be valid whether the test result is subsequently positive or negative. Procedures can only be justified if the individual for whom the exposure is proposed will receive a benefit that outweighs the detriment, or if there is an overall net benefit to society.

2.10   Optimisation of every medical exposure is the responsibility of the practitioner and of the 'operator' who undertakes the practical aspects of a medical exposure, to the extent of their respective involvement. To assist in optimisation, the employer must ensure that written protocols are in place for all standard procedures which must be specific to each piece of equipment. Such protocols should include exposure factors for each routine examination.

2.11   Effective strategies for reducing radiation exposure due to CT require attention to several aspects of clinical, technical and operational management and practice (as part of serial and parallel processes):

(a)   Justification of examinations, including consideration of the use of alternative technologies

(b)   Optimisation of examinations

(c)   Maximising the capability of the equipment

(d)   Maximising the capability of staff (practitioners and operators)

2.12   These and other governance issues are discussed in further detail in the following chapters.

Applications of CT

2.13   In the past 15 years, the major breakthrough in CT technological development has been the introduction of multi-slice or multi-detector helical CT, which has made it possible to acquire and analyse patient data within

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[*]   The Ionising Radiations Regulations (Northern Ireland) 2000 for Northern Ireland.

seconds rather than minutes. Representation of a volume of body tissue is now possible with uniform resolution images reformatted in multiple planes, or in three dimensions. As a consequence, new investigations are now possible – for example, investigation of blood flow through organs or blood vessels.

2.14   General clinical indications for CT scanning include, but are not limited to:

(a)   Staging of cancer – response, assessment and surveillance

(b)   Gastroenterology – bowel and organ pathology, including masses, sepsis, bleeding and trauma

(c)   Thorax – lung and mediastinal disease, masses, vasculature and trauma

(d)   Urology – identification/characterisation of masses, sepsis, anatomical abnormalities, ureteric and renal colic

(e)   Gynaecology – masses and sepsis

(f)   Colo-rectal – large bowel pathology, extent and spread of disease

(g)   Trauma – assessment of injuries

(h)   Musculoskeletal – structural abnormalities, disease or trauma

(i)   Neurology – trauma, disease, sepsis, vascular and to exclude haemorrhage

(j)   ENT/head and neck – disease, masses, sepsis and anatomical abnormalities

(k)   Cardiology – angiography

(l)   Vascular – abnormalities, disease and trauma

(m)   Intervention – guide treatment; biopsy, drainage and ablation

2.15   CT has also enhanced the capabilities of nuclear medicine imaging by providing an anatomical dimension previously missing in this functional imaging modality, leading to the production of hybrid imaging systems. CT provides a means of localising disease processes shown by the nuclear medicine techniques of positron emission tomography (PET) CT and single photon emission computed tomography (SPECT) CT. The advent of hybrid PET CT and SPECT CT systems has simplified image registration – the PET or SPECT and CT datasets are collected sequentially, on the same system, without the need for the patient to move to another scanner. This removes the image registration problems introduced by different patient set-up positions.

2.16   The acquisition parameters of the CT component will be determined by the clinical question to be answered by the procedure, and whether a diagnostic CT is performed before, or after, the PET/SPECT imaging. The CT in PET CT/ SPECT CT systems provides information to assist in the correction of the attenuation of photons from the radionuclide as they pass through the body in order to improve the PET imaging. A relatively low dose CT examination may be appropriate for the purpose of co-registration and localisation of abnormalities detected on the PET component (where images of lower quality/ higher noise than diagnostic CT are acceptable). A higher dose CT will provide a diagnostic quality image, making a separate CT examination unnecessary unless contrast is required.

2.17   In other cases, a diagnostic CT examination may sometimes be acquired in conjunction with the PET imaging, resulting in a study of comparable, and sometimes higher, radiation exposure. Clinical indications for the use of PET CT include, but may not be restricted to (RCP/RCR, 2013):

(a)   Malignancies

(b)   Neurological abnormalities

(c)   Cardiological abnormalities

(d)   Vasculitis

(e)   Sarcoidosis

(f)   Infection imaging

2.18   A recent development has been so-called 'cone beam' CT (CBCT). This particular imaging technique uses a flat panel detector (in contrast to the array of individual detectors of conventional CT), coupled with beam exposure that is similar to that of conventional radiography. It is essentially a form of rotation radiography and its dosimetry differs significantly from that of CT. CBCT images contain inherently fewer image data than conventional CT and are acquired at lower radiation exposure. The technique was developed for specific clinical applications, such as dentistry, but is now being used more widely wherever it can be applied. In view of the fundamental difference between CBCT and conventional CT, the technique is not considered in detail in this report. However, CBCT, where it is clinically applicable, may offer a dose-sparing alternative to conventional CT and its use should, therefore, be considered when justifying referrals for CT.

2.19   CT also has applications in veterinary medicine and in industry; however, these are not considered in this report.

2.20   In the clinical environment CT is now established in a range of differing roles. These may be categorised as:

(a)   Diagnostic and staging

(b)   Guiding

(c)   Planning

(d)   Monitoring

Additionally, CT has been employed in health assessments of asymptomatic individuals. This practice was the focus of the 12th COMARE report (COMARE, 2007).

Diagnostic and staging CT   2.21   CT is the most frequently used imaging technique where cross-sectional information is necessary for diagnosis or staging. It is applicable to diseases of the brain, musculoskeletal system, chest, abdomen and pelvis, either as a complement to other imaging investigations such as radiography, or ultrasound, or increasingly as the primary investigatory technique.

2.22   Early use of CT provided information within the head that was previously unavailable. Rapid development of body scanners quickly established that the technique was an accurate method of detecting or excluding many diseases, and in showing the extent of disease. This led to changing treatment to a more appropriate regime, with the possibility of an improved health outcome. Research studies have confirmed the clinical effectiveness of diagnostic CT in influencing patient management (Kumta et al, 2002; Moore et al, 1987).

2.23   Multi-planar and three-dimensional imaging created from the exposure volume are now common approaches that have further extended the role and contributed to an increased demand for CT. Time-based exposures make it possible to investigate the perfusion characteristics of disease and the combination of speed and multi-planar reformatting has allowed CT to replace a large number of conventional angiograms (Rathbun et al, 2000; Wittram et al, 2004).

2.24   The capability of demonstrating or excluding disease within the trunk has established CT as a means of investigating patients before, or instead of, surgery. CT has, in effect, become a non-invasive alternative to investigatory laparotomy – for example, in suspected critical damage in abdominal trauma (Salim et al, 2006). Many of these applications have been supported by research studies confirming both the clinical value and cost-effectiveness of this approach (Kocher et al, 2011). However, it is perceived that the value of this application of CT has led to an impression among some surgeons that all patients under-going surgery to the trunk merit CT beforehand. Further research is required to determine whether such an extended application of CT has an appropriate evidence base.

2.25   The accuracy of CT has also led to important changes in documenting the extent of disease, especially malignant tumours. The margins of the primary lesion can be evaluated and the involvement of other organs, by direct extension or by vascular spread, can be assessed. Disease staging rapidly became, and has remained, a leading use of CT.

2.26   The high diagnostic accuracy of CT has meant that it is becoming increasingly essential in the early diagnosis phase of trauma care. CT is more often being used in place of conventional radiographic imaging and there is emerging use of whole-body CT for trauma patients (Smith and Mason, 2012). The value of immediate whole-body CT of severely injured trauma patients is still to be determined (Sierink et al, 2012a). An initial review of the current data suggests that the practice reduces the time spent by the patient in the emergency department when compared with conventional radiography (Sierink et al, 2012b). CT provides complex imaging that answers a wide range of clinical questions in all regions of the body. It affords the ability to reconstruct in any plane while being able to focus on small areas of concern. It can include venous and arterial phases in a fast single scan and is becoming common practice to use in place of conventional imaging when a trauma patient has been stabilised.

2.27   Magnetic resonance imaging (MRI) is an alternative imaging modality, free from ionising radiation, which is used for many applications. It was developed after CT was already established. MRI is now the investigation of choice in many clinical situations involving the brain, musculoskeletal system and trunk (RCR, 2012). It is arguable that the timing of the development of MRI, combined with the relative speeds of acquisition and comparatively limited availability and higher cost, has caused the clinical use of MRI to lag behind that of CT. The relative use of CT and MRI is considered in more detail in Chapter 6.

Guiding interventions

2.28   The cross-sectional display afforded by CT has been used to guide the percutaneous placement of instruments for diagnostic or therapeutic use. These so-called 'interventional' uses of CT include guided biopsy, catheter placement and drainage of pathological fluid collections such as abscesses, nerve blocking or other tissue ablative techniques. They represent a particular use of CT in assisting a procedure. A specialised form of interventional guidance is real-time CT using specialised equipment (CT fluorography). This technique poses particular protection issues relating to its individual technology. Interventional techniques including CT will be reviewed separately by COMARE and are not covered within this report.

Treatment planning

2.29   Research studies in the 1970s quickly established the advantages of using cross-sectional imaging in cancer treatment planning. The technique shows the spatial relationships of lesions such as tumours, and can be used to determine the appropriate treatment regime. If a tumour is shown to be

localised, its resectability can be predicted pre-operatively and the appropriate surgical approach defined in advance.

2.30   Radiotherapy planning represents a particular use of this aspect of CT, for which a separate examination is usually needed under standardised conditions. Radiotherapy planning uses CT in two distinct activities, as follows.

Accurate localisation of the volume to be treated – three-dimensional localisation is now the standard for all but a few radiotherapy episodes. The clinical target volume and adjacent critical organs are defined on the CT images and these are then fed into the dosimetry planning system

Dosimetry – the CT images are used to define the patient contour incident to the treatment beams and provide information for the planning algorithm on tissue inhomogeneities. Variation between tissues will influence absorption of radiation as the beam passes through and, therefore, the dose distribution achievable within the treatment volume

Monitoring the effects of treatment

2.31   The advantages of CT in defining disease make it suitable for demonstrating how diseases respond to treatment, when this information is important for further clinical management of the patient. Advantages apply to both benign and malignant disease, as follows.

Defining response to ongoing treatment – a major impetus for the increased use of imaging in follow up arises from a wider range of treatment options being available for many diseases, including malignant tumours. The frequency of monitoring depends on the nature of the disease and whether treatment management decisions rest on the result. In acute illnesses such as refractory abdominal abscesses, repeat CT may be required every few days, whereas in malignant tumours the examination may be needed to assess progress every few weeks. Monitoring examinations may be required frequently or over a long period and represent an important source of cumulative exposure in individual patients. Hybrid imaging has the potential to provide further information during a particular treatment episode, eg within a course of chemotherapy

Early recognition of relapse – where treatment options exist for relapsed disease there may be clinical advantage in early detection. CT is widely used for this purpose in both benign and malignant disease. The frequency of investigation should be determined by current knowledge of the natural history of the individual disease and evaluation of the clinical situation of the individual patient.

Population screening or individual health assessment

2.32   In recent years, CT has been used on individuals who are asymptomatic. The diagnostic accuracy of CT has led to proposals for its use for screening populations for disease, or for screening apparently healthy individuals for possible disease. The radiation exposure of healthy subjects can only be justified on the basis of demonstrable benefit to the population or the individual, balanced against the risks involved.

2.33   Research studies are proceeding to determine whether screening programmes using CT are justifiable, but currently there is no strong evidence base supporting this use of the technique for the general population. The National Cancer Institute National Lung Cancer Screening Trial (NLST) in the USA published findings that low dose CT shows promise as a method for detecting lung cancer in highest risk individuals who have yet to show symptoms, reducing deaths by 20% compared with chest X-rays (NLST, 2011).

The American Lung Association only recommends lung cancer screening using low dose CT scans for people meeting specific criteria – current or former smokers (aged 55 to 74 years) with a smoking history of an average of a pack a day for 30 years and with no history of lung cancer[*].

2.34   A recent publication (Melgies et al, 2013) has considered the place of CT coronary angiography (CTCA) as a screening tool for the diagnosis of coronary artery disease. The authors conclude that, as yet, CTCA is unable to predict the potential vulnerability of plaque and that there is insufficient evidence to support a screening role.

2.35   COMARE previously reviewed personally initiated CT scanning services (individual health assessments) in its 12th report (COMARE, 2007). The report concluded that the practice may provide benefits to the individual, but these would not be the same as those associated with the use of diagnostic CT in a symptomatic patient. The justification for this practice could, therefore, not be considered in the same way as justification for patients. Based on the available evidence, it was not possible to recommend the use of whole-body CT scanning on asymptomatic individuals. It was recognised, with the constant developments in the field, that the recommendations from the report should be reviewed as new evidence was presented. As a consequence of the COMARE report, the Ionising Radiation (Medical Exposure) Regulations were amended in 2011 to specifically include the provision of individual health assessments as an exposure requiring justification (Department of Health, 2011).

Summary

2.36   CT is a powerful, highly flexible clinical tool with its use governed by the radiation protection principles of justification and optimisation. In the UK, CT scanning is governed largely by three sets of regulations: the Justification of Practices Involving Ionising Radiation Regulations 2004, the Ionising Radiations Regulations 1999 and the Ionising Radiation (Medical Exposure) Regulations 2000.

2.37   Technological developments in CT have greatly expanded its applications. In a clinical environment, CT has a distinct role in the diagnosis and staging of disease, guiding interventions, treatment planning and monitoring the effects of treatment. It is applicable to a range of clinical conditions, including diseases of the brain, musculoskeletal system, chest, abdomen and pelvis. The use of CT is becoming increasingly common in the early diagnosis phase of trauma care and it also has a role in investigating patients before, or instead of, surgery.

2.38   The increase in scanning speed means that it is now possible to investigate perfusion characteristics of disease.

2.39   CT is often performed in conjunction with other modalities: for example, to enhance the capabilities of nuclear medicine with PET CT and SPECT CT.

2.40   CT has been used in recent years in scanning asymptomatic individuals, aimed as a form of preventive medicine. COMARE previously reviewed these services in its 12th report and determined that the benefits would differ from those associated with symptomatic patients. COMARE was not able to support the use of whole-body CT scanning on asymptomatic individuals. Research studies are in progress to determine if the use of CT is justifiable in population screening programmes, but there is currently no strong evidence to support it.

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[*]   www.lung.org/about-us/our-impact/top-stories/guidance-on-ct-lung-cancer.html

CHAPTER 3

DETRIMENTS ASSOCIATED WITH RADIATION DOSE FROM CT SCANS

Benefit versus detriment with diagnostic CT scans

3.1   While the use of CT has had a clearly beneficial effect on advancing the accuracy of diagnostic radiology (see Chapter 2), there are potential detriments associated with its use as well. One of the fundamental principles in the practice of medicine is 'First do no harm'. In the context of this report this means balancing the potential benefit to be gained by having a CT scan against the potential harm that might be caused by the radiation exposure (Lautin et al, 2008; Pilling, 2008). Although other risks from CT scans exist, such as those inherent in the use of contrast agents (Martin and Bradley, 2012), this report focuses on the principal risk associated with the exposure to ionising radiation, where the dose received by the patient may be significant when compared with those from other diagnostic imaging procedures.

3.2   In general, the risks associated with ionising radiation can be divided into those defined as stochastic effects and deterministic effects.

> *Stochastic effects* – generally somatic effects (cancer) in the directly exposed population, and potential genetic effects to their offspring. Those effects which occur by chance, affecting the probability of a change rather than the severity and are a function of dose without a threshold

> *Deterministic (tissue reaction) effects* – radiation injury due to cell killing and radiation disease, defined by the ICRP in its 1990 recommendations (ICRP, 1991). These are now termed tissue reaction effects through recognition that some effects are not determined solely at the time of irradiation, but can be modified after radiation exposure (ICRP, 2007). It is assumed that there is a threshold dose, below which there is no effect, and the response (probability of effect) smoothly increases above that point

3.3   For diagnostic exposures, the potential deleterious effects are usually considered to be stochastic and consist of potential malignancy arising many years after exposure. In addition, benign effects (primarily cataracts) and cardiac effects may occur earlier. Deterministic (tissue reaction) effects are not expected to occur following exposure from diagnostic CT scans carried out correctly. However, rare instances of equipment or administration error have resulted in a greater radiation exposure than denoted for the particular examination, with visible tissue reaction effects.

Levels of radiation exposure in medicine

3.4   Ionising radiation is a potent mutagen and carcinogen. Exposure to ionising radiation is a known factor for the induction of human malignancies (Cardis et al, 2007; Gilbert, 2009; Mullenders et al, 2009). Radiation can induce germline mutations in a variety of experimental systems (Dubrova, 2003; Morgan, 2003).

3.5   Epidemiological studies have demonstrated that malignant disease, particularly leukaemia, is a significant risk for occupational groups such as radiologists who have received substantial doses (see the review by Goodhead,

2009). The risk of heritable genetic mutations was also considered to be the primary concern for human populations exposed to radiation. These investigations continue to form a part of the current system of radiation protection, although direct demonstrations of such risks in humans remain elusive (Goodhead, 2009).

3.6   For low dose exposures, such as from medical X-rays used in radiographs, there are substantial uncertainties in the magnitude of the health risk. It has generally been assumed that ionising radiation risks at moderate to low doses and dose rates are dominated by stochastic cancer risks in exposed individuals. For protection purposes, it is assumed that the risk increases in line with increasing dose – the linear no-threshold (LNT) model – but the evidence for this is unclear (for more detail see the review by Little et al, 2009a).

3.7   As outlined by Harris and others (Harris, 2005; UNSCEAR, 1993, 2000) there are biological data to suggest that cancer arises from a failure of cell differentiation, and that it may predominantly originate from mutagenic damage to a single cell, via damage to the DNA (UNSCEAR, 1993, 2000), although a role for non-DNA targeted effects cannot be ruled out (Morgan, 2003).

3.8   At high radiation doses, such as those received by patients treated with radiotherapy, a variety of other (so-called deterministic or tissue reaction) effects are observed, resulting from inactivation of large numbers of cells and associated functional impairment of the affected tissue.

3.9   The effective radiation dose from CT scans has a broad range, depending on the examination undertaken (see Table 3.1).

3.10   Reports concerning radiation risk tend to be population-based risk projection studies and make no allowance for the age or medical prognosis of the individual patient (ARSAC, 2006; Berrington de Gonzalez and Darby, 2004). Population studies to assess the risk from exposure to ionising radiation are different from studies relating to medical exposure where the risk is to an individual patient. Relevant factors which influence the risk can be taken into account, which is not possible in population studies.

3.11   The benefit is also individualised. It may be argued that other sources of potential radiation exposure benefit the population, such as nuclear power

Table 3.1   Examples of typical effective doses from diagnostic procedures, equivalent number of chest X-rays and equivalent period of natural background radiation (RCR, 2012)

Examination	Typical effective dose (mSv)	Equivalent number of chest X-rays	Equivalent period of natural background radiation[*]
Chest X-ray (single PA film)	0.015	1	2.5 days
Skull X-ray	0.07	5	12 days
Abdomen X-ray	0.4	30	2 months
CT head	1.4	90	7.5 months
CT abdomen	5.6	370	2.5 years
CT chest	6.6	440	3 years
CT chest, abdomen and pelvis	10	670	4.5 years
PET CT head	7	460	3.2 years
PET CT body	18	1200	8.1 years
[*] UK average = 2.2 mSv per year			

installations which provide electricity, but in medical exposures the benefit is to an individual patient and thus can be more readily appreciated. Patients having CT scans (or other investigations using ionising radiation) are expected to derive some benefit from the examination in terms of directing the management of their illness.

3.12   The potential harm that might be caused to a patient is determined by a range of factors. The radiation dose is dependent on the size of the patient, the body position and extent of the scan and also the number of scans undertaken. The gender and age of the patient will affect the risk level, with lifetime cancer mortality risks from radiation exposure decreasing with increasing age. The radiosensitivity of the patient and the prognosis of the disease for which the patient requires the CT scan should also be taken into account when considering the potential harm.

3.13   Since imaging with ionising radiation is just a part of the diagnostic process and management of the patient, the risk caused by a CT scan has to be judged in relation to the sum of the other risks that occur. For instance, if the patient is to have radiotherapy, then the radiation dose from a CT scan might be perceived to be negligible in relation to the radiotherapy dose. However, if the patient has a benign disease with a good prognosis then the radiation risk assumes more importance.

Radiation dose from CT scans

3.14   The organ or effective radiation dose from a CT scan can vary depending on the area(s) of the body scanned and the type of procedure performed. A scan to image the chest, abdomen and pelvis has a typical effective dose of 10 mSv (Wall et al, 2011). This type of scan is associated with a lifetime cancer risk in a 30 year old of 520 per million for males and 740 per million for females (see Table 3.2).

3.15   However, this risk is age dependent. For patients below the age of 10 years the risk for males is 960 per million and 1500 per million for females for a CT examination of the chest, abdomen and pelvis. Conversely, for patients aged 60–69 years the risk is 240 per million for males and 360 per million for females for the same examination (Wall et al, 2011). Thus, the risk of developing cancer following an effective dose of 10 mSv varies by three- to five-fold, depending on the age at which the exposure occurs.

3.16   Lifetime cancer risk associated with CT scans can be categorised into broad risk bands according to a scheme proposed in 1995 by the Chief Medical Officer of the Department of Health (Department of Health, 1995).

Negligible	Less than 1 in a million risk	$(<10^{-6})$
Minimal	1 in a million – 1 in 100,000 risk	$(10^{-6} – 10^{-5})$
Very low	1 in 100,000 – 1 in 10,000 risk	$(10^{-5} – 10^{-4})$
Low	1 in 10,000 – 1 in 1,000 risk	$(10^{-4} – 10^{-3})$
Moderate	1 in 1,000 – 1 in 100 risk	$(10^{-3} – 10^{-2})$

3.17   For most of the examinations listed in Table 3.2, the risks typically lie in the upper half of the 'low' risk band for younger patients. However, in some cases (CT of the chest in girls aged 0–9 years and CT of the chest, abdomen and pelvis in girls aged 0–19 years) the risk moves into the 'moderate' band.

