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Measures for Optimising Radiological Information and Dose in Digital Imaging and Interventional Radiology (DIMOND III)

Introduction

The DIMOND III project has supported and contributed to many of the key areas identified in the Basic Safety Standards Directive and the Medical Exposures Directive (MED) Euratom ED97/43. The MED identifies interventional radiology and mammography as areas within the broad area of medical exposures which require particular attention. In interventional radiology and cardiology, radiation doses can be relatively high. This combined with the restenosis rate, means that some patients have multiple high dose procedures with an associated risk of potential deterministic injuries. In mammography, a population of women are irradiated, to identify a small fraction that may have breast cancer.

Justification of medical exposures is a fundamental objective of radiation protection. Various justification issues have been addressed by the DIMOND project, through the development of referral criteria and the performance of risk/benefit studies.

Within DIMOND III, various technical and clinical approaches to the optimisation of medical exposures have been developed. One simple practical approach is to stratify procedures into three image quality dose bands. This approach allows the dose to be adjusted to enable the optimisation of projection radiography using digital imaging.

Interventional radiology, cardiology and digital mammography are rapidly developing branches of minimally invasive medicine. The applications of these techniques expand as clinicians develop new techniques. These groups of examinations have a large social dimension, in that individuals who would have previously required expensive and traumatic operative procedures often requiring an extended period of hospitalization. Techniques are available which permit the individual to be treated as an outpatient. Patients understand the benefits of these techniques and demand greater access. On the other hand, the public are sceptical about the introduction of new techniques and the use of ionising radiation.

Objectives

A main objective of the DIMOND III project is to support the legislative agenda of the European Union. The DIMOND III project addresses virtually all the priorities identified at the recent meeting in Luxemburg:-

- 1) It has established quality criteria for interventional radiology and digital imaging.
- 2) Acceptability criteria for interventional and digital imaging equipment have been developed.
- 3) The application of the justification principle to a range of procedures has been considered.
- 4) Referral criteria and reference levels have been proposed.
- 5) Design criteria have been produced.
- 6) A number of training issues have been addressed.

Results

Digital projection radiology (either with phosphor plates or flat panels) will become the norm in European Radiology Departments in the near future. High image quality should be achieved at appropriate levels of patient dose, thus both parameters are in effect user selectable variables. In the absence of definitive advice there has been a tendency to use the highest available dose level. Digital imaging presents new and wide ranging challenges for the establishment of quality assurance. These challenges must be addressed if the Medical Exposures Directive is to be effectively implemented. The DIMOND III project has produced guidance which addresses these issues.

The DIMOND III project has identified various radiation protection questions associated with the introduction of new technology. For example, the quality control of digital imaging systems, hard copy devices and storage systems should be established and evaluated in clinical practice. Connectivity between x-ray systems, patient dosimetry devices, radiological information systems and picture archiving and communication systems must be addressed to facilitate on-line audit. Quality criteria established for conventional radiology are not always applicable for digital imaging and new detectors. Existing approaches have been modified and adapted for digital imaging to demonstrate their effectiveness. The DIMOND III project contributed to all these priorities as well as the effective implementation of the Medical Exposures Directive in respect of justification, optimisation, reference leads, acceptability criteria and referral criteria in an area at the forefront of radiology. These radiation protection tools will transpose to other areas of radiology.

Similar issues have arisen with the development of digital mammography. This has two main applications, the first for routine screening/imaging of symptomatic women, and the other in the assessment of suspected lesions. Whilst the former has the greater potential impact for the population of Europe, it is the latter application which will occur first. Consequently, the role of digital mammography for the assessment of breast lesions using either fine needle aspiration cytology or core biopsy has been studied. Digital stereotactic mammography

systems have been introduced into many centres. These systems facilitate the assessment of suspect mammography lesions, but have not been studied from a protection perspective. This area has many parallels with interventional radiology and demands that various research issues are addressed. Digital mammography is a new technique which offers women a better diagnosis, with less morbidity and in a shorter period of time. There are no competing techniques as such. DIMOND III has commenced the investigation of various aspects of digital mammography by developing QC tools, guidelines and clinical audits.

Clinical image quality criteria have been developed for conventional radiology, paediatric radiology and computed tomography examinations. These criteria were based on expert opinions of a group of radiologists and scientists. This approach has been adapted for digital and interventional radiology procedures. However, the transposition of image quality criteria to interventional radiology is harder because the procedures are more complex as the image display and processing procedures must be considered. In order to facilitate the development of criteria all available technologies to assist with the process have been used. Thus the circulation of hardcopy images, a CD-ROM containing clinical images and teleradiology have been used to share the information. Standard methods of assessing clinical image quality have been adapted for assessing interventional procedures. Various protocols and guidance have been developed.