3.18   All patient risks must be taken in their clinical context. Most CT scans are performed for diagnosis or to follow the treatment of a serious disease. In

Table 3.2   Typical total lifetime cancer risk as a function of age at exposure and sex for selected CT examinations (per million) (taken and abridged from Table 20 in Wall et al, 2011)

Examination	Sex	Total lifetime cancer risk (per million)									
		Age at exposure (years)									
		0–9	10–19	20–29	30–39	40–49	50–59	60–69	70–79	80–89	90–99
CT head	M	250	190	130	100	80	57	36	20	9.0	1.2
	F	190	140	100	77	71	46	27	13	4.8	0.3
CT chest	M	530	440	350	300	260	220	160	99	42	2.2
	F	1100	860	680	560	490	390	290	180	68	1.7
CT abdomen	M	670	530	400	310	240	170	110	56	21	1.5
	F	610	480	380	300	240	170	110	59	20	0.6
CT abdomen and chest	M	850	670	520	410	320	230	150	78	29	1.9
	F	740	590	470	370	310	230	150	80	28	0.8
CT chest, abdomen and pelvis	M	960	780	630	520	440	340	240	140	58	3.3
	F	1500	1100	910	740	640	500	360	210	80	2.1

the context of, for example, pancreatic cancer – with a 5-year survival of 2% (Cancer Research UK, 2009) – the radiation risk to the individual is of minimal relevance to life expectancy. However, other types of cancer have good, and increasingly better, prognoses. In these patients, while there may be little difficulty justifying an initial CT scan, multiple follow-up scans can result in a significant radiation dose and hence increased risk, which needs careful consideration, particularly if there is a prospect of cure. In some conditions the use of CT in place of conventional investigations results in significantly higher radiation exposure, as in the case of Crohn's disease (Jaffe et al, 2007). It should be determined whether the additional information provided by the CT scan is relevant to management decisions for these patients.

3.19   The use of CT in some diseases may result in patients receiving a large number of scans – for example, in excess of 10 – in the course of a single illness (Meeson et al, 2009). These higher exposures may be documented by departmental dose audit, which is a crucial part of dose monitoring. Limiting the number of examinations to only essential events offers an important means of dose constraint.

3.20   The wider use of CT in patients with advanced malignancy may have little impact on late radiation effects since long-term survivors are rare. Of greater concern is the use of CT and PET CT in curable malignancies in young patients. This applies in particular to those individuals with germ cell tumours and lymphoproliferative conditions including Hodgkin's and non-Hodgkin lymphoma.

3.21   In the case of disease which does not affect longevity or have a good long-term prognosis, the risk from the radiation dose must be considered in terms of the dose against the benefit. This judgement can be difficult since the justification process is, to a large degree, subjective.

Stochastic effects associated with radiation exposure

3.22   Stochastic effects are those effects which are thought to occur as a result of a chance mutagenic damage to a single cell. The probability of occurrence is proportional to radiation dose, while the severity is independent of dose. In the context of radiation protection, the linear no-threshold (LNT) model

is accepted as a core principle and is fundamental to the additive system of radiation protection. It also allows the use of effective dose as a surrogate for risk (Goodhead, 2009). The main stochastic effects are cancer in the directly exposed population and heritable effects (genetic risks to offspring).

3.23   For any individual the exposure to radiation can be thought of as increasing the probability that stochastic effects will occur: the higher the dose absorbed, the higher the chance of developing cancer and other stochastic effects (Holmberg et al, 2010). Two recent large epidemiological studies provide strong supporting evidence for low dose cancer risk. A UK CT study (Pearce et al, 2012a) suggests that there are excess leukaemia and brain cancer risks associated with a dose-response finding of about 50 mGy exposure in childhood. The risks of such exposure are consistent with those for childhood exposures in the Life Span Study (LSS)[*] of Japanese atomic bomb survivors, and suggest that there is little sparing effect of low dose rate exposure. This view is reinforced by the results of a large UK case-control study suggesting an excess leukaemia risk at even lower levels of dose (about 5 mSv), associated with natural background (gamma) radiation exposure (Kendall et al, 2012). However, uncertainties in risks in the UK CT study, and to a lesser extent also those of Kendall et al, may be substantial. Although recall bias is not an issue in the CT study, other sorts of bias (eg confounding by indication) cannot be discounted, although their contribution to the observed leukaemia risk is likely to be modest.

Deterministic (tissue reaction) effects associated with radiation exposure

3.24   A deterministic (tissue reaction) effect describes damage induced by ionising radiation where a dose threshold exists, below which there is no effect, and for which the severity of damage increases with increasing dose above that threshold (ICRP, 2007, 2011). Examples include radiation burns (skin reddening), hair loss, radiation sickness (nausea, vomiting and diarrhoea), depression of blood cell formation, decrease in fertility, and teratogenic effects. All of these effects result from acute high doses of radiation to either a part of the body or to the whole body. For whole-body exposure it is generally thought that an absorbed dose of between 3 and 5 Gy will cause 50% of those exposed to die within 30 days if medical intervention is not given. This is known as the LD_{50} dose. Deterministic effects depend on the rate at which the dose is absorbed in the tissue. Cells affected by a lower dose rate may be repaired or replaced more quickly if they are damaged.

3.25   Cell killing is thought to be central to all tissue reaction effects, although it is not clear whether this is the case for cataracts (Ainsbury et al, 2009) or for circulatory disease (Little et al, 2008, 2010, 2012; Schultz-Hector and Trott, 2007). When a sufficiently large number of cells are damaged within a certain critical time period in which the body cannot replace them (Edwards and Lloyd, 1998), a loss of function in the tissue or organ is observed. Harm to a tissue or organ should be nearly zero at low doses, but once the dose increases above a minimum level or threshold, detrimental effects would be seen.

3.26   The ICRP has reviewed recent epidemiological evidence suggesting that there are some tissue reaction effects, particularly those with very late manifestation, where threshold doses are, or might be, lower than previously considered (ICRP, 2012). For example, the absorbed dose threshold for circulatory disease may be as low as 0.5 Gy for potential damage to the heart or brain. Patient doses of this magnitude could be reached during some complex interventional procedures, but are unlikely in CT.

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*   www.rerf.jp/glossary_e/lss.htm

3.27   The ICRP continues to recommend that optimised protection should be applied in all exposure situations and for all categories of exposure. With the recent evidence, the ICRP further emphasises that protection should be optimised not only for whole-body exposures, but also for exposures to specific tissues, particularly the lens of the eye, and to the heart and the cerebrovascular system.

3.28   With the complexity of current CT systems, there are rare and extreme cases recorded when patients receive significantly more radiation than would be indicated for a particular examination. This can be due to either operator error or equipment error. In Mad River Community Hospital in Northern California in 2008, a radiologic technologist (radiographer) was reported to have administered 151 cervical spine CT scans to a toddler in 68 minutes. There was obvious evidence of the overexposure after the examination, with skin reddening extending downward from a clearly defined line just below the boy's eyes. The technologist reported administering the examination several times, but not 151, in response to table movement errors reported by the CT system.

3.29   The standard warnings used in a CT system at the Cedars-Sinai Hospital in Southern California were somehow bypassed in a specially programmed examination for CT brain perfusion used in the diagnosis and management of strokes. The sequence correctly reported the radiation dose emitted during the examination (up to eight times greater than required); however, the system did not provide the failsafe warning about potential overdose. In total, 385 patients from six hospitals were identified as having been exposed to excess radiation during CT brain perfusion scans. Some patients reported obvious deterministic effects of radiation overexposure, such as hair loss or skin reddening[*].

Cataracts

3.30   A cataract is a clouding of the lens of the eye that affects vision. Most cataracts are related to ageing. However, the lens is one of the most radiosensitive tissues in the body and radiation-induced cataracts have been demonstrated in staff involved in interventional procedures using X-rays (Vano et al, 1998). Radiation-induced cataracts may take many months or years to appear.

3.31   Cataracts can be induced by acute doses of less than 2 Gy of low linear energy transfer (LET) ionising radiation and less than 5 Gy of protracted radiation. Recent evidence from the LSS cohort indicates a radiation effect for vision-impairing cataracts at doses less than 1 Gy (Neriishi et al, 2012). The ICRP currently categorises a radiation-induced cataract as a deterministic (tissue reaction) effect, only appearing when a threshold dose is exceeded. Although some work has been conducted in this area, the exact mechanisms of radiation cataractogenesis are not fully understood, with factors such as genetics and cell communication yet to be resolved. Several lines of evidence have suggested that radiation cataracts may be stochastic (see the review by Ainsbury et al, 2009).

3.32   The latest guidance from the ICRP gives the threshold dose for radiation-induced eye cataracts as around 0.5 Gy for both acute and fractionated exposures (ICRP, 2012). In a study using multi-detector row CT scanners and a human head phantom, the dose to the lens received from a single whole-brain CT scan was estimated as 50–100 mGy (Suzuki et al, 2010). Research from Taiwan reported that repeated head and neck CT exposure is significantly associated with an increased risk of cataract (Yuan et al, 2013). Cumulative lens dose from a series of CT head scans should, therefore, be a consideration from the perspective of radiation protection.

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[*]   www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm185898.htm

Cardiac effects

3.33   It has generally been assumed that ionising radiation risks at moderate to low doses and dose rates are dominated by cancer risks in the directly exposed individuals. At high radiation doses, such as those used in radiotherapy, a variety of other effects are observed, presumably resulting from inactivation (via cell killing) of large numbers of cells and associated functional impairment of the affected tissue. Among such effects are direct damage to the structures of the heart – including marked diffuse fibrotic damage, especially of the pericardium and myocardium, pericardial adhesions, microvascular damage and stenosis of the valves and to the coronary arteries (Adams et al, 2003).

3.34   There are plausible, if not completely understood, mechanisms of effects at the high doses relevant to radiotherapy (Schultz-Hector and Trott, 2007). However, there is emerging evidence of an excess risk of cardiovascular damage at much lower radiation doses and occurring over much longer intervals after radiation exposure in the LSS cohort (Wong et al, 1993; Yamada et al, 2004) and in other groups (Azizova et al, 2010; Howe et al, 2004; Ivanov et al, 2006; Laurent et al, 2010; McGale and Darby, 2005, 2008; McGeoghegan et al, 2008; Muirhead et al, 2009). A number of recent systematic reviews have highlighted the accumulating evidence of an excess risk of circulatory disease in different occupationally exposed groups, with cases at both very low dose rates and high cumulative doses (Little et al, 2008, 2010, 2012). If these associations are interpreted causally, the circulatory disease risks in a general population are expected to be similar to those of cancer (Little et al, 2012). Therefore, the radiation exposure levels associated with repeated diagnostic scans could be relevant.

3.35   A mechanistic (mathematical) model of cardiovascular risk following low dose and low dose rate radiation exposure has been proposed (Little et al, 2009b). The radiation-induced risks predicted by the model are quantitatively consistent with the magnitude of excess risk observed in occupational groups (Little et al, 2009b). However, the detailed assumptions made by the model have yet to be verified.

Groups at high risk for radiation exposure

Children

3.36   Children have a greater radiosensitivity than adults at the same effective dose due to more proliferating tissue and different distribution of tissue within the body (Vock, 2005). Children not only have smaller organs than adults, but usually also have less fat acting as a contrast layer between organs of similar density. Additionally, the lifetime cancer mortality risks attributable to the radiation exposure from a paediatric CT scan are estimated to be considerably higher than from a comparable scan for adults (BEIR V Committee, 1990). A single abdominal CT examination on a 1-year-old child is estimated to give a lifetime cancer mortality risk of 1 in 550, which is an order of magnitude higher than for the equivalent examination on an adult (Brenner et al, 2001). The cancer risk is cumulative over a lifetime, with a contribution due to each radiation exposure. Many radiation-induced solid cancers will not be evident for decades and, therefore, radiation exposure in older adults does not carry the same risk level as does exposure in children.

3.37   The use of CT examinations in children is increasing and reflects the growing availability and technological developments in CT. For the 10-year period from 1993 to 2002 in the hospitals included in the UK CT study of Pearce and colleagues, the number of examinations approximately doubled, from an estimated 25,000 to 48,000 scans per year in patients under 22 years of age (Pearce et al, 2012b). The most common examination was of the head, particularly in infants. For examinations in young children, the increasing speed of CT scans is a notable advantage of CT over other imaging modalities, particularly MRI, which may require the use of sedation or anaesthesia to obtain the required image.

3.38   There is evidence of excess leukaemia and brain cancer risks associated with cumulative radiation doses of about 50 mGy in childhood from CT scans in the UK (Pearce et al, 2012a). In a retrospective study, almost 180,000 patients under 22 years of age who underwent a CT scan between 1985 and 2002 were studied and the excess incidence of leukaemia and brain tumours calculated. A total of 74 patients were diagnosed with leukaemia and 135 with brain cancer. The authors calculated that the relative risk of leukaemia increased by 0.036 per extra milligray received and for brain tumours the increased risk was 0.023. When compared with patients receiving a dose of less than 5 mGy, patients receiving a cumulative mean dose of 50 mGy had around three times the risk of developing leukaemia, while those receiving a cumulative mean dose of around 60 mGy had triple the risk of developing brain tumours. Further increased follow-up and analysis of other cancer types is required to identify the total excess risk for all cancers associated with CT scans of children.

3.39   A recent study in Australia considered the cancer risk from diagnostic CT scans carried out during childhood or adolescence between 1985 and 2005 in 680,000 people (Mathews et al, 2013). A 24% increase in the incidence of all cancers was reported when compared with over 10 million unexposed people and the increase was greater for people exposed at younger ages. The incidence was also significantly increased for many types of solid cancers, leukaemia, myelodysplasia and some lymphoid cancers specifically. For leukaemias and myelodysplasias, the estimated excess rate ratio per milligray was 0.039 (based on a one-year lag) and for brain cancer the estimate was 0.021, both of which are comparable to the UK estimates by Pearce and colleagues (discussed above). This is the largest population-based study on diagnostic medical radiation exposure to date and suggests evidence of increases in other cancers in addition to leukaemias, myelodysplasias and brain cancers following exposure to ionising radiation from CT scans.

3.40   Due to the rising concerns with radiation protection in young people undergoing CT scans, an epidemiological study to quantify the risks in paediatric computed tomography and to optimise doses (EPI-CT) has been set up to investigate the relationship between the exposure to ionising radiation from CT scans in childhood and adolescence and possibly attributable late health effects (Thierry-Chef et al, 2013). This multinational collaborative study is bringing together the national studies already in progress in France, Germany, Sweden and the UK, and has established additional studies in four other European countries, with the initial results expected in 2015. For each country-specific study, cohorts of paediatric and adolescent patients are assembled from the records of radiology departments, as in the original UK CT study. The patients will be followed over time to ascertain information on the incidence of leukaemia, brain tumours and possibly other cancers. Similarly, there are also studies underway in Australia, Canada and Israel (Hricak et al, 2011), with a new CT study planned for Brazil.

3.41   Radiation exposure from fixed parameters results in a relatively higher dose for a child's smaller cross-sectional area compared with that of an adult. Technological parameters, such as tube current, tube voltage and collimation, can be adjusted to minimise the radiation dose. At a minimum, basic scanning parameters should be adjusted to manage the radiation dose to a paediatric patient (Strauss et al, 2010). With the great variability in body size in the paediatric population these adjustments are important and necessary to reduce the radiation dose received. There is evidence in some countries of the use of adult exposure parameters and protocols on paediatric patients (Muhogora et al, 2010).

3.42   The ICRP has produced some guiding principles for referring clinicians and clinical staff when performing diagnostic imaging on paediatric patients (ICRP, 2013). One of the unique aspects of paediatric imaging is the wide range of size and weight in children. These are far more important factors than age alone and should invoke special attention to the optimisation and modification of equipment, techniques and imaging parameters. Use of up-to-date dose reduction technology, when appropriate, is also recommended for paediatric CT scans.

Genetic susceptibility

3.43   There are some genetic conditions associated with an increased susceptibility to ionising radiation, characteristically due to DNA repair defects. Several of these cancer susceptibility conditions are due to inherited alterations in genes which collaborate in DNA repair and cell cycle checkpoint control.

3.44   Many of the conditions are rare, and are recognised because of the clinical phenotype. Some of these conditions are also associated with immune deficiency. Individuals with an inherited susceptibility to specific cancers due to the inheritance of germline alterations in certain cancer-predisposing genes may have an abnormal response to external irradiation, which could promote the initiation of cancer.

3.45   Several of these genetic conditions have been characterised and include ataxia telangiectasia, Fanconi's anaemia, Bloom's syndrome, Werner syndrome, Nijmegen breakage syndrome and xeroderma pigmentosum (see Table 3.3). They are predominantly autosomal recessive conditions. Ionising radiation exposure should be avoided in affected individuals (eg homozygotes for recessive mutations). Clinical radiosensitivity is evident in most of these syndromes (Digweed et al, 1999; Turnbull et al, 2006). The position regarding any radio-sensitivity in individuals heterozygous for the mutation in autosomal recessive conditions is unclear. For example, ataxia telangiectasia is an autosomal recessive disorder characterised by radiosensitivity and an increased risk of lymphoid malignancies, but it is uncertain whether or not heterozygotes (individuals carrying one copy of a faulty ataxia mutated (*ATM*) gene) have increased radio-sensitivity (Taylor et al, 2004). However, there is accumulating evidence that some heterozygotes may indeed have an increased risk of breast cancer (Renwick et al, 2006).

3.46   There are also some autosomal, dominantly inherited, conditions which predispose strongly to certain cancers. Gorlin syndrome is one example, which predisposes the individual to basal cell carcinomas (BCCs) of the skin, with demonstrable radiosensitivity through increases in the development of BCCs in the irradiated area (Strong, 1977). Li-Fraumeni syndrome is another example of an autosomal dominant cancer susceptibility with radiosensitivity that is linked to a predisposition to breast cancer, lymphomas, leukaemias, brain tumours, adrenal carcinoma and many other early onset cancer. Sarcomas and solid cancers were found in individuals with this syndrome after radiotherapy (Li and Fraumeni, 1982; Turnbull et al, 2006). Radiation exposure should be kept to a minimum in such individuals.

3.47   Children with a germline alteration in the tumour suppressor gene *Rb* have a high risk of developing one or more retinoblastoma of the retina in childhood. Long-term follow-up of such children has shown an increased risk of a second cancer in the irradiated patients, predominantly in the radiation field (Kleinerman et al, 2005, 2007).

3.48   Individuals who are carriers of germline mutations in the *BRCA1* or *BRCA2* genes have significantly increased risks of developing breast and ovarian cancer or prostate cancer, and a smaller increased risk of certain other

cancers. Women carrying such germline mutations have up to an 80% lifetime risk of developing breast cancer, and a smaller, but significant risk of developing ovarian cancer (Thompson and Easton, 2004; Turnbull et al, 2006). A recent publication reported that women with germline mutations in *BRCA1* and *BRCA2* exposed to any diagnostic radiation before the age of 30 years had an increased subsequent risk of developing breast cancer (hazard ratio 1.90, 95% CI 1.20–3.00), with a clear dose-response effect. If accurate, this gives clear clinical implications that diagnostic radiation exposure should be kept to a minimum in carriers of germline mutations in these genes (Pijpe et al, 2012).

3.49   About 30% of women with breast cancer also show slightly increased lymphocyte radiosensitivity compared with 10% in the general population. The observation suggests that such individuals are more likely to develop cancer if exposed to radiation, as in CT scans (Scott et al, 1998). However, this has not been examined further in any research study to date and the conclusions remain speculative.

3.50   Increased susceptibility has also been demonstrated in a variety of other rare conditions in addition to those listed in Table 3.3. In these conditions the evidence is based mainly on increased relative risks of cancers after radiotherapy, but it is also possible that smaller doses such as from CT scans could have some effect on cancer risks.

Other groups

3.51   There are other groups, such as pregnant women, who require additional consideration with regards to radiation protection when undergoing CT scans. Maternal and fetal radiation exposure and dose are clearly affected by gestational age, anatomical site, modality and technique. Imaging should be used to evaluate pregnant patients only when the benefits outweigh the risks (Wang et al, 2012).

Summary

3.52   The potential benefit to a patient gained through a CT scan must be balanced against the potential detriments. The principal risk is associated with the exposure to ionising radiation, where the level of the dose received may be significant compared with those from other diagnostic imaging procedures. The potential harm may be determined by three factors – the radiation dose, the age of the patient and the prognosis of the disease. The radiation dose is dependent on the size of the patient, the body position and the extent of the scan.

3.53   Risks associated with ionising radiation are divided into stochastic effects (genetic effects which occur by chance, eg cancer) and tissue reaction (deterministic) effects (radiation injuries with a threshold dose). For diagnostic exposures, the potential effects are usually considered to be stochastic and may arise years after the exposure. Cataracts and cardiac effects may also occur.

3.54   The radiation dose from a CT scan can vary depending on the type of procedure performed and the area(s) of the body scanned. The management of some diseases can require patients to undergo multiple scans and it would be advantageous to limit the number of CT scans to only essential events during the care pathway.

3.55   Certain groups are at higher risk from radiation exposure. Children have a greater radiosensitivity than adults at the same effective dose. Cancer risk is cumulative over a lifetime, with a contribution from each radiation exposure, resulting in CT scans giving a higher risk to children than to older adults. In the UK, there is evidence of excess leukaemia and brain cancers being associated with an exposure of approximately 50 mGy in patients under 22 years of age. Children present a unique wide range of size and weight against age and these factors require special consideration in optimisation and modification of equipment, techniques and imaging parameters.

Table 3.3   Examples of some genetic disorders characterised by genomic instability and predisposition to cancer (reproduced in part from Little, 2003)

Clinical disorder	Gene	Function	Major cellular abnormalities	Cancer types
Ataxia telangiectasia	*ATM*	DNA damage sensor	Chromosomal instability, radiosensitivity, cell cycle abnormalities	Primarily leukaemia and lymphoma and some solid tumours
Bloom's syndrome	*BS*	Helicase (DNA replication)	Chromosomal instability, elevated sister chromatid exchanges	Multiple cancers of all types – *in vitro* studies show impaired accuracy of repair of double strand breaks in breast cancer cells in this syndrome[‡]
Fanconi's anaemia	*FA*[*]	DNA damage sensing and repair	Chromosomal instability, sensitivity to DNA cross-linking agents	Leukaemia and solid tumours
Familial breast cancer	*BRCA1, BRCA2*	Recombinational DNA repair	Chromosomal instability, radiosensitivity	Breast and ovarian cancer
Hereditary non-polyposis colon cancer	MMR[†]	Mismatch DNA repair	Microsatellite instability, mutational instability	Colon and certain other solid tumours
Li-Fraumeni syndrome (1)	*TP53*	Control of cell division	Cell cycle abnormalities	Breast cancer, sarcoma, adrenocortical carcinoma, astrocytoma and glioblastoma
Nevoid basal cell carcinoma syndrome (Gorlin syndrome)	*PTCH1*	Tumour suppressor	Production of an abnormal version of receptor (patched-1 protein), uncontrolled proliferation	Basal cell carcinoma and medulloblastoma
Nijmegen breakage syndrome	*NBS1*	Recombinational DNA repair	Chromosomal instability, radiosensitivity, cell cycle abnormalities	Lymphoma and leukaemia
Schwachman-Diamond syndrome	*SBDS*	Ribosome biogenesis and RNA processing/ RNA metabolism	Increase apoptosis	Myeloid hematological malignancy (leukaemia, myelodysplastic syndrome)
Werner syndrome	*WRN*	Critical for DNA replication and maintaining DNA at the end of chromosomes (telomere)	Disruption in DNA replication, repair and transcription	Sarcoma, melanoma and thyroid cancer
Xeroderma pigmentosum (A)	*XPA*	Nucleotide-excision repair	Mismatch repair activity, cell cycle abnormalities	Basal cell carcinoma, squamous cell carcinoma and melanoma
Xeroderma pigmentosum (C)	*XPC*	DNA repair/nucleotide excision repair pathway	Recognition of bulky DNA adducts in nucleotide excision repair	Basal cell carcinoma, squamous cell carcinoma and melanoma

[*]   There are seven interacting *FA* genes
[†]   Mismatch repair. There are several different MMR genes, inactivation of any one of which will give rise to the disorder
[‡]   Tachibana (2004)

3.56   Some genetic conditions are associated with increased sensitivity to ionising radiation. Most conditions are rare and radiation exposure in homozygotes of autosomal recessive disorders of this type should be avoided. Certain dominantly inherited disorders also confer radiosensitivity, notably Gorlin syndrome and Li-Fraumeni syndrome, and radiation exposure should be minimised in individuals with these conditions. There is evidence of an increased risk of developing breast cancer for women carrying germline mutations in the *BRCA1* or *BRCA2* genes if exposed to any diagnostic radiation before the age of 30 years.

CHAPTER 4

DEVELOPMENTS IN CT AND TECHNOLOGICAL STRATEGIES FOR DOSE REDUCTION

CT technology

4.1   CT uses X-rays to produce cross-sectional images of the body. X-rays are produced when electrons, emitted by the cathode, strike a target (the anode) made of a high atomic number material, often tungsten. The energy with which the electrons strike the target is dictated by the potential difference (tube voltage) between the anode and the cathode. In diagnostic and interventional radiography this is expressed as kilovoltage (or kV) – the greater the tube voltage, the greater the maximum possible energy of the X-rays and, therefore, the more penetrating the resultant X-rays will be.

4.2   The production of X-rays is directly proportional to the tube current. In diagnostic and interventional radiography, the tube current is expressed as milliamperes (or mA) – the greater the tube current, the greater the quantity of X-rays produced. The time over which the tube is generating X-rays is important, and therefore, in CT, the product of tube current and time expressed as milliampere seconds (or mAs) is a useful parameter as it relates to the total amount of X-rays produced. It may be required to be known for a single rotation of the tube or for the total examination, being referred to as the mAs per rotation or the total mAs, respectively. The tube-current–time product is often used when discussing radiation dose, as dose is proportional to mAs when other parameters are constant for a particular examination.

4.3   CT has undergone technological developments rapidly from slice-by-slice image acquisition to continuous helical scanning, with volume data acquisition providing flexible image manipulation (see Appendix C for a timeline of CT development). These advances are well documented in the literature[*].

4.4   In October 1975 CT scan times were approximately 20 seconds per slice for a 320×320 pixel image matrix, although early scanners took minutes to perform an image slice. By the late 1980s scan times were down to only 3 seconds and matrix sizes were up to 1024×1024 pixels, reducing movement artefacts and improving resolution. The early 1990s saw the introduction of helical (continuous) scanning and the development of multi-slice scanners, with the availability of four-slice (per rotation) scanners and scan times of 0.5 second by the end of the century. These advances increased both the speed of scanning and the volume covered in a single breath hold. Developments in technology in the 21st century have included 320-slice scanners, dual-source and dual-energy CT scanners and modern iterative reconstruction techniques.

4.5   While the development of CT in the mid-1990s and following decade could be described as relentless, the introduction of dose reduction technology within CT only became a major focus in the second half of this period. Innovation in CT dose reduction technology is expected to continue as the number of CT scans performed worldwide increases and new applications, such as cardiac CT, become commonplace. Sub-millisievert scanning has already

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[*]   www.impactscan.org/bluecover.htm

become a reality for a few CT applications (cardiac and paediatric) (Kalender, 2011; Schuhbaeck et al, 2013), while the goal of sub-millisievert scanning in general will require a significant reduction in dose. Developments in hardware are helping to play a part in this.

4.6   Technical advances in CT that have an impact on dose include:

(a)   Detector technology

(b)   X-ray beam width

(c)   Tube current modulation

(d)   Tube voltage optimisation

(e)   Iterative reconstruction

(f)   Dynamic scanning/perfusion

(g)   Dual energy

(h)   Cardiac scanning and reconstruction techniques

Each has an effect on dose, dependent on how it is used. Some features are built into scan protocols which may not be changed on a daily or individual basis. However, the operator needs to understand these technologies and their implications to ensure patient safety and maximise the use of the equipment.

4.7   In this report it is assumed that hospital trusts and departments will have met their legal requirement to ensure that the equipment they install is appropriately selected, correctly installed and adequately maintained and monitored, with appropriate quality assurance programmes.

Detector technology   4.8   The first-generation CT scanner used a single sodium iodide scintillation detector in the scan plane, and a single narrow X-ray beam. This design also incorporated a detector in a neighbouring plane to create a two-slice system. This concept gave the first multi-slice scanner, but was discontinued until modern multi-slice scanners were developed. Second-generation scanners were introduced in the mid-1970s with multiple detectors (eg 20) against a small angle fan beam. Development of a fan-beam X-ray and the use of an array of detectors resulted in the third generation of scanners. Initial models incorporated around 250 detectors in the array; later designs expanded this to around 750 detectors. This generation also introduced xenon gas detector arrays, although these have been superseded by solid-state detectors. Fourth-generation scanners (single-slice) used a ring of detectors (Goldman, 2007). However, this design was not favoured and the third-generation design proved to have lasting value.

4.9   Modern multi-slice scanners are based on the third-generation design and were introduced in the early 1990s, with four-slice systems becoming available in about 1998. Multiple detector rows enable multiple image or data slices to be acquired simultaneously. These detector rows are manufactured for the individual detector elements to be extremely small (around 0.5 mm) to allow for very narrow image widths. The detector elements are separated by septa to prevent photons crossing to neighbouring detectors.

4.10   The number of detector rows does not necessarily match the number of data or image slices acquired. There may be more rows – particularly for the lower-slice scanners (eg four) where the number of data acquisition channels was limited – but by having more detector rows there was a greater flexibility in terms of acquired image widths. The number of detector rows can also be less than the number of slices – this is where the tube technology allows an

oscillating focal spot to acquire double the number of projections – each at a slightly different angle from its neighbour. Alternatively, three-dimensional reconstruction techniques with the large cone beam scanners can allow for a greater number of slices to be produced from one acquisition.

4.11   Modern CT scanners use ceramic or crystal-based scintillators as the detector material. These have greater detection efficiency than the older – no longer used – xenon gas detectors.

4.12   Manufacturers continue to develop their detectors for increased sensitivity, faster response times and less afterglow – all intended to afford dose reduction opportunities and increase the accuracy of image data with higher spatial and temporal resolution.

4.13   Consideration should be given to detector performance when procuring a new system. Involving the medical physicists in the procurement process, as well as the radiologists and radiographers, is invaluable.

X-ray beam width

4.14   Traditionally, the extent of the beam along the patient length is called the beam width. As the beams have extended beyond fan beams with narrow beam widths to those with wider beam widths, it is more correct to talk about a 'cone beam'– from both an imaging and a dosimetric perspective.

4.15   Typically, the beam width might be about 40 mm for modern systems; however, there are currently two scanners which have greater beam coverage, at 80 and 160 mm. These systems allow a greater extent of the patient to be scanned at any one time, which is advantageous, especially for single organ coverage, with a particular application in dynamic scanning.

4.16   For the wider beam scanners to provide continuous image coverage, a small amount of overlap is required in successive irradiations along the patient length, due to the narrower projection of the beam at the patient's surface compared to the iso-centre (centre of rotation).

4.17   In multi-slice scanning, primarily only the main beam is used to cover the active detectors involved in image reconstruction, and the penumbra of the beam is not used for image reconstruction. This is to ensure uniformity of data projections and reconstructed slices. The penumbra extends about 2–4 mm either side of the main beam along the z-axis, and is generally a fixed amount regardless of the beam width. This means that the dose efficiency along the z-axis improves with wider beam widths.

4.18   In helical scanning, data are required outside the image volume to reconstruct the first and last images in that volume, and this is achieved by one or more rotations of the tube and detector assembly at each end beyond the required image limits. Wider beam widths, therefore, add an additional amount of unnecessary irradiation since only part of the beam is required, namely the portion that irradiates the detectors whose signal is being used to reconstruct the end images. Some manufacturers have developed technology that temporarily, and dynamically with the table movement, blocks the part of the X-ray beam not used for image reconstruction so that only targeted tissue is irradiated, affording dose reduction. Dose reductions of up to 40% have been reported, particularly for high pitch and small scanning ranges (Christner et al, 2010).

4.19   Additional dose reduction opportunities offered with advanced collima-tion technology should be taken into consideration and evaluated when procuring a CT system.

Tube current (mA) modulation

4.20   Operators also need to be familiar with the optimal beam width required for the appropriate clinical scan. For example, the majority of scans would be undertaken with the widest beam as it is more dose efficient.

4.21   Traditionally, a tube current was established for a given scan protocol and subsequently used for all patients (including children). Over time, separate protocols were sometimes established for paediatrics, but with both these and the adult protocols the fixed tube current was used. With concerns beginning to emerge on the use of the same tube current for different patient sizes, some sites established protocols for ranges of patient sizes. This ensured that slimmer patients did not receive unnecessary radiation dose and larger patients received an appropriate amount to ensure an adequate image quality.

4.22   Consideration of the variation of attenuation due to overall patient size, along a given patient's length, and around a cross-sectional view, led to the use of variable tube current for, and during, an examination. This concept of using tube current variation to reduce radiation dose while still maintaining image quality was introduced by Haaga and colleagues in 1981 (Haaga et al, 1981). In 1994, GE Medical Systems produced the first commercial machine to incorporate a tube current modulation system, with which dose reductions of up to 20% were achievable (McCollough et al, 2006).

4.23   Tube current modulation, also known as automatic exposure control (AEC), is available on all new CT systems and, since it has tended to be added with software upgrades, also to much of the installed base. It automatically adjusts the tube current according to patient size, differences in attenuation along the patient axis (*z*-axis modulation) and differences around the patient (angular modulation).

4.24   AEC systems have a number of potential advantages, including better control of patient dose, avoidance of photon starvation artefacts (for example, through the pelvis region), reduced load on the X-ray tube, and more uniform image noise both on a single patient examination and over a wide range of patients (Lee et al, 2008).

4.25   Each manufacturer has a slightly different implementation of AEC, with some systems enabling all three aspects of modulation to occur at once. The level of adjustment is based on measurements taken from one or two (anteroposterior and lateral) scan projection radiographs (SPRs), and in two instances, for the *z*-axis modulation, it is also adjusted according to the measured attenuation on a previous rotation of the X-ray tube through the patient. Tube current is then modulated in response to rapidly changing patient size or attenuation within a slice position or from one slice position to the next. This potentially can reduce the mAs through the shoulder regions, for example, by 50% (Kalender et al, 1999).

4.26   The overall adjustment to the tube current is made to a nominated required image quality figure (related to image noise), or to a suggested reference value tube current – which in turn relates to a pre-determined required image quality. Some systems allow the user to specify a maximum and minimum tube current limit, which can assist in the overall control of the tube current.

4.27   Manufacturers are taking into account that it is not always required – or even possible – to adjust the tube current to achieve the same image noise for large patients. Conversely, if the tube current is adjusted accordingly for small patients, the level of image noise may not be suitable for diagnosis as such patients have less fat around the organs. The tendency is now to adjust the tube

current to a higher noise level for larger patients and a lower noise level for small patients. This has already been implemented for some time by one manufacturer, and the others all have this feature in development.

4.28   Implementation of the AEC systems requires understanding of each system particular to its manufacturer. Tube current modulation can be customised for each protocol and site. It is often guided by the applications training specialists, working closely with the users to understand individual site preferences and image quality requirements.

4.29   Reducing tube current is a valuable manoeuvre when issues of image resolution are not paramount. For example, an increase in image noise does not compromise diagnosis when looking for renal stones. This applies especially to examinations of tissues with inherent high contrast, such as the lung or bone, and some evidence is available from research studies indicating those applications where reduced current can be used without critically compromising diagnostic quality (Diederich et al, 2004; Gurung et al, 2005; Hu et al, 2011).

4.30   Tube current may also be reduced in follow-up examinations when the initial examination has indicated that demonstrating the disease process does not require maximal resolution.

4.31   Automatic exposure control has demonstrated reductions in dose of about 20–40% when image quality is appropriately specified (McCollough et al, 2009). Although there is some variation in the dose reduction seen with each of the manufacturers' systems, dose modulation software claims dose reduction of up to 50% (Raman et al, 2013).

4.32   Clear explanation of how modulation is achieved, and the factors influencing this, is crucial. At installation and applications training, a focus on the importance of exact positioning at iso-centre is key to understanding the correct use of this dose reduction tool.

4.33   Patient centring is important for optimal dose and image quality distribution even without AEC. For example, patients positioned in the antero-posterior position and placed too high in the gantry will receive a lower anterior surface dose and associated higher noise in the anterior region (and conversely a higher posterior dose and lower noise in the posterior region). The explanation for this can be understood by considering the X-ray tube in the lateral position. At this point in the rotation of the tube, the X-ray beam through the iso-centre of the patient will be attenuated by the thicker region of the beam shaping filter. This type of effect will occur for both vertical and lateral mis-centring, and the extent of the effect will also be dependent on the beam shaping filter (Toth et al, 2007). With AEC the requirement of patient centring is even more important as there is the additional scope for inaccurate calculations for the AEC (Gudjonsdottir et al, 2009; Singh et al, 2011).

4.34   If the scan projection radiograph (SPR) does not cover the entire area for examination it is important that the operators are aware that modulation may not be applied to the area missing from the SPR. For example, a default tube current may be implemented which may be inappropriate for the region scanned or for the size of patient, or the tube current at the last slice position may be used, which again, may be inappropriate. In some situations it may be appropriate to repeat the SPR to include all the anatomy required. This highlights the need for operators to be adequately trained and familiar with the technology.

4.35   All manufacturers offer tube current modulation on their latest equipment and it is widely used throughout the CT community. Manufacturers

have different implementations of the AEC; one manufacturer integrates tube current modulation with simultaneous automatic tube voltage (kV) optimisation, offering consistent image quality with the two dose reduction programmes working together.

4.36   It is essential that operators and physics support have full understanding of the operation and implications of the use of these AEC systems, since inappropriate use can easily result in increased radiation dose (Keat, 2005). Therefore, continuous specialist training throughout the life of the equipment is essential to maintain and promote awareness of new techniques, technology and innovations.

X-ray tube voltage (kV) optimisation

4.37   The X-ray tube voltage may be increased in large patients to achieve adequate image quality without needing to raise other exposure factors such as tube current. Raising the tube voltage to give a required noise value can have a smaller increase in patient dose than the equivalent process of applying an increased tube current (Nagel, 2000). It can also be advantageous where there is an upper tube current limitation.

4.38   Lowering the tube voltage allows for greater image contrast with the use of intravenous iodine contrast and, therefore, this introduces the potential for lower dose scanning. It also allows for the automatic adjustment of exposure according to patient size (including children) circumventing any tube current limitation at the lower limit.

4.39   Tube voltage in CT examinations should be varied more often than is common practice today and done, not only based on patient size, but also according to the substance imaged to minimise dose (Kalender et al, 2009). For imaging involving iodine or bone, the optimal values are typically 80 kV and lower, due to the greater image contrast of these substances, compared with tissue. Similarly, low tube voltage values are appropriate for paediatric imaging and offer a potential for dose reduction.

4.40   An overall dose reduction of 25% has been demonstrated when using 100 kV (compared with the standard 120 kV protocol) for CT angiography on a per-patient basis using automatic tube voltage and current modulation (Winklehner et al, 2011a). Similarly, when the tube voltage was reduced from 120 kV to 100 kV in a paediatric patient, a dose reduction of 23% was achieved, demonstrating improved contrast and bowel visualisation (Yu et al, 2009).

4.41   Some manufacturers offer the ability to automatically change the tube voltage. However, if this is not the case, it is still possible to manipulate (reduce or increase) the tube voltage on an individual basis to answer specific clinical questions or relating to patient size. The use of this potential dose reduction tool is closely linked with balancing acceptable image quality. Tube current modulation is often used in conjunction with a reduction in tube voltage to ensure adequate image quality. Manufacturers have recognised tube voltage adaptation as a dose reduction opportunity and some are offering options from 70 kV through to 140 kV.

4.42   This approach to dose optimisation has not always been common practice for various reasons. Operators may have felt reluctant to reduce the tube voltage, concerned for the effect on image quality, producing an image unfit for diagnostic purposes. Historically, there were fewer options available to change the tube voltage and a more limited portfolio of examinations. As technology has developed and facilitated new applications (such as cardiac CT and CT colonography), the dynamics of the operator's role have evolved. Operators are

now presented with more options to use technology, change parameters and reduce dose.

4.43   Clinical staff can embrace this change in practice, with the associated potential dose reduction, where there are supporting data available to confirm optimal tube voltage for specific tissues/compounds, patient size (particularly for paediatrics), and where there is appropriate training. Ongoing applications training by manufacturers is essential to encourage the appropriate use of all the dose reduction tools offered on each individual system.

Iterative reconstruction   4.44   The first CT scanner model used standard algebraic iterative reconstruction techniques, which were unsatisfactory in terms of the length of time required to process the images. Subsequently, CT images have been reconstructed using the analytical filtered back projection technique. With wider beam widths and multi-slice acquisitions (greater than about 12 slices), modified versions of filtered back projection are used and, with even wider beams, modified three-dimensional complex reconstructions are required.

4.45   Iterative reconstruction was introduced in modern scanners in 2008 and all manufacturers have such packages available (Karpitschka et al, 2013; Neroladaki et al, 2013).

4.46   Iterative reconstruction works on the basis of taking the filtered back projected image, forward projecting from this to compare with the actual measured attenuation profiles, applying a correction and repeating the process a number of times. There are two approaches, a statistical approach and a model-based approach – the latter is the more complex whereby the forward projection process uses real dimensions of the focal spot and detectors. This approach has longer computational times, and its implementation has to be considered in the context of the workflow. Iterative reconstruction affects the look of the image, which can influence its clinical acceptance, but uses more of the projection data to the extent that there is lower noise in the images compared to filtered back projection.

4.47   Many iterative reconstruction packages allow for a combined approach of filtered back projection and partial iteration. This approach reduces the reconstruction time and also keeps the appearance of the images similar to that of filtered back projection to enable clinical acceptability.

4.48   Generally, the post-reconstruction reduction in noise enables the protocol to use a lower mAs than normally used. This has the potential for dose reduction, for example, quoted in the order of 30–50% (Winklehner et al, 2011b) for CT pulmonary angiogram. A greater than 45% dose reduction, at maintained image quality, has been evaluated in oncological patients (Karpitschka et al, 2013), demonstrating the potential dose savings achievable with iterative reconstruction techniques.

4.49   Each manufacturer achieves this by a slightly different route; however, this process can have one of three aims:

(a)   Keep image quality the same and lower doses

(b)   Keep doses the same and improve image quality

(c)   A balance of lower doses and better image quality

4.50   The challenge for operators is in setting up iterative reconstruction for each individual protocol and gaining a consensus of agreement from clinicians as to acceptable image quality. It is crucial to 'ring fence' sufficient time and

effort with applications training specialists, physicists and radiologists to choose, and then objectively evaluate, image quality. Dose audits should be completed to ensure a measurable evaluation can be undertaken.

Dynamic scanning/ perfusion

4.51   The ability to take successive images of blood or contrast perfusion through organs or vessels is dependent on the scanner's ability to use sequences of sets of projections overlapping in time to provide a suitable image refresh rate, while scanning the same volume of tissue. Special software packages are required to undertake this function. This ability is also dependent on the extent of organ coverage provided by the scanner; a wider beam scanner can provide a wider region for investigation.

4.52   The widest beam scanners can perform dynamic scanning for single organs, such as the brain or liver. However, other scanners can achieve the same volume coverage by moving the couch rapidly from one neighbouring scan position to another (either axially or helically) to provide continuous imaging for dynamic studies. Special software and hardware facilities are required for this; two of the terms used are 'jog scan' and 'helical shuttle'.

4.53   Dynamic scanning for perfusion studies can provide extensive single-site irradiation and, therefore, has the potential to give high doses if standard scan parameters are used (Imanishi et al, 2005). Close attention needs to be given to the scan protocols. Most scanners by default will operate at a low tube current, with a limited time period for the examination exposure. If standard tube currents are used accidentally, there is scope for overdose to a single region[*].

4.54   Operators and physicists need to work closely with applications specialists to develop protocols to reflect the dose implications with this technique. These should include default limits for patient safety and regular reviews of the protocol.

Dual energy

4.55   Dual-energy CT techniques have become possible with the new technologies of fast tube voltage switching and dual X-ray source scanners. Some manufacturers refer to this as spectral imaging.

4.56   Dual-energy techniques were primarily developed to give improved image quality. By scanning the same volume at two different tube voltages, materials whose composition gives rise to a significant variation in CT number with energy, can be separated from other materials. In particular, iodine contrast has a significant difference in CT number when scanned with the range of tube voltages (ie peak energies) available on a CT scanner. Various technologies and methods are available to achieve this. The options include: performing a scan at one tube voltage value, then undertaking a repeat scan at a different value; scanning using two tubes simultaneously – each operating at a different tube voltage; switching tube voltage rapidly during a scan; or using a detector that can discriminate between low and high energy photons in one irradiation.

4.57   Dual-energy CT, therefore, might allow for better discrimination of certain tissues and pathology. For example, it can potentially provide accurate differentiation between urinary stones that do and do not contain uric acid, and improve the visualisation of tendons of the hand and foot; it might also support bone removal, provide an additional method that can remove bony structures from CT angiography scans or provide differentiation between plaque and contrast media in arteries.