The measurement of subjective and objective physical image quality parameters has been developed over a number of years. The use of noise power spectrum, modulation transfer function and information content has been successfully applied to radiological imaging devices. Most of the work was performed nearly 20 years ago on obsolete equipment. However, these general approaches to the measurement of objective indices remain valid. The existing close liaison of DIMOND III with manufacturers has enabled the acquisition of on-line data on quality criteria and dose. Various systems have been assessed using this technique in close collaboration with the manufacturers.

Subjective image quality assessment has been around for some time. Contrast detail test objects may easily be adapted for use in interventional radiology and digital mammography. This approach has been supplemented by the development of alternative fixed choice test phantoms which pose a more clinically realistic decision task to the observer. This has been used to assess digital radiology and digital mammography units.

Measurement of reference values for interventional radiology is reliant on achieving a consensus on a minimum patient dosimetry dataset. Agreement on patient dose protocols and patient dosimetry dataset has been achieved within the DIMOND III project. Connectivity between instruments, x-ray equipment and computer systems is a key issue. This has been achieved in liaison with dosimetry instrumentation manufacturers by the consensus workshop approach. Proposals for international standards have been made which are being actively discussed by the International Electrotechnical Commission.

Derivation of reference values has been a DIMOND III priority. Given the access of the consortium, this has not been a problem, except for the most infrequent of procedures.

Application of the concept of justification in interventional radiology and digital imaging has been poorly addressed in the areas of digital imaging and interventional radiology, before DIMOND III. The area has been almost bereft of any serious scientific study. Interventional radiology poses an entirely new set of questions when considering justification. Specifically,

risks (including deterministic effects) to both patients and staff have to be considered on the one hand. Whilst on the other hand there are risks from radiation, contrast media complications etc. Benefits which patients accrue relate to reduced morbidity. Very few studies have compared clinical outcomes of interventional radiology with alternative surgical approaches. This is crucial for the development of referral criteria. The problem of restenosis has been monitored. This very important social discussion must be addressed if European citizens are to be given an informed choice about alternative techniques.

Analysis of Results and Implications for Radiation Protection

Specification of equipment standards and input into standardisation policy are key European issues at both a Strategic and industrial/social level. This has been recognised by the European Medical Exposures Directive. This research project has produced tools and techniques which have influenced the standardisation process undertaken by the interventional Electrotechnical Commission. This will in turn be reflected in the European Standards agenda by European Committee for Standardization/European Committee for Electrotechnical Standardization (CEN/CENELEC).

The International Electrotechnical Commission (IEC) is in the process of drafting a number of standards relating to radiological imaging equipment. The standardisation bodies are promoting the use of detective quantum efficacy as a key parameter to assess and quantify equipment performance. Assessment tools have been field tested on a number of systems. The results of these tests are in the process of being published.

IEC has commissioned a work item regarding the standardisation of dosimetry in the Digital Communications (DICOM) header. All images in the future will contain this information. The data may be interrogated by suitable software developed within the DIMOND III consortium. The DIMOND III consortium is pressing for standards to be written so that data extraction can be simplified in the future. This is the future of patient dosimetry. Online software which can perform audits of patient doses and quality assurance is the way forward. It is anticipated that this will be the approach promoted in the future.

Europe is a leading manufacturer of x-ray equipment. Interventional radiology, cardiology, digital imaging and mammography represent large growth areas in the future. Developments in these fields are technologically driven. This project has developed a number of radiation projection tools and software which will facilitate the evaluation of new imaging techniques. Manufacturer's need to know what clinical image quality is required for a given imaging procedure.

In turn clinical image quality has to be related to inaccessible physical image quality indices, such as defective outturn efficacy. Developments in medical imaging tend to be technologically driven. Manufacturers require a close liaison with clinical users if they are to maintain their current position.

Dose and quality management in digital imaging should commence with the establishment of clear definitions and indications for the procedures. These criteria have been developed within the DIMOND III project and are based upon the methods of evidence-based medicine. The referral guidelines originally published by the EC have been adapted for use in digital imaging. Dose and hence image quality are user selectable variables. A three image quality band concept (i.e. high, medium, low) has been developed for image quality and dose

management in digital imaging. Consensus guidelines on dose/image quality have been produced which should influence clinical practice for years to come.

In summary the DIMOND project has:-

- 1) contributed to improving the quality of to life by assisting with the implementation of minimally invasive radiologically guided therapies.
- 2) supported the manufacturers and standardisation process.
- 3) underpinned the Medical Exposures Directive.

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