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*   www.fda.gov/medicaldevices/safety/alertsandnotices/ucm185898.htm

4.58   There is strong evidence that dual-energy CT with dual-source CT is not associated with increased radiation dose levels. Radiation dose data on dual-energy techniques based on rapid tube voltage switching to date are inconclusive. Judicious use of dual-energy techniques holds the potential of drastically reducing radiation exposure – for example, by the elimination of unenhanced CT scans (Henzler et al, 2012).

Cardiac

4.59   Cardiac imaging is a demanding application of multi-slice CT and is only possible due to recent technological advances. Two of these advances include faster rotation times and data acquisition at sub-millimetre slice thickness. These techniques afford high temporal (for motion-free images) and spatial resolution (for visualisation of small coronary segments).

4.60   To image the rapidly moving heart, data must be acquired as fast as possible to freeze the heart motion. This can be achieved either by prospective ECG triggering or retrospective ECG gating.

4.61   Prospective ECG triggering is similar to conventional CT, step-and-shoot. The patient's cardiac rhythm is ECG monitored and the scanner starts the scan at pre-determined intervals to acquire sufficient data for image reconstruction. X-rays are on for a limited period and these sequential scans typically result in a lower radiation dose.

4.62   When retrospective ECG gating is used, the X-rays are on continuously and scan data are collected throughout the heart cycle. Retrospectively, data from selected points in the cardiac cycle are selected for image reconstruction. The radiation dose is greater with this type of scan mode compared to that from prospective triggering.

4.63   Technological improvements have enabled cardiac CT angiography to operate at much reduced doses from its first implementation. For example, the fast pitch scanning mode, which allows full coverage of the whole heart in one cardiac cycle offers markedly reduced doses, averaging approximately 1 mSv (Achenbach et al, 2010; Yu et al, 2009).

Scanning time

4.64   Radiation dose rises in line with the time the X-ray exposure is applied. In practice, this parameter is usually dictated by the need to cover the examination volume in a short enough time to avoid problems from patient movement. Exposure time can, however, be reduced by limiting the examination volume or manipulating pitch factors, as below.

Pitch factors

4.65   The term 'pitch' relates to the speed of table movement during image acquisition. Setting a pitch factor greater than one allows a larger volume to be covered in a shorter time, with proportionately less exposure to the tissues contained within the imaging volume. With single-slice scanners this resulted in a dose reduction and also a decrease in image resolution due to a wider image width. This may not be suitable where high resolution volume acquisition is required. For example, to facilitate high resolution multi-planar post-processing (three-dimensional image manipulation) or where image resolution does not need to be maximal, increasing the pitch factor is a valuable method of reducing exposure (Kalender, 2004).

4.66   However, in multi-slice scanning on some scanners the tube current is automatically adjusted to allow for the average reduced dose along a scanned volume. With multiple detectors available the image width will generally be unaffected.

Summary

4.67   CT has undergone dramatic technical advances, with the introduction of helical and also multi-slice scanners, dual-source and dual-energy scanners and modern iterative reconstruction techniques. The speed of scanning has also increased, allowing a greater volume to be scanned during a single breath hold.

4.68   There has been a focus on dose reduction technology since the turn of the century, with sub-millisievert scanning already a reality for some applications of CT. Technological advances that have the potential for dose reduction include detector technology, X-ray beam width, tube current modulation, tube voltage optimisation, iterative reconstruction, dynamic scanning/perfusion, dual energy and new approaches to cardiac scanning and reconstruction techniques. Each of these developments offers potential dose reductions depending on how it is employed.

4.69   It is, therefore, important that the operators understand the different technologies and how to maximise their use, while being aware of the implications to ensure patient safety. This is best achieved by education, training and continuing professional development related to the concepts of CT and their specific application for individual scanners. This, in turn, requires manufacturers to ensure that their applications specialists are fully familiar with the capabilities of the equipment and the changes enabled by any software upgrades installed as part of routine servicing.

CHAPTER 5

DOSE MEASUREMENTS, DOSE SURVEYS AND DIAGNOSTIC REFERENCE LEVELS

Dose measurements

5.1   In general, CT has the same dose quantities as other imaging technologies that use ionising radiation. However, there are some additional quantities that are specific to CT.

General exposure and dose quantities

5.2   Absorbed dose (expressed in gray, Gy) is the radiation energy imparted per unit mass of irradiated material, eg air or tissue. In CT, it is proportional to the intensity of the emitted X-ray beam and the time for which the material is irradiated. Differences in scanned lengths will contribute scatter to the absorbed dose at a given position.

5.3   A related quantity is kerma, which stands for kinetic energy released in matter. It depends on the same factors and has the same units as absorbed dose and, at the X-ray energies used in radiography and CT, kerma is equal to absorbed dose.

5.4   In projection radiography, air kerma per unit mAs may be measured with a calibrated ionisation chamber at a fixed distance from the X-ray tube for a range of tube voltage and filtration values. Such data may be used to calculate the entrance surface kerma and entrance surface (absorbed) dose for specific radiographic projections. Subsequently, it is possible to estimate absorbed dose at depth or organ dose for a generic patient. The latter requires simulation of radiation interactions in tissue (using Monte Carlo methods) and a mathematical model of patient anatomy. For practical purposes, organ doses for particular investigations are presented in tabular form. Sensitivity to the effects of radiation varies between organs, and organ dose is regarded as a good indicator of radiation risk (Bushberg et al, 2012).

5.5   Equivalent dose (expressed in sievert, Sv) takes account of the fact that different types of radiation cause different biological effects for the same absorbed dose; it is given by the absorbed dose multiplied by the radiation weighting factor (ICRP, 2007). For X-rays, this weighting factor is one and so the equivalent dose is numerically equal to the absorbed dose in CT.

5.6   A further quantity, effective dose (also expressed in Sv), is calculated as the sum of the product of equivalent dose and a tissue weighting factor; this factor represents the relative radiosensitivity of the tissue or organ. The summation is done over all exposed tissues and organs. Clearly, calculation in this way requires an estimate of organ dose. In addition to the factors that determine absorbed and equivalent dose, effective dose in CT depends on the scan length and the anatomical region imaged.

5.7   Effective dose is a useful means of expressing radiation detriment for partial-body irradiation, which is characteristic of diagnostic medical exposures to ionising radiation. It is the uniform whole-body dose that carries the same risk of stochastic biological effects as an actual irradiation. However, effective dose is not intended as an indication of risk to an individual patient who has

been subjected to a particular radiological investigation, but may be used, for example, to compare one type of investigation with another.

5.8   In projection radiography and fluoroscopy, the quantity dose-area product (DAP) is widely used. It is the product of absorbed dose in air and X-ray beam area; typical units are $cGy\,cm^2$. DAP is easily measurable at the point where the beam leaves the X-ray tube, and, since the X-ray beam is usually well collimated to the clinical area of interest, it will represent all the dose the patient receives.

CT-specific exposure and dose quantities

5.9   The geometrical features of patient irradiation in CT differ from those that apply in projection radiography. First, the radiation source (X-ray tube) rotates so that irradiation is continuous around the patient. Second, at any instant only a relatively short length of the patient is exposed to radiation, but the exposed region moves along the patient until the required volume of tissue has been imaged.

5.10   The rotational irradiation geometry means that dose distribution within the patient is much more uniform in CT than is the case for radiography and fluoroscopy. Both of the latter are characterised by large dose gradients from the point at which the X-ray beam enters the patient to the exit point. Dose uniformity in CT is further enhanced by the use of a beam-shaping (bow-tie) filter.

5.11   In CT the whole beam is not incident on the patient, indeed it is designed such that the outer edges of the fan beam are incident on reference detectors at the end of the arc of the imaging detector array. Therefore it is not possible to have a DAP-equivalent parameter in CT.

5.12   Instead there are two dose quantities that have been specifically developed for use with CT: the CT dose index (CTDI) and dose-length product (DLP). These have been introduced because of the unique geometrical features of patient irradiation in CT.

5.13   Organ dose in CT is estimated using a reference measurement of air kerma at the iso-centre of the scanner. As with projection radiography, organ doses for specific exposure factors are tabulated using the results of Monte Carlo simulations.

CT dose index (CTDI)

5.14   The CTDI is a measure of the absorbed dose (in Gy) from a single rotation of the CT scanner gantry (with no movement of the patient couch); it depends on the output of the X-ray tube and the width of the X-ray beam in the axial direction (along which the patient lies) (Hufton, 2002). It is defined as the integral (with respect to distance) of the dose profile in the axial direction, divided by the nominal collimated width of the X-ray beam in the same direction. The existence of beam divergence, beam penumbra and scattered radiation means that the dose profile has long tails on both sides of the central maximum (at zero distance), and so the limits of integration are infinite (Hsieh, 2003; IPEM, 2003; Shope et al, 1981).

5.15   In practice, the CTDI is measured with a calibrated pencil-shaped ionisation chamber which is 100 mm long, thus measuring the integration of the single-slice dose profile over 100 mm. With this pencil chamber, the dose profile is integrated with limits of ±50 mm, which overcomes the difficulty of evaluating an integral over infinite distance. The resulting index is known as $CTDI_{100}$.

5.16   The CTDI parameters in common use are the CTDI measured in air ($CTDI_{free-in-air}$) or in standard phantoms ($CTDI_w$ – weighted, $CTDI_{vol}$ – volume).

5.17   For the measurement of the $CTDI_{free-in-air}$ the ionisation chamber is placed at the iso-centre of the scan field of view.

5.18   For the measurement of the $CTDI_w$ and $CTDI_{vol}$, the ionisation chamber is placed in a cylindrical phantom (test object) made of poly(methylmethacrylate) (PMMA, also known as Perspex™) which is positioned at the centre of the CT scanner gantry during exposure.

5.19   There are two standard adult CT dosimetry phantoms for the measurement of $CTDI_{100}$: a body phantom with a diameter of 32 cm and a head phantom with a diameter of 16 cm. Both are 15 cm long. The head phantom also serves as a torso phantom for children. The phantoms are used purely for the determination of CTDI; more sophisticated phantoms are available for the optimisation of dose and image quality.

5.20   The ionisation chamber may be inserted into either a central or peripheral hole in the phantoms. Adding one-third of the central $CTDI_{100}$ measurement and two-thirds of that at the periphery gives a $CTDI_w$ value. This is a good estimate of the average dose to the phantom at the central CT slice of an examination, as though it were scanned with contiguous slices for a range of 100 mm.

5.21   Dose is inversely related to helical pitch, which is defined as the axial movement of the patient couch for one complete rotation of the gantry divided by the nominal X-ray beam width. Dividing the $CTDI_w$ by the pitch gives the $CTDI_{vol}$, an approximation to the average absorbed dose within the volume that has been scanned (Allisy-Roberts and Williams, 2008).

5.22   Wide beam scanners have a modified approach to the measurement of the $CTDI_{vol}$. This definition has gone through a few iterations by the IEC and, therefore, requires close attention when looking at the $CTDI_{vol}$ for scanners with beams wider than about 60 mm (IEC, 2010). The current accepted definition of CTDI for wide beam scanners requires the $CTDI_{vol}$ to be measured using a beam width of less than or equal to 40 mm. This is corrected using the ratio of $CTDI_{free-in-air}$ values measured for the wide beam and the narrower beam (for which the $CTDI_{vol}$ has been measured). The $CTDI_{free-in-air}$ for the wider beam can be measured by stepping the chamber through the beam, thereby measuring the integration of the dose profile. This is described in an IAEA report on the status of CT dosimetry for wide cone beam scanners (IAEA, 2011).

5.23   The $CTDI_{vol}$ is unique for the particular beam shaping filter that is used for an examination. Sometimes a 16 cm phantom is used for the quotation of the $CTDI_{vol}$ for paediatric body examinations. Whenever paediatric $CTDI_{vol}$ values are compared, the specifying phantom must also be quoted.

Dose-length product (DLP)

5.24   Dose-length product (DLP), the second CT-specific dose quantity, is defined as the product of $CTDI_{vol}$ and the scanned length of the patient. It is a measure of the total radiation delivered by the CT scanner. Usually CT scanners display both the predicted and actual DLP.

Applications of CTDI and DLP

5.25   The CTDI and DLP have specific applications and uses in CT, as well as some limitations.

5.26   The $CTDI_{free-in-air}$ is a useful measure of tube output and it can also be normalised to the tube-current–time product, ie expressed as mGy per unit mAs. In this form, it may be used as an alternative to air kerma as a reference

measurement for quality control (IPEM, 2003), as well as with Monte Carlo generated organ dose datasets in order to estimate organ doses and hence effective dose (ImPACT CTDosimetry calculator[*], NRPB-SR250[†]).

5.27 The $CTDI_{vol}$ and its precursors were originally developed as a means of comparing different CT scanners and protocols, and as such the $CTDI_{vol}$ is a very valuable tool.

5.28 DLP is approximately proportional to effective dose for a particular type of CT investigation and factors are available to convert DLP (in mGy cm) to effective dose (in mSv). These values are available for specific scanned regions of the body, and for adults and children. They originated with European quality criteria (European Commission, 1999) and have since been updated (AAPM, 2008; Shrimpton et al, 2005).

5.29 Although there have been isolated reports of deterministic effects, the major concern as regards patient safety in CT is the stochastic risk of cancer induction at some time in the future. Effective dose, whether calculated with knowledge of organ doses or estimated from DLP, allows the estimation of risk to a member of the general population; the accepted risk coefficient for radiation-induced fatal cancer is 5.7% per Sv. However, effective dose is not suitable for risk estimation in individual patients since it does not take account of factors such as the patient's age, sex and body size.

Pre- and post-scan dose estimates

5.30 The IEC has a requirement for the display of $CTDI_{vol}$ and DLP (IEC, 2010).

Display of $CTDI_{vol}$ and DLP

5.31 The majority of CT scanners have the facility to display the predicted $CTDI_w$ (and/or $CTDI_{vol}$) and DLP, prior to the patient scan after the scan protocol has been set (see Table 5.1). This is possible because scanner manufacturers have measured the $CTDI_w$ for each scanner model over a range of conditions, such as tube current and voltage, X-ray beam filter combinations, beam collimations and focal spot sizes. The displayed quantity ($CTDI_w$ or $CTDI_{vol}$) is calculated using the relevant measurement and the values of exposure factors and pitch for the scan protocol as appropriate.

5.32 In some cases, the actual CTDI is shown after the scan has been completed; this may differ from that predicted due to the operation of automatic exposure control (AEC) during the scan acquisition. The actual CTDI (usually expressed as an average) from the scan and the associated DLP are usually presented in the protocol page, and the DICOM dose reporting object. The average tube current, and rotation time, can also be extracted from the DICOM headers for each image for more exact calculation of the CTDI.

Notifications and alerts

5.33 Following a number of high profile CT incidents in the USA[‡], a US technical standard (XR 25) was published in 2010 by the National Electrical Manufacturers Association (NEMA, 2010). CT scanners in compliance with this standard can be configured to inform users when scan settings would probably yield values of $CTDI_{vol}$ or DLP that would exceed pre-assigned values. Compliant scanners allow users, before proceeding with scanning, to confirm or correct settings that might otherwise lead to unnecessarily high exposures. Manufacturers may include pre-assigned values in their default protocols, but all values are user-configurable.

* www.impactscan.org/ctdosimetry.htm
† www.hpa.org.uk/Publications/Radiation/NPRBArchive/NRPBSoftware/
‡ www.fda.gov/medicaldevices/safety/alertsandnotices/ucm185898.htm

Table 5.1   Normalised values of effective dose per dose-length product (DLP) over various body regions and (standard) patient age (Shrimpton et al, 2005)

Region of body	Effective dose per DLP (mSv(mGy cm)$^{-1}$) by age				
	0[*]	1 y[*]	5 y[*]	10 y[*]	Adult[†]
Head and neck	0.013	0.0085	0.0057	0.0042	0.0031
Head	0.011	0.0067	0.0040	0.0032	0.0021
Neck	0.017	0.012	0.011	0.0079	0.0059
Chest	0.039	0.026	0.018	0.013	0.014
Abdomen and pelvis	0.049	0.030	0.020	0.015	0.015
Trunk	0.044	0.028	0.019	0.014	0.015

[*]   All data normalised to CTDI$_w$ in the standard head CT dosimetry phantom
[†]   Data for the head and neck regions normalised to CTDI$_w$ in the standard head CT dosimetry phantom; data for other regions normalised to CTDI$_w$ in the standard body CT dosimetry phantom

5.34   There are two important definitions in the XR 25 standard – a 'notification' value and an 'alert' value. The notification value is where a value of CTDI$_{vol}$ (in units of mGy) or DLP (in units of mGy cm) is used to trigger a notification when the value would probably be exceeded by the prescribed scans. The alert value is where a value of CTDI$_{vol}$ (in units of mGy) or DLP (in units of mGy cm) is used to trigger an alert when the system projects that the prescribed scans within an ongoing examination would result in a cumulative dose index value that exceeded the user-configured alert value.

5.35   The cumulative dose index value is compared with the alert value at each anatomical position throughout an examination. While any individual scan might not trigger a notification or alert, if the cumulative dose index value at any anatomical position were expected to exceed the alert value when the next scan was performed, an alert would be triggered prior to scanning. An alert value is associated with a complete examination protocol, not with individual scans. On some systems, it may be possible to set different alert values for different examination protocols.

5.36   The NEMA Standards Publication XR 25-2010 Computed Tomography Dose Check (NEMA, 2010) supplements IEC Standard 60601-2-44 Editions 2.1 and 3 (Particular Requirements for the Basic Safety and Essential Performance of X-ray Equipment for Computed Tomography) (IEC, 2010) until the latter is updated to include a version of the features specified.

Limitations of CTDI and DLP

Patient size and scanned length

5.37   The CTDI$_{vol}$ is valuable for the purpose intended, and it is not meant to represent the dose given to an individual patient since it does not match the size or composition of the patient, nor does it represent the typical scanned length. Therefore, it should not be used to represent the dose to an individual patient (McCollough et al, 2011).

5.38   However, for a scanner operator (a radiographer) the CTDI$_{vol}$ presented on the scanner console can be misleading in that it represents the dose to a specific size of phantom, regardless of the size of the patient (Table 5.2). Therefore, when image quality is estimated to be similar for two patients of different sizes, a large patient would appear to have a higher dose than a slim patient, since a higher tube current is used. However, if actual organ doses were measured, the doses would be similar.

Table 5.2   Display of CTDI and DLP on the operator's console for models reported in 2009 *(Note: this is provided for information purposes only and is not designed to demonstrate any advantage of one machine over another)*

Scanner	CTDI	DLP
Wide bore CT scanners (NHS CEP, 2009a)		
GE LightSpeed Xtra, RT 16	$CTDI_{vol}$	Predicted
Philips Brilliance Big Bore	Yes	Yes
Siemens SOMATOM Sensation Open (24/40)	$CTDI_{vol}$	Predicted before scan Actual after scan
Toshiba Aquilion LB	$CTDI_w$ or $CTDI_{vol}$	Planned Actual after scan
128- to 320-slice CT scanners (NHS CEP, 2009b)		
Philips Brilliance iCT	Yes	Yes
Siemens SOMATOM Definition AS+	$CTDI_{vol}$	Predicted before scan Actual after scan
Toshiba Aquilion ONE	$CTDI_{w.e}$[*] or $CTDI_{vol.e}$[*]	Planned Actual after scan
64-slice CT scanners (NHS CEP, 2009c)		
GE LightSpeed VCT	Predicted Actual	Predicted Actual
GE LightSpeed VCT XT	Predicted Actual	Predicted Actual
Philips Brilliance CT 64	Yes	Yes
Siemens SOMATOM Sensation 64, Definition AS 64, Definition Dual Source	$CTDI_{vol}$	Predicted before scan Actual after scan
Toshiba Aquilion 64	$CTDI_w$ or $CTDI_{vol}$	Planned Actual after scan
16-slice CT scanners (NHS CEP, 2009d)		
GE BrightSpeed Elite	Yes	Yes
Philips Brilliance CT 16	Yes	Yes
Siemens SOMATOM Emotion 16	$CTDI_{vol}$	Predicted before scan Actual after scan
Toshiba Activion 16, Aquilion 16	$CTDI_w$ or $CTDI_{vol}$	Planned Actual after scan

[*]   Termed by the manufacturer as the 'extended' CT dose index

5.39   Body size has a strong influence on organ dose derived from the $CTDI_{vol}$ and this is a limitation of the index. It arises because the $CTDI_{vol}$ is based on the measurement of absorbed dose (or kerma) in air at two locations in a PMMA phantom whose diameter is greater than the average diameter of most members of the general population. Hence the $CTDI_{vol}$ as a dose index would also underestimate dose for the majority of patients. However, it is possible to derive correction factors based on effective patient diameter (AAPM, 2011). These are called the size-specific dose estimates (SSDE) for paediatric and adult body CT examinations, taking into account a typical scanned length for an abdomen scan.

5.40   Another limitation of the $CTDI_{vol}$ arises because scattered radiation is an important contributor to radiation dose in CT. Scatter dose profiles extend long distances from the primary beam in the axial direction. As the length of the

scanned patient region increases, the dose at its centre increases due to an increased scatter contribution. However, this increase is asymptotic and as the scan length approaches the range of the scattered radiation dose profile tails, the dose at the centre approaches a limit. It is possible to address this problem by deriving correction factors based on scan length (AAPM, 2010).

5.41   Dose may be estimated for a representative patient by correcting the CTDI and DLP for patient diameter and scan length. The more accurate estimates of organ doses obtained in this way may be multiplied by age- and sex-specific risk coefficients and these products summed to give a more appropriate estimation of the risk of radiation-induced fatal cancer (BEIR VII Committee, 2005). However, even this cannot be considered as more than a probabilistic risk associated with a representative patient, derived from accepted models.

Image quality measures

5.42   Dose cannot be considered in isolation from image quality, and there are a number of objective approaches to image quality determination in addition to the clinical interpretation of the final images.

5.43   As with other radiological imaging technologies, the information about an object that may be retrieved from a CT image may be expressed in terms of contrast, spatial resolution and noise as indices of image quality. Contrast depends on the physical properties of the object, while spatial resolution depends on the construction and operation of the scanner hardware and software. Statistical noise, however, depends on radiation dose.

5.44   A figure of merit is a quantity that relates dose and image quality and is defined for CT by the *Q*-factor (ImPACT, 2000). The *Q*-factor is given by

$$Q = \sqrt{(f^{3}/\sigma^{2} \, z \, \text{CTDI}_{\text{w}})}$$

where *f* is the spatial resolution in the plane of the image slice (expressed as a spatial frequency), σ is the statistical noise (expressed as a percentage standard deviation in CT number) and *z* is the width of the image slice profile (expressed as a full width at half maximum). The *Q*-factor is useful for comparing the dose efficiency of different CT scanners, with a high *Q*-factor indicating good image quality at low dose. It is appropriate to be applied for standard resolution imaging.

5.45   Noise power spectra calculations can be made to quantify the frequency content of the noise, thus more comprehensively combining spatial resolution together with noise. The DQE (detection quantum efficiency) and the NEQ (noise equivalent quanta) also can provide valuable information. Further work is underway in the area of subjective assessments of image quality including objective 'subjective' approaches using 'model observer' techniques. These are all more complex and comprehensive approaches, but there are no standardised approaches as yet.

National and international dose surveys

5.46   National CT dose surveys can provide data for use in determining population dose from medical X-rays, as well as offering a snapshot of clinical practice for diagnostic CT scans on adults and children.

5.47   In the absence of a methodology necessary for more comprehensive assessments of patient exposure, doses from CT were initially thought to be broadly comparable with those from corresponding conventional X-ray examinations (Perry and Bridges, 1973). Early CT dose surveys concentrated on quality control measurements in standard dosimetry phantoms (Conway et al, 1992; McCrohan et al, 1987). The high patient doses from CT compared with conventional radiography were first established by a national survey for 1989

conducted in the UK by the then National Radiological Protection Board (NRPB) that included assessments of organ and effective doses from typical CT procedures (Shrimpton et al, 1991). By 1992, data from national surveys in eight other countries had confirmed, as a general pattern, the increasing importance of CT as a significant source of exposure for populations and so a necessary focus for efforts in patient protection (Shrimpton and Wall, 1995). Accordingly, diagnostic reference levels (DRLs) were developed to promote improved CT practice in Europe (European Commission, 1999). The values were updated in 2004 on the basis of a European survey for multi-slice CT (MSCT) that included 53 CT centres in eight countries (MSCT, 2004). As with conventional radiological examinations, DRLs are dose levels for typical examinations for groups of standard-sized patients for broadly defined types of equipment. They are not intended to be applied to individual patients.

5.48   A second CT survey for the UK (for 2003) demonstrated the continuing existence of wide variations in practice between CT centres for 12 common types of CT examination and their associated specific clinical indications. The overall levels of exposure were in general lower by 10–40% than the previous UK survey data for 1991 (Shrimpton et al, 2005). However, there was an apparent trend for slightly increased doses from MSCT (four or more slices) relative to single-slice CT scanners. On the basis of these survey data, an updated assessment of population dose from medical X-rays in the UK for 2008 reported an increase in the dominance from CT examinations, to 68% of the total medical population dose (Hart et al, 2010). Similar patterns are now prevalent in the USA ((Mettler et al, 2009; NCRP, 2009), elsewhere in Europe (Jarvinen, 2012) and worldwide (UNSCEAR, 2010). A third CT survey for the UK (for 2011) is shortly to be published by Public Health England (Shrimpton et al, 2014).

5.49   The periodic assessment of dose is an essential part of quality assurance and routine performance testing within X-ray departments in support of patient protection. In the UK, the recommended frequency for conducting local surveys of typical doses from CT (values of $CTDI_{vol}$ and DLP) is on a three-year basis (IPEM, 2005), in support of the local setting and application of DRLs (IPEM, 2004).

5.50   The national CT surveys for the UK (for 1989, 2003 and 2011) have so far involved voluntary participation in the submission of data, but with reasonably robust sample sizes (in excess of 25%). Completion of the 2011 CT survey will provide a timely opportunity to review and revise methods for streamlined data collection. Imminent further developments in European legislation concerning radiation protection for patients may impact on the electronic health care information systems used for the national monitoring of patient doses. The 2011 survey will allow consideration of analyses that will make the best use of this information system.

5.51   The UK dose surveys were also used in establishing a database of organ doses for paediatric and young adult CT scans in the UK, with the objective of quantifying the magnitude of the cancer risk in relation to the radiation dose (Kim et al, 2012). The younger children received higher doses in the pre-2001 period, when the use of adult CT settings for children was more common.

Role of national surveys   5.52   Regular national radiation dose surveys report levels and trends in population exposure and are the main strategic tool in planning safe practice. National surveys establish a framework within which operational safe practice can be defined. To date, only a minority of UK radiology departments contribute data to such surveys.

5.53   Evidence from surveys suggests that many CT installations operate considerably above the threshold exposure that delivers adequate image quality (Hausleiter et al, 2009). There is a natural anxiety to avoid low exposure CT for fear of risking an inadequate and unsuccessful examination, resulting in the patient requiring repeat examination and therefore increased exposure. However, published research studies document selected applications in which exposure reduction may be achieved without adversely affecting diagnostic quality (Iannaccone et al, 2003; Newton et al, 2011; Tamm et al, 2011; Winklehner et al, 2011b). Results continue to be published, but the number of applications for which this information is available remains small compared with the overall applications of CT. Wider research is required to provide a stronger evidence base on which standard protocols may be recommended for each application of CT.

5.54   Reviews of these standard protocols could be used to establish DRLs for a much wider range of CT applications. DRLs can then be used as a trigger for assessing examination protocols in use at other institutions (Mohiy et al, 2012; Moss and McLean, 2006). The approach would help to standardise practice and reduce the wide variations in exposure observed between institutions.

5.55   Currently, national DRLs are available for the most common CT procedures and local radiology departments, together with associated medical physics or radiation protection services, should produce both site-specific and scanner-specific dose data for these examinations. The employer has a duty to establish DRLs under the Ionising Radiation (Medical Exposure) Regulations 2000 (IR(ME)R 2000) which should be available to staff working in an area. The availability of dose data nationally can help to encourage higher standards of practice.

5.56   National surveys are also key to establishing current experience of best practice, resulting in information which can be conveyed to radiology departments as recommended performance criteria.

5.57   A challenge exists in CT dosimetry technology in that it has to adapt continuously to emerging technology. Survey bodies, therefore, require adequate research capacity to extend and update their methods.

Diagnostic reference levels (DRLs)

5.58   IR(ME)R 2000 require that employers establish DRLs and undertake appropriate reviews if these are consistently exceeded.

5.59   Typical patient doses for the same type of X-ray examination can vary considerably between hospitals. Reference doses for specific examinations can give an indication of unusually high values. The NRPB recommended national reference doses for common diagnostic X-ray examinations from 1990; in recent years these recommendations have been provided by the Health Protection Agency (HPA) and now by Public Health England (PHE). The recommended reference doses are reviewed by the Department of Health (DH) and formally adopted as DRLs.

5.60   The reference doses were originally based on a national patient dose survey conducted by the NRPB in the mid-1980s (Shrimpton et al, 1986) and are now based on the regular reviews of the (now) PHE National Patient Dose Database (Hart and Wall, 2003). Reference doses are set at about the third-quartile value of the distribution of typical doses seen in this database from hospitals all over the country. Hospitals found to be consistently exceeding the national reference doses should investigate the reasons for using such abnormally

high doses. If they cannot be clinically justified, the hospitals should carry out corrective action to bring their doses more into line with the majority.

5.61　　National dose surveys are of primary importance in providing the underpinning data required to set national DRLs. Subsequent local and regional surveys enable local and regional DRLs to be established, and also to be compared to national DRLs. The ICRP encourages the development and regular updating of local/regional/national DRLs to assist in the optimisation process, particularly with paediatric patients (ICRP, 2013).

5.62　　The current national DRLs for CT examinations, as agreed by the DH DRL working party, are based on the 2003 review of the National Patient Dose Database (Shrimpton et al, 2005). These DRLs include twelve types of CT examination on adult patients and four types of CT examination on paediatric patients (for three age ranges) (see Tables 5.3 and 5.4).

Table 5.3　National DRLs for CT examinations on adult patients (Shrimpton et al, 2005)

Examination (clinical indication)		$CTDI_{vol}$ (mGy) SSCT	$CTDI_{vol}$ (mGy) MSCT	DLP (mGy cm) SSCT	DLP (mGy cm) MSCT
Routine head (*acute stroke*)	Posterior fossa	65	100	–	–
	Cerebrum	55	65	–	–
	Whole examination	–	–	760	930
Chest (*lung cancer or metastases*)	Lung	10	13	–	–
	Liver	11	14	–	–
	Whole examination	–	–	430	580
Chest – high resolution (*diffuse lung disease*)	Whole examination	3	7	80	170
Abdomen (*liver metastases*)	Whole examination	13	14	460	470
Abdomen and pelvis (*abscess*)	Whole examination	13	14	510	560
Chest, abdomen and pelvis (*lymphoma staging or follow-up*)	Lung	10	12	–	–
	Abdomen/pelvis	12	14	–	–
	Whole examination	–	–	760	940

Table 5.4　National DRLs for CT examinations on paediatric patients (Shrimpton et al, 2005)

Examination (clinical indication)		Age (y)	$CTDI_{vol}$ (mGy)	DLP (mGy cm)
Head (*trauma*)	Posterior fossa	0–1	35	–
		5	50	–
		10	65	–
	Cerebrum	0–1	30	–
		5	45	–
		10	50	–
	Whole examination	0–1	–	270
		5	–	470
		10	–	620
Chest (*detection of malignancy*)	Whole examination	0–1	12	200
		5	13	230
		10	20	370

5.63   A new set of national DRLs for CT examinations will be based on the review of CT doses for 2011 (Shrimpton et al, 2014). The survey has collected data from about 30% (183) of the scanners in the UK. This is a similar percentage to the previous survey, and represents a slightly higher number of scanners (Table 5.5). While the 2003 survey contained data from a mixture of single- and multi-slice scanners, all the scanners contributing data to the 2011 survey are multi-slice scanners.

Table 5.5   Data collected for the three national CT dose surveys

Survey	Main scanner type	Sample size	Sample type	Doses
First (1989)	100% single slice	144 scanners (83% UK)	Protocol data – adult	Organ + effective dose ($CTDI_{vol}$, DLP in 1999[*])
Second (2003)	63% single slice	126 scanners (27% UK)	Protocol data – adult + paediatric	$CTDI_{vol}$, DLP UK mean effective dose
Third (2011)	100% multi-slice	183 scanners (30% UK)	Patient data – adult + paediatric	$CTDI_{vol}$, DLP UK mean effective dose
[*] $CTDI_{vol}$ and DLP values were derived retrospectively from the first survey data (European Commission, 1999)				

Table 5.6   Comparison of national reference dose data from 2003 and 2011 (Shrimpton et al, 2014)

Examination (clinical indication)		$CTDI_{vol}$ (mGy)			DLP (mGy cm)		
		2003		2011	2003		2011
		SSCT	MSCT	MSCT	SSCT	MSCT	MSCT
Routine head (*acute stroke*)	Posterior fossa	65	100	80	–	–	–
	Cerebrum	55	65	60	–	–	–
	All sequences	–	–	60	760	930	970
Chest (*lung cancer or metastases*)	Lung	10	13	–	–	–	–
	Liver	11	14	–	–	–	–
	All sequences	–	–	12	430	580	610
Chest – high resolution (*interstitial disease*)	Axial	–	–	4	–	–	140
	Helical	–	–	12	–	–	350
	All sequences	3	7	–	80	170	–
Abdomen (*liver metastases*)		13	14	14	460	470	910
Abdomen and pelvis (*abscess*)	All sequences	13	14	15	510	560	745
Chest, abdomen and pelvis (*lymphoma staging or follow-up*)	All sequences	12	14	–	760	940	1000
Paediatric head: 0–1 y (*trauma*)[*]	Posterior fossa	35[†]	–	–	–	–	–
	Cerebrum	30[†]	–	–	–	–	–
	All sequences	–	–	25	270[†]	–	350
Paediatric head: >1–5 y (*trauma*)[*]	Posterior fossa	50[†]	–	–	–	–	–
	Cerebrum	45[†]	–	–	–	–	–
	All sequences	–	–	40	470[†]	–	650
Paediatric head: >5 y (*trauma*)[*]	Posterior fossa	65[†]	–	–	–	–	–
	Cerebrum	50[†]	–	–	–	–	–
	All sequences	–	–	60	620[†]	–	860
[*] Doses refer to measurements in the 16 cm standard CT dosimetry phantom							
[†] Analysis over all practice (single-slice CT and multi-slice CT scanners together)							

5.64   In the 2011 survey $CTDI_{vol}$ and DLP data were collected from actual patient studies, with the focus on 14 clinical protocols covering 14 clinical indications. Data were collected for both adult and paediatric patients.

5.65   Preliminary results show $CTDI_{vol}$ values to be approximately equivalent to 2003 levels, with DLP values from some examinations showing a small (around 5%) increase, and others demonstrating a more significant increase (over 30%). The full results are in Table 5.6, demonstrating the trends against the 2003 survey.

5.66   While it may be preferable to consider that new technology in CT scanners has brought a decrease in dose levels, the 2011 data suggest alternative interpretations. For example, the similarity of $CTDI_{vol}$ levels would support the view that new technology has resulted in improved image quality, and therefore improved diagnostic efficacy. The increase in some of the DLP values (essentially implying increased or repeated coverage) demonstrates a change in usage of the scanners for certain conditions, where the benefit of this change is considered to be a diagnostic advantage.

5.67   During the period between the last two CT surveys some examinations, such as cardiac scanning, have grown in frequency and have undergone significant dose reduction as a consequence of improvements in technology (Gosling et al, 2013). Therefore, future developments in CT will require more regular surveys or real-time access to dose data to provide an accurate picture of CT dose in the UK.

Summary

5.68   There is evidence from dose surveys that the radiation exposure from similar CT investigations can vary widely between different hospitals and, sometimes, even within the same radiology department. Optimisation of examination protocols is often regarded as one of the most pressing needs in modern CT practice.

5.69   The ALARP principle (as low as reasonably practicable) is used in the optimisation process in the UK, on the understanding that examinations are performed to an adequate diagnostic quality without excessive radiation dose. Research into applications where exposure reduction could be achieved without affecting diagnostic quality could be used to establish DRLs for a wider range of CT applications than currently available. National DRLs are currently available for most common CT investigations.

5.70   A variety of emerging technologies are focusing on CT dose reduction and, for a few applications, sub-millisievert scanning has become a reality. Developments such as the optimisation of X-ray spectra (tube voltage), more efficient detectors, dose management (tube current modulation), image reconstruction techniques (dose reduction software) and X-ray beam collimation can afford dose reduction potential, if available and if used appropriately.

5.71   Since image quality is a key factor determining the extent of use of these dose reduction techniques, the evaluation of image quality, in conjunction with the measurement of dose, is paramount for quantification of these effects.

CHAPTER 6

CLINICAL STRATEGIES FOR DOSE REDUCTION

Justification and optimisation of examinations

6.1   As described in Chapter 2, justification and optimisation are key elements used to protect the patient from the hazards associated with ionising radiation. These processes are particularly important in the practice of CT owing to the relatively high level of radiation exposure compared with many other radiological investigations (Brenner and Hall, 2007; Hricak et al, 2011).

6.2   Adequate patient protection requires that the medical and other staff of radiology, radiotherapy and nuclear medicine departments take an active and practical approach to implementing these principles in each individual case when using CT. They should also be able to demonstrate that their practice is in accord with statutory requirements. To serve the needs of patient protection effectively, the process of justification is applied on an individual basis to each referral for any examination that involves radiation exposure.

Optimisation

6.3   Optimisation requires that the examination is conducted as efficiently and effectively as possible using the lowest reasonably practicable radiation exposure, consistent with the intended purpose. The optimisation process consists of a chain of responsibilities extending from appropriate manufacture, selection and maintenance of equipment to the exposure parameters selected for the individual examination (Lewis and Edyvean, 2005; Meeson et al, 2012). For the purpose of this report, only those aspects of optimisation which come under the control of staff in the radiology department are considered.

Justification

6.4   Justification is a responsibility of the practitioner who carries out the CT examination and is based on information provided by the referrer. It is a fundamental principle of medical investigation that any health risks associated with the investigation, including exposure to ionising radiation, are outweighed by the putative medical benefit (Lautin et al, 2008). The process of justification is conducted to demonstrate that the radiation exposure incurred in the examination is justified by the probability of conferring benefit to the individual patient.

Importance of referral information in ensuring appropriate justification

6.5   The referrer who requests CT must ensure that they provide correct and adequate information concerning the clinical needs of the individual patient so that the decision on whether radiation exposure is justified may be fully informed.

6.6   It is inevitable, in practice, that on occasion it is necessary for the person justifying the CT examination to obtain additional clinical information from the referrer by enquiry. It is recognised that this may be time-consuming and operationally undesirable in busy departmental practice, but this must not be allowed to impede the justification process. To accept a referral for CT when it may not be the optimal modality, on the basis that it is easier to do so than to seek the relevant information, is inappropriate practice.

6.7   Justification of examinations must be carried out by staff who possess adequate knowledge and experience of the imaging investigation and its clinical application, to make a fully informed judgement for each individual case. Under

ideal circumstances the radiologist should be responsible for supervising or reporting that CT examination. Where this is not practicable, other staff may provide the justification or authorise a procedure under written guidelines. Clinical radiology departments should ensure that they have appropriate clinical governance arrangements in place to guarantee competent justification in every case.

6.8   The process of justification in CT should be based on the following key questions:

Is the investigation required?

Does the clinical problem require CT, or would another imaging modality using less or no ionising radiation be as effective?

Does the patient require the volume of CT requested?

Does the patient require the exposure usually employed, or would reduced exposure give equal clinical information?

What is the risk of adverse effects from the scan (radiation, contrast, etc)?

Is the investigation required?

6.9   The criterion to be employed in deciding if CT is necessary at all is based on the impact on the clinical management of the patient. The person justifying the CT scan should consider what action may result depending on the probable range of findings from the examination.

6.10   In 1990, a joint publication by the Royal College of Radiologists and the National Radiological Protection Board suggested that approximately 20% of X-ray studies may be clinically unhelpful (RCR/NRPB, 1990). It is quite possible that this situation persists in CT. A comprehensive study in Sweden investigated the degree of justification of all CT examinations performed in a single day (Almén et al, 2009). Referrals were retrospectively evaluated. The main finding was that approximately one in five of all examinations was not justified. The degree of justification also varied considerably depending on the organ examined. The study concluded that if unjustified examinations could be avoided, a large dose reduction for the population would result.

Does the clinical problem require CT?

6.11   If the clinical problem can be adequately answered by an investigation that does not employ ionising radiation, then CT may not be appropriate. Answers to the clinical problem may be obtained through other diagnostic investigations such as biochemical laboratory tests or, if imaging is required, by ultrasound or magnetic resonance imaging (MRI), neither of which employs ionising radiation. However, there may be occasions when alternative techniques would be preferable, but other factors such as availability, local expertise and time constraints may result in CT being the best option. Wherever possible, every investigation should yield a result which is adequate and relevant to the clinical problem in a timely manner. Misleading, incomplete or inaccurate results may impede clinical care, increasing treatment duration and costs.

6.12   Radiology departments should take active steps to guarantee that they have in place a process ensuring that they have the appropriate knowledge and skills to provide informed advice on the alternative investigations. This might involve consultation with the referring clinician or appropriate multi-disciplinary team.

6.13   Effective justification requires responsible action from clinical referrers. There may be lower acceptance among referring clinicians for ultrasound or MRI. Greater preference of clinicians for CT can be a significant source of an

unjustified increase in exposure (Boland et al, 2009). Some clinicians may regard CT as an appropriate confirmatory investigation following abnormal findings on ultrasound. This may be neither appropriate nor necessary; if information appropriate to the clinical problem has been adequately revealed by ultrasound or MRI then CT is, by definition, unjustifiable. Radiology departments should ensure that inappropriate referral patterns do not become established in their practice, by providing appropriate advice to referring clinicians.

Use of alternative technologies

6.14   In 1992 the NRPB drew attention to the rising contribution to population exposure from CT, indicating that the technique made a disproportionate contribution to population exposure compared to the incidence of use (NRPB, 1992). It advised that increasing the use of ultrasound and MRI would result in decreased exposure to radiation from CT, particularly in children and in other groups at risk. Substitution of CT with techniques that do not use ionising radiation remains fertile ground for patient protection.

6.15   To provide a diagnostically viable substitute, techniques must be of comparable reliability to CT. In imaging practice objective comparison of techniques is made by determining their sensitivity and specificity to the presence of disease. These two measures define the clinical reliability of an imaging investigation by analysing the extent to which the technique detects or excludes disease, ie whether positive or negative findings are true or false. A high sensitivity score indicates that a test detects disease reliably. A high specificity score indicates that the test excludes disease reliably.

6.16   Ultrasound has comparable sensitivity and specificity compared with CT in many applications involving the abdomen, pelvis, neck, chest wall and soft tissues of the limbs. Ultrasound is also a simpler, less expensive alternative to CT and it is logical that it should be used as the primary investigation in the areas where it provides a clinically reliable alternative.

6.17   The applications of diagnostic ultrasound technology include, but are not limited to[*]:

(a)   Cardiology (echocardiography)

(b)   Endocrinology

(c)   Evaluation of structures such as breast, thyroid, testicle and skin

(d)   Obstetrics

(e)   Gynaecology

(f)   Gastroenterology

(g)   Musculoskeletal

(h)   Urology

(i)   Vascular

(j)   Intervention

6.18   As indicated above, disease findings on ultrasound, if conclusive, should not be regarded as an indication for the use of CT for confirmation.

6.19   MRI offers the most comparable cross-sectional technique to CT in more complex examinations of the trunk and is also applicable to examination of the brain, head, neck and limbs.

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[*]   www.bmus.org/about-ultrasound/GoingforanUltrasoundScan1.pdf

6.20   Areas of common application where CT is conventionally regarded as the investigation of choice, but where MRI may be regarded as an acceptable alternative include:

(a)   Abdominal sepsis

(b)   Abdominal masses and tumours

(c)   Pancreatic disease

(d)   Liver disease

(e)   Vascular disease

(f)   Mediastinal tumours

(g)   Renal disease, including renal transplants

(h)   Pelvic tumours, abscesses and fistulas

(i)   Disease of the pharynx, larynx and neck

(j)   Congenital anomalies of the skeleton and face

6.21   Throughout Europe MRI has been regarded as constrained by its limited availability, greater cost and greater complexity of operation, and the acceptability of the test to the patient when compared with CT. Patient throughput is also much lower with MRI compared with CT. However, these perceived disadvantages have been progressively obviated by advancing technology and may be minimised by operational change. MRI offers a greater challenge in substituting for CT, but is better adapted to the situations of complex anatomy and disease in which CT has made its major diagnostic impact. This approach is especially important where the extent of the CT examination usually delivers high radiation exposure (Clarke et al, 2001).

6.22   Clinical research studies have already demonstrated applications in which MRI has a greater sensitivity and/or specificity than CT: for example, in the examination of the lumbar spine (Forristall et al, 1988; Janssen et al, 1994). In these circumstances, MRI should be regarded as the investigation of choice on the grounds of both clinical effectiveness and radiation protection. In applications where the sensitivity and specificity of MRI and CT are comparable, MRI may be regarded as the investigation of choice on the grounds of radiation protection.

6.23   Where sufficient capacity exists, departments may also consider using MRI as an initial investigation despite reduced sensitivity or specificity compared to CT. This approach would result in some patients needing to proceed to CT for conclusive investigation, but others would not require an examination using ionising radiation when the information from MRI had proved adequate for the clinical problem. How effective this approach can be in practice depends upon the number of patients who would need to proceed to CT, and would need to be established by clinical research studies.

6.24   A proactive approach in radiology departments to replace CT with MRI where practicable would make a significant impact on the levels of population radiation exposure. Departments might not be able to adopt this policy in the short term. However, there should be the capacity to change patient pathways as time allows services to be restructured: for example, by transferring trained staff from one technique to the other. In the longer term, departments should be encouraged to develop business plans for substituting some CT installations with MRI scanners when equipment comes up for replacement.

6.25   Further clinical research is needed to establish how effectively substitution of CT may be made across the whole spectrum of its applications.

Studies should concentrate on establishing the relative effectiveness of techniques in clinical practice, and the extent to which radiation may be avoided in each application to clinical problems.

6.26   A proactive approach to the substitution of CT by other imaging techniques would represent a significant change of culture in UK hospitals, but offers a large degree of scope for exposure reduction and an effective response to the continual rise in population exposure resulting from CT. To support this, radiology departments should ensure that their staff are adequately trained to realise the full potential of all of their imaging equipment in offering an alternative to CT.

Role of clinical guidelines

6.27   Clinical guidelines which advise on the relevant investigation pathway for different diseases and clinical circumstances, such as those produced by the Royal College of Radiologists (RCR, 2012), have an important role in ensuring that unjustifiable or irrelevant patient pathways are not followed and that patients are not subjected to unwarranted investigation. However, guidelines make general recommendations, and the justification process is applied on an individual basis. The fact that CT is recommended by guidelines for the clinical circumstances of a patient does not automatically mean that CT is justified in that case. As always, justification should be applied at the level of the individual referral.

6.28   Patients should not be denied appropriate investigation on the grounds of radiation protection alone. In these cases it is advisable, for the interests of the patient, the person providing the justification, and the institution, that the circumstances supporting justification are adequately documented.

Does the patient require the volume of CT requested?

6.29   Successive international surveys of practice (Shrimpton et al, 2014; Zanca et al, 2012) have shown a growing tendency to extend CT examinations to a larger volume than that immediately relevant to the clinical problem under consideration. This tendency has been facilitated by the ease and speed with which CT can now be carried out as a result of advances in technology. It also appears to be fuelled by a wish to avoid overlooking additional or incidental disease (Dixon and Goldstone, 2002). However, this approach is a failure in justification unless supported by adequate published evidence.

6.30   The total absorbed dose rises in direct proportion to the volume of the body included in CT (Kalender, 2004; Zanca et al, 2012). Limiting the examination to the area of the clinical problem can achieve a significant reduction in the absorbed dose. All examination protocols should be designed to cover only the areas of the body relevant to the individual disease process in the application and irrelevant areas should be excluded. The clinical value of finding incidental abnormalities by otherwise unwarranted extension of CT has not been established.

6.31   In nuclear medicine hybrid imaging, the tendency to extend the CT component of the examination to cover the whole body is rarely helpful clinically and produces unnecessary radiation exposure. The misconception that the CT component provides a small element of the total dose compared with that arising from the radiopharmaceutical may influence this practice. These protocols should be reviewed.

6.32   Departments must have in place standard protocols for the conduct of CT, based on application to recognised clinical problems. The protocols should specify the volume of examination appropriate to the clinical problem, using an evidence-based approach. Extension of examinations with no evidence base should be resisted. Repeat or follow-up examinations for monitoring known disease offer a particular opportunity to limit the volume of examination. This

makes a significant contribution to the protection of patients whose clinical management requires exposure to CT on multiple occasions.

6.33   This is an issue affecting both justification and optimisation. A decision on whether a standard or reduced exposure can be employed may be taken when CT is optimised at the beginning of the examination. However, an evaluation of clinical need at the time of justification, when appropriate clinical information is available, may be valuable in exposure constraint by indicating in advance that a reduced exposure would be appropriate.

6.34   Circumstances where this approach is possible include:

(a)   The patient is undergoing follow-up CT for monitoring disease progress, where the volume of the examination may be limited to the area of interest only

(b)   Where previous CT has indicated that disease depiction is of sufficient clarity that optimal image resolution is not required (Lewis and Edyvean, 2005; Tamm et al, 2011)

(c)   When CT is used to guide interventional procedures such as biopsy or drainage and in hybrid imaging

Relationship between justification and optimisation

6.35   Decisions on the above questions have implications as to how some examinations may be optimised, particularly regarding the volume of examination and reduced exposure. However, it is important that a decision on justification does not preclude further consideration of dose constraint at the stage of optimisation. The justification decision clears the patient for examination and may define the appropriate examination technique, but circumstances influencing optimisation may be evident when the patient attends for examination.

6.36   Evidence from surveys has indicated that there is wide variation in the radiation exposure employed in CT for similar applications in different hospitals and sometimes within the same radiology department (Golding et al, 2008; Koller et al, 2003; Olerud, 1997; Shrimpton et al, 1991, 2005). While some variation in exposure necessarily results from differences in examination technique dictated by individual circumstances, the extent of the variation is not adequately explained by this alone. Some variation will be due to differences in dose efficiency of the systems (ImPACT, 2006), which could potentially account for the difference in dose for the same image quality. Other variations will be from the individual radiologist's accepted benchmark of subjective image quality from their own training, preference or hospital culture. Optimisation of examination protocols is commonly regarded as one of the most pressing needs in the modern practice of CT (Golding, 2005; Scheck et al, 1998).

6.37   Underlying the process of optimisation is the principle that examinations performed are of adequate diagnostic quality and obtained without excessive radiation dose. Adequate diagnostic image quality is not an objectively defined term and is dependent on the individual radiologist's preference, training or radiology culture. The aspect of 'without excessive radiation dose' is expressed for all radiation-based investigations by the ALARP principle (as low as reasonably practicable) used in the UK. The clinical radiology officers of the Royal College of Radiologists agree in principle with the COMARE Medical Practices Subcommittee's statement (see Appendix D):

> 'Where a specific clinical question has been asked by the referrer of a patient for CT scan, the CT examination should be carried out at the lowest dose required to answer the question, accepting that other organs in the scan field may not be optimally visualised.'

6.38   In the case of CT, as described above, a large number of factors influence the radiation exposure employed during the examination. CT technology has a high in-built tolerance to radiation dose and overexposure of the patient is not revealed by obvious changes in the resulting images.

6.39   Nevertheless, staff supervising or operating CT scanners have considerable scope for limiting exposure of the individual patient by manipulating exposure factors according to established principles, as noted in Chapter 5. The ideal approach is to establish a standard examination protocol that uses a minimal threshold exposure which has been established by prior research. Even in a large number of applications where this is not available, staff may adapt a range of exposure factors to limit exposure, particularly where maximal image quality is not required for diagnostic purposes.

Staff training and optimisation of site-specific CT protocols

6.40   CT has evolved into a flexible and challenging modality that provides varying imaging solutions. These may offer less invasive, safer, day-case investigations that afford improved patient acceptability and potential cost savings. With the introduction of innovative technologies, new applications such as CT coronary angiography and CT colonography are now being performed. These bring with them the challenge for operators of training in these techniques, to understand the radiation dose implications and have robust processes to ensure the whole team is competent in all applications. If the full potential of new CT technology is to be realised, the engagement of radiologists, radiographers and technicians, physicists and manufacturers' training specialists is required to optimise site-specific protocols. The clinical question to be answered, dose and image quality need balance when establishing protocols and all parties should afford appropriate time to communicate and reflect on this.

6.41   A core CT team is imperative, with an ongoing training plan and continuing professional development (CPD) sessions. On-site and remote applications training and support throughout the life of the equipment is a requirement to ensure continuing optimisation. Focus and training on CT dose, groups at high risk for radiation exposure and areas for optimisation should be made available for all CT operators, across all modalities using CT. User group meetings, workshops and web-based educational material are key to encouraging communication between sites and sharing best practice.

6.42   A representative training programme should reflect an understanding of key optimisation features and may include:

(a)   Importance of patient positioning and iso-centre

(b)   Understanding clinical questions being asked

(c)   Ensuring only the area required for diagnosis of the clinical question is included

(d)   Awareness of when low dose scans are appropriate

(e)   Minimising multi-phase scans

(f)   Understanding dose implications when manipulating parameters including pitch

(g)   Understanding features of tube current (mA) modulation and, where appropriate, automatic tube voltage (kV) software

(h)   Implementating and using dose reduction software

(i)   Understanding and using dose alert and predicted dose software

(j)   Familiarity with local diagnostic reference levels (DRLs) for common CT examinations

Summary

6.43   Justification and optimisation are key elements of radiation protection for CT examinations. Justification is the responsibility of the practitioner carrying out the CT examination and the process should be individually applied to each referral. The health risks associated with the medical investigation must be outweighed by the medical benefit to the patient. Optimisation requires the examination to be carried out as effectively and efficiently as possible, using the lowest radiation exposure practicable.

6.44   Justification must be carried out by staff with adequate knowledge and experience of the examination and with sufficient correct referral information, so that a fully informed judgement can be made for each individual case. Justification should answer whether the investigation is required, if CT is the most appropriate modality, if the patient requires the volume of CT requested and whether a reduced exposure would suffice for the investigation. This may also influence the optimisation of the examination, particularly regarding the volume of the examination and reduced exposure.

6.45   Alternatives to the use of CT in an investigation may include biochemical laboratory tests or other imaging modalities, such as ultrasound and MRI (neither of which uses ionising radiation). Use of alternative technologies should consider availability, local expertise and time constraints and there may be occasions when CT is the best option. Radiology departments should ensure that their staff are adequately trained to realise the full potential of all of the imaging equipment, so that the most appropriate modality is used in an investigation.

6.46   Clinical guidelines exist, such as those from the Royal College of Radiologists, which advise on the relevant investigation pathway for different diseases. However, recommendation of the use of CT for a specific circumstance may not mean that the use of CT is justified at the individual level.

6.47   There is evidence of a wide variation in radiation exposure between similar CT applications undertaken in different hospitals. The ALARP principle underlies the process of optimisation for CT applications, with the aim of achieving adequate diagnostic quality without excessive radiation dose. However, there is no definition of 'adequate diagnostic quality', no objective image quality parameter that adequately mimics the radiologist's eye – though there are many parameters that are along the spectrum towards that goal. 'Acceptable image quality' is also dependent on the clinical task, on the individual radiologist's training, preference and radiology culture. This is the primary challenge still to be achieved in CT.

6.48   CT is continuing to evolve. For the full potential of new technologies to be realised, it is important for radiologists, radiographers and technicians, physicists and manufacturers' training specialists to be engaged in optimising the site-specific protocols for a department. An ongoing training plan is imperative to ensure continuing optimisation, not only for image optimisation, but also for dose optimisation. This should be supported throughout the life of the equipment.

CHAPTER 7

GOVERNANCE

7.1   In addition to the specific legal requirements identified through regulation and legislation discussed previously, there is the potential for an array of other factors and initiatives to influence the governance of diagnostic CT scanning.

Role of industry

Transparency of industry

7.2   As described, rapid technological developments have shaped the clinical use of CT. Industry has developed dose reduction technology within its scanners. However, it has given insufficient emphasis on the training of radiology department staff to ensure they are fully aware of the functions of their scanners and how to implement appropriately the protocols and dose reduction technology now available.

7.3   Initial applications training is often focused on acquiring the best images from new technology. Emphasis should also be placed on the provision of suitable images to answer the clinical question, even if this means a reduction in image quality. Initial training should be supplemented by review visits and updates and follow-up training within six months and throughout the lifetime of a scanner. At every stage, a key objective of training should be the full understanding of potential dose reduction strategies. Employers need to demonstrate their commitment to training by making clinical staff available whenever this is scheduled.

Role of dose monitoring and audit

7.4   In the UK, IR(ME)R 2000 require radiology departments to document factors relating to radiation doses from individual examinations and industry can facilitate this by providing clear and unambiguous data as part of the examination record. These data can be used as part of a regular audit against established practice[*]. Examinations where the radiation dose departs significantly from national levels should be reviewed.

7.5   As more information becomes available concerning threshold examination protocols and diagnostic reference levels (DRLs) it should become possible to define best practice for most routine applications of CT. Industry can help to provide and disseminate information, and departments should monitor this emerging evidence and audit their practice against it, adapting their protocols as necessary.

7.6   To further reduce the likelihood of widely varying exposures between different institutions, hospitals should be encouraged to share their audit data with other hospitals and industry alike.

National, European and international initiatives

UK initiatives

7.7   The UK has a long history in radiation protection and in CT dose reduction in particular, and has produced a range of documents, training and advice through the NRPB, HPA and now PHE, and other medical and scientific bodies and organisations. Many of these have attracted international interest and acclaim.

*   www.rcr.ac.uk/content.aspx?PageID=293

7.8   As part of a range of activities, over 25 years ago the Department of Health established and supported ImPACT (Imaging Performance Assessment of CT scanners), an independent evaluation group. The group provided a wide range of support and services to the CT scanning community in the NHS, including:

(a)   Technical evaluation of the imaging and dose performance of CT scanners

(b)   User evaluation of the overall CT system function

(c)   Dose and image quality optimisation

(d)   Dose issues in CT

(e)   Consultancy for CT scanner purchases

(f)   Educational courses

(g)   Market guides

7.9   The evaluations were designed to be objective, independent and comparative and the reports produced were used worldwide by professionals and by industry. CT courses were rated highly by professionals in the CT and regulatory communities. ImPACT was closed in September 2011[*] and the international reaction demonstrated the depth of feeling regarding the loss of this valuable asset.

HERCA/COCIR collaboration

7.10   In 2010 the Heads of the European Radiological protection Competent Authorities (HERCA) proposed a collaboration with CT manufacturers because of their unique role in the optimisation of medical exposures in a healthcare setting[†]. Following meetings between the two groups, a voluntary self-commitment regarding CT dose was produced by the European Radiological, Electromedical and Healthcare IT Industry (COCIR)[‡]. This document included four commitments:

(a)   Development of a standardised benchmarking to characterise a specific CT system

(b)   Implementation of dose reduction measures in CT

(c)   Improved user-friendly dose management and reporting system

(d)   Provision of specific training curricula for CT users

COCIR believes that these measures will help reduce patient dose from CT examinations. HERCA continues to work with industry at a general and technical level with regard to CT.

FDA

7.11   In 2010, the US Food and Drug Administration (FDA) investigated the radiation overexposure of 206 patients at the Cedars-Sinai Hospital in Southern California from CT brain perfusion scans. The investigation uncovered a total of 385 patients in six hospitals who were exposed to excess radiation from these specific scans[§]. The investigation also revealed improvements that could be made by industry to the equipment, user information and training to improve safety and reduce the likelihood of occurrence of overexposures.

7.12   As a consequence, the FDA launched an initiative to reduce unnecessary radiation exposure from medical imaging[¶]. Through this initiative, the FDA

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[*]   www.impactscan.org/

[†]   www.herca.org/WGs.asp?WGnr=3

[‡]   www.cocir.org/site/fileadmin/5_Initiatives/COCIR_CT_MANUFACTURER_Commitment_Version_2_13_May_2011_released.pdf

[§]   www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm185898.htm

[¶]   www.fda.gov/Radiation-EmittingProducts/RadiationSafety/RadiationDoseReduction/default.htm

aims to promote patient safety by extrapolating two of the principles of radiation protection – justification and optimisation – developed by the ICRP.

7.13   Using its unique position as a regulatory authority, the FDA is pursuing key partnerships with professional organisations and industry, and other governmental agencies, with an aim to aid the incorporation of radiation protection principles into quality assurance and training requirements for facilities.

7.14   This initiative aims to help ensure that each patient is getting the correct imaging examination, at the most suitable time, with the appropriate radiation dose. The FDA hopes to provide a comprehensive approach for this effort with collaborative activities in the following areas:

(a)   Facility guidelines and personnel qualifications

(b)   Education and communication

(c)   Appropriate use

(d)   Equipment safety features

(e)   Monitoring dose data and adverse events

(f)   Research and development

7.15   In 2012, the FDA launched an initiative to help reduce unnecessary radiation exposure of children[*]. In its draft guidance[†], the FDA recommended that manufacturers design new X-ray imaging devices with protocols and instructions that address use for paediatric patients. It also proposed that manufacturers who do not adequately demonstrate that their new X-ray imaging devices are safe and effective for paediatric patients should include a label on their device that cautions against use with paediatric populations.

7.16   In addition to this initiative, the FDA launched a website on paediatric imaging that includes information on the benefits and risks of imaging using ionising radiation, recommendations for parents and health care providers to help reduce unnecessary radiation exposure, and information for manufacturers of X-ray imaging devices[‡].

Image Gently and Image Wisely

7.17   Also in the USA, two initiatives have been set up by the imaging community to promote radiation awareness and radiation protection – Image Gently and Image Wisely. The Image Gently campaign was established by the Alliance for Radiation Safety in Pediatric Imaging, with the aim to change practice by increasing awareness of the opportunities to promote radiation protection in the imaging of children[§]. The Alliance chose to focus first on CT scans based on the dramatic increase in the number of paediatric CT scans performed in the USA in the past five years and the rapid evolution, change and availability of CT technology and equipment. The campaign's second focus concerns safety in paediatric interventional radiology and began in late August 2009. Image Gently provides information for staff and parents as well as providing guidance on how to develop CT protocols for children.

7.18   Image Wisely (which focuses on adult imaging) is run by the American College of Radiology, the Radiological Society of North America, the American

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[*]   www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm303386.htm

[†]   www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm3008 50.htm

[‡]   www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/ucm298899.htm

[§]   www.pedrad.org/associations/5364/ig/

Association of Physicists in Medicine and the American Society of Radiologic Technologists, with the objective of lowering the amount of radiation used in medically necessary imaging studies and eliminating unnecessary procedures[*]. The campaign offers resources and information to radiologists, medical physicists, other imaging practitioners and patients.

7.19   Both campaigns invite staff to pledge to promote radiation protection and reduce the radiation dose from imaging.

Local governance

IR(ME)R

7.20   As described previously, regulation of radiation protection of those subject to medical exposures is provided by IR(ME)R 2000. These regulations follow a health and safety format and require employers to provide a framework of procedures under which professionals can act as further duty holders. These duty holders have responsibilities relating to justification and optimisation.

7.21   Responsibilities regarding justification are placed on a single practitioner, but those relating to practical aspects of an examination, including those elements which ensure optimisation, are placed on the operator. In practice, it falls on a number of operators who undertake a range of activities, including calibrating equipment, performing scans and evaluating the resulting images.

7.22   While the regulations require individual duty holders to be identified, they also require duty holders to work together on optimisation. By recognising the operator as a duty holder, the regulations establish the importance of all the professional groups and individuals involved in optimisation.

Governance within departments

Governance of protocols

7.23   Increasingly, consistent and good quality imaging is delivered through adherence to written protocols, required by employers, but established by professionals, taking into account clinical requirements, service provision, equipment availability and capability, and staffing structures. Protocols need to be reviewed annually by the key professional groups involved in their management, unless significant practice or equipment changes require more frequent revision.

7.24   Areas that need attention are the image quality and dose levels required, and consistent protocol nomenclature, as well as the actual scan parameters in the protocols.

7.25   Robust protocol management systems should be in place. It is important to consider all scanners within the same organisation – in particular taking into consideration variations in scanner type and model, staff training and expertise, etc – to ensure consistent services and standard of care for all patients, regardless of where and when a patient presents to the organisation.

Guidance to staff as to what is available for monitoring dose, eg dose monitoring software

7.26   To support these requirements, a number of commercial companies have launched dose monitoring software products. These have a range of functions which include monitoring protocols, patient doses and performing dose benchmarking within or between organisations. These products also allow for alerts to be set which notify staff when DRLs or other dose levels are exceeded.

Radiology department rules

7.27   It may be possible for radiology departments to establish good practice guidelines for undertaking examinations that would aid dose reduction.

7.28   A representative set of guidelines for optimisation may include:

(a)   Ensure the exposure is justified

(b)   Plan your approach to optimisation

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[*]   www.imagewisely.org/

(c)   Know your equipment

(d)   Know what is required from the image to answer the clinical question

(e)   Ensure all staff are appropriately trained to be competent in all aspects and applications of the equipment

(f)   If changes are implemented, make sure all staff are aware and have a robust system in place to ensure all staff are informed

(g)   Do not simply adopt manufacturer setting/protocols – develop locally optimised protocols to answer the clinical question, focusing on dose image quality

(h)   Establish local DRLs

(i)   Share good practice

(j)   Get advice from specialist centres

7.29   Vock (2005) suggested seven rules for optimised CT dose reduction in children:

(a)   Justify CT examination rigorously

(b)   Prepare the patient

(c)   Accept noise as long as the scan is diagnostic

(d)   Optimise scan parameters within the axial plane

(e)   Optimise scan parameters for volume coverage

(f)   Scan minimal length

(g)   Minimise repeated scanning of identical area

Importance of key professional groups and the appointment of 'radiation protection champions'

7.30   While optimisation covers a range of activities within CT services, protocol development and review offers perhaps the greatest opportunity to optimise and improve on existing safe practices. Within the process, input will be required from a number of key professional groups if this is to be successful and the key components and stages of protocol development are reviewed, revised and adopted.

7.31   Physicists have a knowledge of the scanners and their performance in different scan parameter conditions. Radiographers implement the protocols and are uniquely aware of the limitations of any protocol and the effect on image quality at the time of scanning. Radiologists have a requirement for the appropriate image quality to be able to interpret the image and to make a satisfactory diagnosis. There may also be the requirement for a specialist in radiology information and picture archiving and communication systems (RIS/PACS).

7.32   All these professionals should work together to ensure the optimal management of protocols and their implementation. However, to reflect the importance of each of these staff groups, the employer should allocate time within job plans to work together to improve the optimisation of clinical protocols. To support these activities, the employer should consider appointing these individuals to form a team of radiation protection champions.

7.33   The role of champion should be on a par with that of the radiation protection adviser, medical physics expert or radiation protection supervisor (RPA, MPE or RPS). The champions should report to the radiation protection or IR(ME)R committee. The period of greatest activity for these staff will always be at the introduction of a new CT scanner. However, they should be involved whenever new hardware or software enhancements are discussed, when techniques and protocols are modified or introduced, and when new services are proposed and introduced.

7.34   To maximise the impact of their role, the champions should:

(a)   Review literature

(b)   Attend national and international meetings

(c)   Liaise with the MPE and RPS

(d)   Represent the department as appropriate regarding the development of new services

(e)   Act as an advocate to ensure that all colleagues are aware of developments within the department

(f)   Implement any protocol changes designed to improve optimisation

Current requirements for the UK

7.35   The establishment of an independent evaluation group would provide impartial and objective assessments of CT scanners that are available in the UK, to take account of manufacturer bias and inconsistency. Scanner evaluation reports that are independent and detailed would help to support purchasing decisions for investment in high cost capital equipment for the NHS and other health care providers. Diagnostic imaging and radiotherapy departments have specific requirements for the applications of a scanner and guidance on these aspects would be of great value, both for radiation protection and for value for money. Departments preparing specifications for the purchase of a scanner require information on many aspects, from its ease of use to its imaging and dosimetric capabilities. The latter two are vital for the optimisation of the image and dose reduction. With further technological developments in CT equipment by all manufacturers, automatic exposure control and dose measurement become essential aspects and will facilitate future dose surveys.

Summary

7.36   Governance of CT works on a variety of different levels, from industry, through to national, European and international initiatives, to local governance and down to the departmental level.

7.37   Industry has a role in developing dose reduction technology and in ensuring that the associated protocols and software are implemented and used appropriately. Data from examination records can be used as part of a regular audit against established practice and help in the definition of best practice for most routine CT investigations.

7.38   A number of initiatives exist at national, European and international levels, which consider radiation protection and dose reduction in CT investigations, some of which are targeted specifically at children, such as the Image Gently initiative in the USA.

7.39   In the UK a wide range of services and support were provided to the CT scanning community by an independent evaluation group (ImPACT) until 2011. It may be argued that there still exists a need for a group that is able to provide impartial and objective advice on CT scanners, balanced against manufacturers, to support equipment purchasing decisions for the NHS and other health care providers.

7.40   For the UK, local governance involves IR(ME)R 2000, which place responsibilities both on the practitioner and operator as well as on the employer. The regulations require the duty holders to work together on optimisation.

7.41   Within radiology departments, the use of protocols establishes another level of governance. These should be reviewed annually by key professional groups involved in protocol management, with particular focus on image quality,

required dose levels and consistent protocol nomenclature. There should be consideration of providing a consistent service and standard of care for all scanners within an organisation. Departments could consider establishing good practice guidelines for examinations, which may be especially applicable to optimising CT dose reduction in children.

7.42   Within radiology departments, input is required from a number of key professional groups (physicists, radiographers and radiologists) to ensure the optimal management of protocols and their implementation. Individuals within these groups could be appointed as 'champions' to optimise and improve on existing safe practices, to support the introduction of new equipment into the department, and maintain an awareness of current research and technological developments in the field.

CHAPTER 8

CONCLUSIONS

8.1   The use of CT in a clinical environment has expanded dramatically since its introduction, as have its technological developments. CT provides a unique combination of features in an imaging modality which makes it applicable to a wide range of clinical examinations.

8.2   The increased use of CT has raised concerns regarding the radiation dose to patients from CT scans. There is evidence that CT makes a larger contribution to the radiation exposure of patients when compared with other imaging modalities based on ionising radiation. There is an associated concern for the increase in the number of younger patients undergoing CT scans, due to their greater radiosensitivity.

8.3   In recent years there has been an emerging use of CT to scan asymptomatic individuals. This issue was covered in the 12th COMARE report (COMARE, 2007), which determined that the benefits to the individual would not be the same as those for a symptomatic patient and that the practice of whole-body scanning on asymptomatic individuals could not be supported.

8.4   The use of CT is governed by the radiation protection principles of justification and optimisation. The potential benefit to a patient must be balanced against the potential detriments. Although other risks exist, the principal risk is from the ionising radiation exposure. For diagnostic exposures the potential effects from the radiation exposure are considered to be stochastic, although cataracts and cardiac effects can also occur. There have been reports of tissue reaction (deterministic) effects being observed in extreme cases.

8.5   Specific groups are at greater risk from radiation exposure. Children have a much higher radiosensitivity than adults at the same effective dose. Some genetic conditions are associated with an increased sensitivity to radiation.

8.6   Since the turn of the century, manufacturers have been developing dose reduction technologies, which offer potential reductions of radiation dose to varying degrees depending on their deployment. Each CT scan undertaken should be optimised to achieve adequate diagnostic quality without excessive radiation exposure. Operators should understand the equipment available to them (including the use of dose reduction technologies) and how to maximise the use of that equipment, while considering the clinical question to be answered and the radiation protection of the patient. Children present a unique range of size and weight against age, which requires special consideration in optimisation and modification of equipment, techniques and imaging parameters.

8.7   Despite developments by manufacturers regarding dose reduction in CT, the modality remains a major contributor to individual and population dose. The demise of the ImPACT group in 2011 has removed the amount of independent cross-manufacturer information available to purchasers and users of CT scanners. Current international initiatives may improve manufacturer transparency, but are not intended to substitute for all the work previously provided by ImPACT.

CHAPTER 9

RECOMMENDATIONS

Recommendation 1

During the next 10 years, the importance of the radiosensitivity of high risk groups is expected to become more widely recognised as a factor in a range of clinical applications involving ionising radiation, including CT. We recommend that the UK is actively involved in further research in this area. Professional bodies and medical and scientific societies should continue to provide educational opportunities to increase the understanding of clinical staff regarding all of the potential risks to patients, and not just the dose received, from CT scans. This is particularly relevant for CT scans on children and other high risk groups.

Recommendation 2

The continuing development of technology and the growing range of clinical applications in CT suggest that individual and population dose from CT will continue to rise. We recommend that Public Health England should undertake more frequent UK dose surveys to provide data to support regular updating of national diagnostic reference levels, including those specifically regarding children. To facilitate this, the Department of Health should include within regulations a requirement for health care providers to submit patient dose data at a frequency which reflects the changes in the application of the modality.

Recommendation 3

Optimisation of CT scanning can be best achieved when scanners include a full range of dose reduction features. We recommend hospitals should be required to include these features and options as part of any procurement process for new equipment. Manufacturers and suppliers should ensure the application and performance of these features is fully understood by customers and should be a major feature of initial and ongoing applications training for radiographers and radiologists. Employers should recognise the value of continued training as part of continuing professional development as well as for patient safety and should release staff so that the benefits of manufacturer training are maximised.

Recommendation 4

Although we recognise the value of a range of international initiatives on radiation dose in CT, there remains a need for detailed independent information on CT scanner performance. We recommend that the Department of Health reviews the sources of available information and, if necessary, provides funding to support an independent evaluation group, acting collaboratively where appropriate, but also providing assessments of CT scanners as and when required.

Recommendation 5

Modern CT scanners are capable of providing precise detail of patient anatomy, but this is not always required. Requests for imaging should include a clear statement regarding the clinical question to be answered and the scan should be performed to provide this. We recommend that the Royal College of Radiologists should continue to work with referrers and its own fellows and members to ensure an appreciation that CT scans should be optimised, taking into account both image quality and dose.

Recommendation 6

The most appropriate use of CT relies upon a range of factors involving the referring clinician and the radiologist or other clinician who justifies the scan. In many cases, the most appropriate outcome of a referral may be that the CT scan is not performed as an alternative diagnostic procedure may be more effective.

We recommend that the Royal College of Radiologists, together with other appropriate organisations, continues to review and produce referral guidelines and includes within these an even greater emphasis on alternative imaging techniques using less or no ionising radiation. The Department of Health should continue to actively support this process by facilitating the availability of referral guidelines and, while doing so, highlight the importance of alternative techniques for patient groups who may have enhanced radiosensitivity.

Recommendation 7   Optimisation of scanning protocols offers significant potential for dose reduction. This can only be achieved at local level through active promotion and cooperation between professional groups. We recommend that in conjunction with the production of new regulations for medical exposures, the Department of Health provides supporting guidance on optimisation, including a requirement for radiology services to consider formally appointing a team of radiation protection champions, consisting of a radiologist, a radiographer and a medical physicist.

We recognise that some of the recommendations may impact on organisations other than the Department of Health, including professional bodies and the NHS. The recommendations are aimed at promoting good practice and encouraging a more proactive approach to protecting the patient and reducing radiation dose, recognising the patient benefit associated with a reduced incidence of radiation-induced disease. Implementation of the recommendations should, where possible, consider equipment and procedures already in place and is not expected to result in a significant additional cost burden. It should be noted, however, that some of the dose reduction features described in this report are only available on newer CT scanners and the use of old machines can result in a significantly higher dose to the patient from some types of examination; this should be borne in mind when formulating capital equipment programmes. Any impact on the NHS that is incurred through the recommendations being implemented should be balanced against the overall costs of diagnostic services and the predicted costs to the service of radiation-induced disease. Stakeholders, such as Public Health England and scanner manufacturers, may be expected to help minimise any impact.

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THE APPENDICES

APPENDIX A

GLOSSARY AND ABBREVIATIONS

ABSORBED DOSE The quantity of energy imparted by ionising radiation to a unit mass of matter such as tissue. Absorbed dose has the units of joules per kilogram ($J\ kg^{-1}$) and the specific name gray (Gy), where $1\ Gy = 1\ J\ kg^{-1}$

ALARP As low as reasonably practicable: the principle used in radiation protection in the UK that doses to people should be as low as possible once all the 'reasonable' methods of dose reduction have been employed

ANGIOGRAM An X-ray of one or more blood vessels, used in diagnosing pathological conditions

ASYMPTOMATIC Without obvious symptoms of disease

AXIAL Relating to, forming, or characteristic of an axis. For CT scans, the term applies to slices through the body

BENIGN Non-cancerous or non-malignant. A benign tumour may grow but it does not invade surrounding tissue or spread to other parts of the body

CARCINOGEN An agent that causes cancer

CARDIAC Pertaining to the heart

CATARACT An opacity, partial or complete, on the lens of the eye which may impair vision and, if dense enough, can cause blindness

COMPUTED TOMOGRAPHY (CT) A special radiographic technique that uses a computer to assimilate multiple X-ray images into a two-dimensional cross-sectional image

CONTRAST AGENT A substance that is introduced into or around a structure and, because of the difference in absorption of X-rays by the contrast medium and the surrounding tissues, allows radiographic visualisation of the structure

CT DOSE INDEX (CTDI) A description of the ionising radiation dose from a single rotation of a CT scanner

CT NUMBER In volumetric (three-dimensional) digital radiology, the radiographic density (= X-ray attenuation power) in each voxel of the volume of interest is expressed by a number called the CT number

DETERMINISTIC A deterministic health effect has a severity that is dependent on dose and is believed to have a threshold level below which no effect is seen

DIAGNOSTIC REFERENCE LEVELS (DRLs) Dose levels in medical radiodiagnostic practices for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment

DOSE A measure of the amount of radiation received. More strictly it is related to the energy absorbed per unit mass of tissue (*see Absorbed Dose*). Doses can be estimated for individual organs or for the body as a whole

DOSE-AREA PRODUCT (DAP)	A measure of radiation risk calculated by multiplying the absorbed dose by the area irradiated (in Gy per cm^2)
DOSE-LENGTH PRODUCT (DLP)	A basic measure of radiation risk calculated by multiplying the CTDI for a scan sequence by the length of coverage (along the patient's length)
EFFECTIVE DOSE	Effective dose is the sum of the weighted equivalent doses in all the tissues and organs of the body. It takes into account the biological effectiveness of different types of radiation and variation in the susceptibility of different organs and tissues to radiation damage. Thus it provides a common basis for comparing exposures from different sources. Unit = sievert (Sv)
ENDOSCOPY	An endoscopy is a procedure where the inside of a person's body is examined internally using an endoscope. An endoscope is a thin, long, flexible tube that has a light source and a video camera at one end
EPIDEMIOLOGY	The study of factors affecting health and illness of populations, regarding the causes, distribution and control
EQUIVALENT DOSE	The quantity obtained by multiplying the absorbed dose by a factor to allow for the different effectiveness of the various ionising radiations in causing harm to tissue. Unit = sievert (Sv)
GENERIC	Something that is general, common, or inclusive rather than specific, unique or selective; relating to or descriptive of an entire group or class
GERMLINE	Usually used to refer to those cells called germ cells as well as the final egg and sperm
GRAY (Gy)	The international (SI) unit of absorbed dose. One gray is equivalent to one joule of energy absorbed per kilogram of matter such as body tissue
HELICAL CT	Combines continuously rotating X-ray tube and table/patient movement through the gantry aperture. The path traced by X-ray tube describes a spiral and produces a volume of data
HETEROZYGOTE	An organism having two different alleles of a particular gene
HOMOZYGOTE	An organism having two identical alleles of a particular gene
ICRP	International Commission on Radiological Protection. It consists of experts in radiology, genetics, physics, medicine and radiological protection from a number of countries. Established in 1928 it meets regularly to consider the research on the effects of radiation and publishes recommendations on all aspects of radiation protection including dose limits to man
INCIDENCE	This is the number of new cases of a disease arising in a population over a specific period of time, usually one year
IONISING RADIATION	Radiation that is sufficiently energetic to remove electrons from atoms in its path. In human or animal exposures ionising radiation can result in the formation of highly reactive particles in the body which can cause damage to individual components of living cells and tissues
IRRADIATION	The process by which an item is exposed to radiation, either intentionally or accidentally
ISO-CENTRE	The intersection of the central scan plane with the axis of rotation of the X-ray tube and detector around the patient

JUSTIFICATION	Consideration that a medical exposure shall show a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefits it produces, including the direct health benefits to an individual and the benefits to society, against the individual detriment that the exposure might cause, taking into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionising radiation
LINEAR NO-THRESHOLD HYPOTHESIS	The hypothesis used in radiation protection to estimate the long-term, biological damage caused by ionising radiation, which assumes that the damage is directly proportional ('linear') to the dose of radiation, at all dose levels and that any radiation exposure is always considered harmful with no safety threshold
LONGEVITY	An individual's lifespan or the duration of an individual life beyond the norm for the species
LEVEL OF RADIATION DOSE	Radiation dose can be defined into different levels. An example is used in Kadhim et al (2013)[*]:

Very high	doses above 15 Gy
High	doses of 5–15 Gy
Medium	doses of 0.5–5 Gy
Low	doses of 0.05–0.5 Gy
Very low	doses below 0.05 Gy

MAGNETIC RESONANCE IMAGING (MRI)	The use of nuclear magnetic resonance of protons to produce proton density images
MALIGNANT	Cancerous growth, a mass of cells showing uncontrolled growth, a tendency to invade and damage surrounding tissues and an ability to seed daughter growths to sites remote from the primary growth
MEDICAL PHYSICS EXPERT (MPE)	An MPE is a physicist, expert in an area of medical radiation, appointed to support and advise the employer in the safe use of radiation for patients (Ionising Radiation (Medical Exposure) Regulations 2000, IR(ME)R 2000). The MPE and RPA may be same individual
MODALITY	The method of application of a therapeutic agent or regimen
MONTE CARLO METHODS	Monte Carlo methods are a statistical approach for modelling X-ray interactions in and through tissue, and are used to determine an estimate of radiation dose
MULTI-DETECTOR CT/ MULTI-SLICE CT (MDCT/MSCT)	A form of CT technology used in diagnostic imaging, where a two-dimensional array of detector elements replaces the linear array typically used in conventional and helical CT scanners. This arrangement allows the acquisition of multiple slices or sections simultaneously and therefore greatly increases the speed of image acquisition
MUTAGEN	Any chemical or physical environmental agent that induces a genetic mutation or increases the mutation rate
MUTATION	A permanent transmissible change in the genetic material, which may alter a characteristic of an individual or manifest as disease

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* Kadhim M et al (2013). Non-targeted effects of ionising radiation – implications for low dose risk. *Mutat Res* **752**, 84–98.

OPERATOR	Any person who is entitled to carry out the practical aspects of a medical exposure
OPTIMISATION	Consideration that a medical exposure be conducted as efficiently and effectively as possible using the lowest reasonably practicable radiation exposure, consistent with the intended purpose. The optimisation process consists of a chain of responsibilities extending from appropriate manufacture, selection and maintenance of equipment to the exposure parameters selected for the individual examination
PAEDIATRIC	Of, or relating to, the medical care of children
PATIENT DOSE	The ionising radiation dose to a patient or other individual undergoing a medical exposure
PERFUSION	The passage of fluid (such as blood) through a specific organ or area of the body (such as the heart)
PHANTOM	Object generally comprised of tissue substitute materials used to simulate a patient or part thereof
PICTURE ARCHIVING AND COMMUNICATION SYSTEM (PACS)	PACS (picture archiving and communication system) is a standard healthcare technology for short- and long-term storage, retrieval, management, distribution and presentation of medical images
PITCH FACTOR	Pitch is the ratio of the distance travelled for one complete rotation of the X-ray tube. When the distance the table travels during one rotation of the tube equals the slice thickness or beam collimation, the pitch ratio is one
POSITRON EMISSION TOMOGRAPHY (PET) SCAN	A diagnostic examination involving the acquisition of physiological images based on the detection of radiation through the emission of positrons. The positrons are emitted from a short-lived radionuclide incorporated into a metabolically active substance administered to the patient prior to the examination
PRACTITIONER	A registered health care professional, who is entitled to take clinical responsibility for an individual medical exposure in accordance with national requirements
PROGNOSIS	A prediction of the probable course and outcome of a disease and the prospects of recovery as indicated by the nature of the disease and the symptoms of the case
RADIATION PROTECTION ADVISER (RPA)	An RPA is an expert in radiation protection, certified as competent by an HSE approved body, to advise the employer in radiation safety for the public and staff (under the Ionising Radiations Regulations 1999, IRR99). The RPA and the MPE may be same individual
RADIATION PROTECTION OR IR(ME)R COMMITTEE	Local hospital or trust group of experts (eg RPA, MPE, RPS, senior clinicians, risk manager and radiology services manager) who meet on a regular basis to discuss radiation safety issues, and ensure the compliance with IR(ME)R 2000 and IRR99 policies and procedures
RADIATION PROTECTION SUPERVISOR (RPS)	An RPS is a line manager, or person of similar status, working in and having knowledge of the equipment and practices in a radiation controlled area – appointed under IRR99 to ensure local rules are adhered to in that area
RADIODIAGNOSTIC	Pertaining to *in vivo* diagnostic nuclear medicine, medical diagnostic radiology and dental radiology

RADIOLOGIST	A medically qualified doctor who specialises in the use of imaging techniques (X-rays, ultrasound, CT, MR, fine needle biopsy, etc) for diagnosis (diagnostic radiologist) or one who specialises in the use of imaging techniques in assisting treatment – for example, in inserting catheters into blood vessels or in choking the blood supply of a tumour by injection of a type of glue (interventional radiologist)
RADIOLOGY INFORMATION SYSTEM (RIS)	A radiology information system is networked software used for managing radiological records and associated data in a multiple locations. It is often seen used in conjunction with a picture archiving and communication system (PACS) to manage workflow
RADIONUCLIDE	A type of atomic nucleus which is unstable and which may undergo spontaneous decay to another atom by emission of ionising radiation (usually alpha, beta or gamma)
RADIOSENSITIVITY	The relative susceptibility of cells, tissues, organs, organisms, or any other substances to the effects of radiation
RADIOTHERAPY	The treatment of disease with ionising radiation. The purpose of radiotherapy is to deliver an optimal dose of either particulate or electromagnetic radiation to a particular area of the body with minimal damage to normal tissues. The source of radiation may be outside the body of the patient (external radiotherapy) or it may be a radionuclide that has been implanted or instilled into abnormal tissue or a body cavity
RECONSTRUCTION	The computerised creation of images from a series of X-ray projections in computed tomography
REFERRER	A registered health care professional who is entitled in accordance with the employer's procedures to refer individuals for medical exposure to a practitioner
RISK	The probability that an event will occur, eg that an individual will become ill or die before a stated period of time or age. This is also a non-technical term encompassing a variety of measures of the probability of a (generally) unfavourable outcome
SENSITIVITY	A measure for assessing the results of diagnostic and screening tests. Sensitivity is the proportion of diseased people who are identified as being diseased by the test. It is the probability of correctly diagnosing a condition in a person who has that disease
SIEVERT (Sv)	The international (SI) unit of effective dose obtained by weighting the equivalent dose in each tissue in the body with the ICRP-recommended tissue weighting factors and summing over all tissues. Because the sievert is a large unit, effective dose is commonly expressed in millisieverts (mSv) – ie one-thousandth of one sievert. The average annual radiation dose received by members of the public in the UK is 2.7 mSv
SPECIFICITY	A measure for assessing the results of diagnostic and screening tests. Specificity is the proportion of normal individuals who are so identified by the screening test. It is the probability of correctly excluding a disease in a normal individual
STAGING	A CT scan to assess the extent to which a cancer has spread from its original source. Staging is used to inform treatment and prognosis
STOCHASTIC	Stochastic effect or 'chance effect' is a classification of radiation effects that refers to the random, statistical nature of the damage. The severity is independent of dose. Only the probability of an effect increases with dose

TERATOGENIC   Of, or relating to, substances or agents that can interfere with normal embryonic development

TORSO   The main part of the human body, without the limbs and head; the trunk

TRANSVERSE   In anatomy, lying in a crosswise direction

TUMOUR   Mass of tissue formed by unregulated growth of cells; can be benign or malignant

ULTRASOUND   The use of ultrasonic waves for diagnostic or therapeutic purposes, specifically to visualise an internal body structure, monitor a developing fetus, or generate localised deep heat to the tissues

VASCULAR   Of, relating to, or containing blood vessels

X-RAY   An image obtained using high energy radiation with waves shorter than those of visible light. X-rays possess the properties of penetrating most substances (to varying extents), of acting on a photographic film or plate (permitting radiography), and of causing a fluorescent screen to give off light (permitting fluoroscopy). In low doses X-rays are used for making images that help to diagnose disease, and in high doses to treat cancer

APPENDIX B

CT VERSUS MRI VERSUS ULTRASOUND

	CT	MRI	Ultrasound
Principle	CT imaging uses X-rays to create visual images of the body. Three-dimensional images can be produced through computer reconstructions	MRI uses strong magnetic fields along with radiofrequency pulses to create visual images of the body	Ultrasound uses high frequency sound waves to create visual images of the body
Details of bony structures and soft tissue	Provides good details of bony structures. Gives less tissue contrast compared to MRI	MRI scans give the best soft tissue contrast of all the imaging modalities. Bony structures may be less detailed compared to CT	Allows visualisation of detailed tissue structure with advanced technology. Not used for bony structures
Contrast agents	Contrast media often used	May be used	Occasionally used
Ionising radiation use	Yes	No	No
Contraindications	Not routinely used for pregnant women but may be considered in certain circumstances	Cannot be used if patient has implanted metal (eg pacemaker)	No current evidence of any contraindications
Expense (equipment)	★★★	★★★★	★
Timing (relative)[*]	~ 5–10 minutes	~30 minutes	~10–15 minutes
Availability in the NHS	Widely available	Available	Very widely available
Portability in the NHS	No	No	Yes
Number of machines in the NHS in the UK	462	369	
Total number of NHS examinations in England in 2010/11[†]	3.98 million	2.12 million	8.60 million
Disadvantages	Involves ionising radiation; often requires contrast enhancement with risks of nephrotoxicity or anaphylaxis; weight limitations	Claustrophobia; noisy exams, possibly lengthy; some nephrotoxic contrast agents; weight limitations; pacemakers and some medical equipment cannot be put in a magnetic field safely	Does not show function, only anatomy; difficult with obese, immobile patients; hard to see deep structures; difficult to scan through bone or gaseous areas (eg lung) in the body

[*] Timings are examination and patient dependent. Times shown are for indicative purposes only

[†] http://www.dh.gov.uk/en/Publicationsandstatistics/Statistics/Performancedataandstatistics/HospitalActivityStatistics/DH_077487

APPENDIX C

KEY EVENTS IN THE HISTORY OF CT AND X-RAYS

Adapted from Impactscan.org
(http://www.impactscan.org/CThistory.htm)

1895	Wilhelm Conrad Röntgen discovers X-rays (Würzburg, Bavaria, Germany)
1896	Francis Henry Williams takes the first successful chest X-ray (Boston MA, USA)
	Carl Schleussner, working with Wilhelm Röntgen, develops the photographic X-ray plate (Frankfurt am Main, Germany)
	First X-ray department established, at Glasgow Royal Infirmary (Scotland, UK)
	Skin burns reported resulting from use of X-rays
1902	First case of skin cancer reported associated with ionising radiation
1913	William David Coolidge invents the hot cathode X-ray tube
1917	Johann Radon demonstrates that the image of a three-dimensional object can be reconstructed from an infinite number of two-dimensional projections of the object, providing the mathematical basis for CT image construction (Vienna, Austria)
1921	André Bocage develops focal-plane tomography (Paris, France)
1930–1931	Alessandro Vallebona develops 'stratigraphy' (Genova, Italy) and Bernard Ziedes des Plantes develops 'planigraphy' (Utrecht, Netherlands): both are forms of tomography
1937	William Watson patents axial transverse tomography and obtains the first radiographic images using this technique (London, UK)
1940	Gabriel Frank patents back-projection (Budapest, Hungary)
1961	William Oldendorf builds a model tomographic scanner that uses the techniques later developed independently by Hounsfield and Cormack (Los Angeles, USA)
	First PET scanner demonstrated by James Robertson and associates (New York, USA)
1963–1964	Allan Cormack publishes a theoretical analysis and the results from experimental scanner using a computer to reconstruct cross-sectional images from data (Medford MA, USA)
1966	David Kuhl, John Hale and Walter Eaton publish a paper with the transmission images of a subject's thorax, using an external radiation source (Philadelphia, USA)
1968	Godfrey Hounsfield's original project proposal at EMI (London, UK)
1971	First patient (head scan) at Atkinson Morley's Hospital using prototype EMI head scanner (London, UK)
1972	Godfrey Hounsfield and James Bull lecture, New York, showing first clinical CT images (New York, USA)
	The first CT scanner demonstration in the USA, at the Mayo Clinic (Rochester MN, USA)
1973	320 × 320 image matrix
	First clinical patient scan in the USA, at the Mayo Clinic (Rochester MN, USA)
	Robert Ledley designs ACTA, a whole-body CT scanner (Washington DC, USA)

1974	First body CT scan (of Hounsfield) in a prototype of the EMI body scanner (London, UK)
	35 EMI head scanners installed worldwide; 60 more on order
1975	Prototype of the EMI CT1010 body scanner installed at Atkinson Morley's Hospital (London, UK)
	First commercial PET scanner installed (Los Angeles, USA)
	First scans from EMI body scanner shown, at first international conference on CT (Bermuda)
	Research body scanner installed at Northwick Park Hospital (London, UK)
	First body scan in the USA, under the direction of Ron Evans at the Mallinkrodt Institute (St Louis, USA)
1976	5 second scan time for an image
	17 companies now offering 'third-generation' CT scanners
	650 scanners now installed worldwide; 450 supplied by EMI
1977	First MRI body scan on humans, by Raymond Vahan Damadian, Larry Minkoff and Michael Goldsmith (Nottingham, UK)
1978	512 × 512 image matrix
	200 scanners sold in the USA
	ECG-synchronised CT scanning
1979	Hounsfield and Cormack jointly awarded the Nobel Prize for Medicine (Stockholm, Sweden)
	Around 1000 scanners in operation worldwide
1980	FONAR markets the first commercial MRI scanner (Melville NY, USA)
1981	3 second scan time for an image
1983	800 CT scanners sold in the USA
1985	1 second scan time
	'Superfast CT' (electron beam tomography) is developed by Douglas Boyd (San Francisco, USA)
1987	1024 × 1024 image matrix
1989	First spiral (helical) CT, manufactured by Siemens, enters the market (Erlangen, Germany)
1992	Elscint CT Twin, first modern multi-slice scanner; sub-millimetre slices (Haifa, Israel)
1994	0.75 second scan time
1998	4-slice scanners
	0.5 second scan time
1999	PET CT developed, by David Townsend and Ron Nutt (Pittsburgh, USA)
2002	8- and 16-slice scanners introduced
2004	640-slice scanners
2005	Dual X-ray source scanner
2007	320-detector row scanner
	72 million CT scans performed in the USA

APPENDIX D

LETTER FROM THE ROYAL COLLEGE OF RADIOLOGISTS

RCR

The Royal College of Radiologists

20th April 2012

38 PORTLAND PLACE, LONDON W1B 1JQ
T: 020 7636 4432 F: 020 7323 3100
enquiries@rcr.ac.uk www.rcr.ac.uk

Dr Giles Maskell
Chair of the Medical Practices Sub-Committee
COMARE
c/o Health Protection Agency
CRCE
Chilton
Didcot
Oxon. OX11 0RQ

Dear Giles,

Re: CT Examination Dosage

Thank you for your letter dated 4th April 2012 addressed to Dr Jane Barrett, which I have been asked to reply to on behalf of the College.

The Clinical Radiology Officers discussed your letter and I confirm that we agree in principle with the statement that "where a specific clinical question has been asked by the referrer of a patient for CT scan, the CT examination should be carried out at the lowest dose required to answer the question, accepting that other organs in the scan field may not be optimally visualised".

Yours sincerely,

Dr Pete Cavanagh
Vice President and Dean
The Royal College of Radiologists

cc: Dr Jane Barrett, RCR President

APPENDIX E

REPORTS OF THE COMMITTEE ON
MEDICAL ASPECTS OF RADIATION
IN THE ENVIRONMENT

COMARE Fifteenth Report	Radium contamination in the area around Dalgety Bay. PHE, Chilton, May 2014
COMARE Fourteenth Report	Further consideration of the incidence of childhood leukaemia around nuclear power plants in Great Britain. HPA, Chilton, May 2011
COMARE Thirteenth Report	The health effects and risks arising from exposure to ultraviolet radiation from artificial tanning devices. HPA, Chilton, June 2009
COMARE Twelfth Report	The impact of personally initiated X-ray computed tomography scanning for the health assessment of asymptomatic individuals. HPA, Chilton, December 2007
COMARE Eleventh Report	The distribution of childhood leukaemia and other childhood cancer in Great Britain 1969–1993. HPA, Chilton, July 2006
COMARE Tenth Report	The incidence of childhood cancer around nuclear installations in Great Britain. HPA, Chilton, June 2005
COMARE Ninth Report	Advice to Government on the review of radiation risks from radioactive internal emitters carried out and published by the Committee Examining Radiation Risks of Internal Emitters (CERRIE). NRPB, Chilton, October 2004
COMARE Eighth Report	A review of pregnancy outcomes following preconceptional exposure to radiation. NRPB, Chilton, February 2004
COMARE Seventh Report	Parents occupationally exposed to radiation prior to the conception of their children. A review of the evidence concerning the incidence of cancer in their children. NRPB, Chilton, August 2002
COMARE and RWMAC* Joint Report	Radioactive contamination at a property in Seascale, Cumbria. NRPB, Chilton, June 1999
COMARE Sixth Report	A reconsideration of the possible health implications of the radioactive particles found in the general environment around the Dounreay nuclear establishment in the light of the work undertaken since 1995 to locate their source. NRPB, Chilton, March 1999
COMARE Fifth Report	The incidence of cancer and leukaemia in the area around the former Greenham Common Airbase. An investigation of a possible association with measured environmental radiation levels. NRPB, Chilton, March 1998
COMARE Fourth Report	The incidence of cancer and leukaemia in young people in the vicinity of the Sellafield site, West Cumbria: further studies and an update of the situation since the publication of the report of the Black Advisory Group in 1984. Department of Health, London, March 1996

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* Radioactive Waste Management Advisory Committee.

COMARE and RWMAC[*]
Joint Report

Potential health effects and possible sources of radioactive particles found in the vicinity of the Dounreay nuclear establishment. HMSO, London, May 1995

COMARE Third Report

Report on the incidence of childhood cancer in the West Berkshire and North Hampshire area, in which are situated the Atomic Weapons Research Establishment, Aldermaston and the Royal Ordnance Factory, Burghfield. HMSO, London, June 1989

COMARE Second Report

Investigation of the possible increased incidence of leukaemia in young people near the Dounreay nuclear establishment, Caithness, Scotland. HMSO, London, June 1988

COMARE First Report

The implications of the new data on the releases from Sellafield in the 1950s for the conclusions of the report on the investigation of the possible increased incidence of cancer in West Cumbria. HMSO, London, July 1986

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* Radioactive Waste Management Advisory Committee.

APPENDIX F

COMMITTEE ON MEDICAL ASPECTS OF RADIATION IN THE ENVIRONMENT

CHAIRMAN

Professor A Elliott BA PhD DSc CPhys FInstP FIPEM
University of Glasgow

PRESENT MEMBERS

Dr P Darragh MD PhD MSc FRCP FFPHM
Public Health Agency for Northern Ireland, Belfast

Professor W Evans MA PhD FInstP FIPEM HonMRCR
University Hospital of Wales, Cardiff

Dr B Howard MBE
Centre for Ecology and Hydrology, Lancaster Environment Centre

Professor M Kadhim PhD
Department of Biological and Medical Sciences, Oxford Brookes University, Oxford

Professor S McKeown MA PhD FSB CBiol
School of Biomedical Sciences, University of Ulster, Coleraine

Professor P Marsden MSc PhD FSRP MIPEM MInstP CRadP
UCL Hospitals NHS Foundation Trust, London

Dr G Maskell MA FRCP FRCR
Department of Radiology, Royal Cornwall Hospital, Truro

Dr T Nunan MD FRCP FRCR
Nuclear Medicine Physician

Dr M Pearce BSc MSc PhD
Institute of Health and Society, Newcastle University, Newcastle upon Tyne

Mr I Robinson BSc CRadP FSRP FNucI
Consultant on Nuclear and Radiation Safety (formerly HM Superintending Inspector of Nuclear Installation, Office for Nuclear Regulation)

Professor R Taylor MA FRCPE FRCP FRCR
School of Medicine, Swansea University

Professor R Wakeford BSc PhD CSci CPhys FInstP CStat CEng MINucE CRadP FSRP
Dalton Nuclear Institute, University of Manchester

Professor P Warwick BA MSc PhD DSc CChem FRSC
Centre for Environmental Studies, Loughborough University

Professor Catharine West BA PhD
University of Manchester

MEDICAL PRACTICES SUBCOMMITEE (CT)

CHAIRMAN

Dr G Maskell MA FRCP FRCR
Department of Radiology, Royal Cornwall Hospital, Truro

MEMBERS

Professor W Evans MA PhD FInstP FIPEM HonMRCR
University Hospital of Wales, Cardiff

Dr S Golding MA MB BS DMRD FRCR FBIR FHEA
University of Oxford

Professor S Hodgson BM BCh DM FRCP
Department of Clinical Development Sciences,
St George's University of London

Professor M Kadhim PhD
Department of Biological and Medical Sciences, Oxford Brookes University,
Oxford

Dr T Nunan MD FRCP FRCR
Nuclear Medicine Physician

Dr M Pearce BSc MSc PhD
Institute of Health and Society, Newcastle University, Newcastle upon Tyne

Ms H Warner
Patient Representative

APPENDIX G

DECLARATION OF MEMBERS' INTERESTS
CODE OF PRACTICE

1 Introduction

This code of practice guides members of COMARE as to the circumstances in which they should declare an interest in the course of the Committee's work. To avoid any public concern that commercial interests of members might affect their advice to Government, Ministers have decided that information on significant and relevant interests of members of its advisory committees should be on the public record. The advice of the Committee frequently relates to matters which are connected with the radiation industry generally and, less frequently, to commercial interests involving radioactivity. It is therefore essential that members should comply with the code of practice which is set out below.

2 Scope and definitions

This code applies to members of COMARE and its subcommittees, subgroups, working groups and working parties which may be formed.

For the purposes of this code of practice, the 'radiation industry' means:

(a) companies, partnerships or individuals who are involved with the manufacture, sale or supply of products processes or services which are the subject of the Committee's business. This will include nuclear power generation, the nuclear fuel reprocessing industry and associated isotope producing industries, both military and civil and also medical service industries

(b) trade associations representing companies involved with such products

(c) companies, partnerships or individuals who are directly concerned with research or development in related areas

(d) interest groups or environmental organisations with a known interest in radiation matters

This excludes government departments, professional bodies, international organisations and agencies.

It is recognised that an interest in a particular company or group may, because of the course of the Committee's work, become relevant when the member had no prior expectation this would be the case. In such cases, the member should declare that interest to the Chairman of the meeting and thereafter to the Secretariat.

In this code, 'the Department' means the Department of Health, and 'the Secretariat' means the secretariat of COMARE.

3 Different types of interest – definitions

The following is intended as a guide to the kinds of interests which should be declared. Where a member is uncertain as to whether an interest should be declared they should seek guidance from the Secretariat or, where it may concern a particular subject which is to be considered at a meeting, from the

Chairman at that meeting. Members of the Committee and the Secretariat are under no obligation to search out links between one company and another, for example where a company with which a member is connected has a relevant interest of which the member is not aware and could not reasonably be expected to be aware.

If members have interests not specified in these notes but which they believe could be regarded as influencing their advice they should declare them to the Secretariat in writing and to the Chairman at the time the issue arises at a meeting.

3.1 *Personal interests*	A personal interest involves current payment to the member personally. The main examples are:

> (a) *Consultancies and/or direct employment:* any consultancy, directorship, position in or work for the radiation industries which attracts regular or occasional payments in cash or kind.
>
> (b) *Fee-paid work:* any work commissioned by those industries for which the member is paid in cash or kind.
>
> (c) *Shareholdings:* any shareholding in or other beneficial interest in shares of those industries. This does not include shareholdings through unit trusts or similar arrangements where the member has no influence on financial management.
>
> (d) *Membership or affiliation:* any membership role or affiliation that the member or close family member has to clubs or organisations with an interest or involvement in the work of the Department. This will not include professional bodies, organisations and societies.

3.2 *Non-personal interests*	A non-personal interest involves current payment which benefits a department to which a member is responsible, but is not received by the member personally. The main examples are:

> (a) *Fellowships:* the holding of a fellowship endowed by the radiation industry.
>
> (b) *Support by industry:* any payment, other support or sponsorship by the radiation industry which does not convey any pecuniary or material benefit to a member personally, but which does benefit their position or department, eg:
>
>> (i) a grant from a company for the running of a unit or department for which a member is responsible;
>>
>> (ii) a grant or fellowship or other payment to sponsor a post or a member of staff in a unit or department for which a member is responsible. This does not include financial assistance for students, but does include work carried out by postgraduate students and non-scientific staff, including administrative and general support staff;
>>
>> (iii) the commissioning of research or work by, or advice from, staff who work in a unit or department for which a member is responsible.
>
> (c) *Support by charities and charitable consortia:* any payment, other support or sponsorship from these sources towards which the radiation industry has made a specific and readily identifiable contribution. This does not include unqualified support from the radiation industry towards the generality of the charitable resource.

(d) *Trusteeships:* where a member is trustee of a fund with investments in the radiation industry, the member may wish to consult the Secretariat about the form of declaration which would be appropriate.

3.3 *Specific interests*

A specific interest relates explicitly to the material, product, substance or application under consideration by the Committee.

A member must declare a personal, specific interest if they currently receive a payment, in any form, for any significant fundamental development work undertaken previously or at this time, on a material, product or substance or its application under consideration. This will include the production of radioactive substances and devices designed to use ionising or non-ionising radiation for diagnostic, treatment or other purposes.

A member must declare a non-personal, specific interest if they are aware that the department to which they are responsible currently receives payment for significant fundamental development work undertaken previously or at this time, on a material, product or substance or its application under consideration, but they have not personally received payment for that work in any form. This will include the production of radioactive substances and devices designed to use ionising or non-ionising radiation for diagnostic, treatment or other purposes.

3.4 *Non-specific interests*

A non-specific interest relates to a company or associated material, product, substance or application, but not to the specific material, product, substance or application under consideration by the Committee.

A member must declare a personal, non-specific interest if they have a current personal interest in a material, product, substance or application from a particular company, which does not relate specifically to the material, product, substance or application from that company under consideration.

A member must declare a non-personal, non-specific interest if they are aware that the department to which they are responsible is currently receiving payment from the company concerned which does not relate specifically to a material, product, substance or application under discussion.

If a member is aware that a material, product, substance or their application under consideration is or may become a competitor of a material, product or substance manufactured, sold or supplied by a company in which the member has a current personal interest, they should declare their interest in the company marketing the rival material, product or substance.

Members are under no obligation to seek out knowledge of such work done for or on behalf of the radiation industry within departments to which they are responsible if they would not reasonably expect to be informed. This applies to all non-personal, specific and non-specific interests.

4   Declaration of interests

4.1 *Declaration of interests to the Secretariat*

Members should inform the Secretariat in writing when they are appointed of their current personal and non-personal interests and annually in response to a Secretariat request. Only the name of the company (or other body) and the nature of the interest is required; the amount of any salary, fees, shareholding, grant, etc, need not be disclosed. An interest is *current* if the member has a continuing financial involvement with the industry, eg if they hold shares in a radiation company, have a consultancy contract, or if the member or the

department to which they are responsible is in the process of carrying out work for the radiation industry. Members are asked to inform the Secretariat at the time of any change in their personal interests, and may be invited to complete a form of declaration when required. It would be sufficient if changes in non-personal interests are reported at the next annual declaration following the change. (Non-personal interests involving less than £5000 from a particular company in the previous year need not be declared.)

The register of interests should be kept up-to-date and be open to the public.

4.2 *Declaration of interests at meetings and participation by members*

Members are required to declare relevant interests at Committee meetings and to state whether they are personal or non-personal interests. The declaration should include an indication of the nature of the interest.

(a) If a member has a current (personal or non-personal) interest in the business under discussion, they will not automatically be debarred from contributing to the discussion subject to the Chairman's discretion. The Chairman will consider the nature of the business under discussion and of the interest declared (including whether it is personal or non-personal) in deciding whether it would be appropriate for the relevant member to participate in the item.

(b) If a member has an interest which is not current in the business under discussion, this need not be declared unless not to do so might be seen as concealing a relevant interest. The intention should always be that the Chairman and other members of the Committee are fully aware of relevant circumstances.

A member who is in any doubt as to whether they have an interest which should be declared, or whether to take part in the proceedings, should ask the Chairman for guidance. The Chairman has the power to determine whether or not a member with an interest shall take part in the proceedings.

If a member is aware that a matter under consideration is or may become a competitor of a product, process or service in which the member has a current personal interest, they should declare the interest in the company marketing the rival product. The member should seek the Chairman's guidance on whether to take part in the proceedings.

If the Chairman should declare a current interest of any kind, they should stand down from the chair for that item and the meeting should be conducted by the Deputy Chairman or other nominee if the Deputy Chairman is not there.

4.3 *Members' declarations of interests – 2013*

Member	Company	Personal interest	Company	Non-personal interest
Dr J Bithell		None		None
Dr P Darragh		None		None
Prof A Elliott		None		None
Prof W Evans		None		None
Prof S Hodgson		None		None
Prof P Hoskin		None		None
Dr B Howard		None		None
Prof M Kadhim		None		None
Prof S McKeown		None		None
Prof P Marsden		None		None
Dr G Maskell		None		None
Dr T Nunan		None		None
Dr M Pearce		None		None
Prof R Taylor		None		None
Mr I Robinson	AMEC	Consultancy		None
Prof R Wakeford	1 Sellafield Ltd	Consultancy		None
	2 Compensation Scheme for Radiation-linked Diseases	Consultancy		
	3 Canadian Nuclear Safety Commission	Contract		
	4 Augean	Contract		
Prof P Warwick	1 Enviras Ltd	Director and shareholder	NDA	Grants
	2 Sellafield Ltd/ Golder	Contract		
	3 NNL/LLWR Ltd	Consultancy		
Prof C West		None		None