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THE DIMOND PROJECT AND ITS IMPACT ON RADIATION PROTECTION

K. Faulkner*
Quality Assurance Reference Centre, Unit 9 Kingfisher Way, Silverlink Business Park, Wallsend, Tyne and Wear, NE28 9ND, UK

The DIMOND III project comprised work packages and subprojects to research digital imaging, interventional radiology and interventional cardiology, i.e. areas where there has been rapid technological change, not matched by radiation protection research. Whilst new practices have great potential benefit, there are risks to patients and staff if the technology is implemented inappropriately. DIMOND aimed to develop generic technology assessment and optimisation tools. Clinical quality criteria and technical parameters were included so that digital imaging procedures can be introduced appropriately. Frequency and dimensions of acceptance and constancy testing for digital imaging systems were studied, along with differences between objective measures of image quality and subjective indices. Patient dosimetry was performed to propose and to establish reference values. Clinical evaluation projects included cardiology, interventional radiology and digital mammography. As a result of the DIMOND project, quality criteria for several procedures were developed. Example results are presented in this paper.

INTRODUCTION

The DIMOND III project supports and contributes to many of the areas identified in the recent Basic Safety Standards Directive and the Medical Exposures Directive[1,2]. The latter directive identifies interventional radiology and mammography as areas within the medical exposures field, which merit particular attention. Thus the DIMOND III project has directly addressed various justification issues that are given prominence in the Medical Exposures Directive[2]. The DIMOND III project has also developed technical and clinical approaches to the optimisation of medical exposures for digital, interventional radiology and mammography. These approaches have had a wide range of applicability and will transpose into other areas of radiology, such as computed tomography and paediatrics.

Interventional and digital radiology are rapidly developing branches of minimally invasive medicine. The applications of interventional radiology broaden as more opportunities to treat diseases on an outpatient basis are recognised and developed. Interventional radiology thus has a large social dimension, in that individuals who would have required expensive and traumatic operative procedures requiring long stays in hospitals can now be treated as outpatients. Patients' confidence in the outcome of these interventional procedures should not be allowed to be undermined because of the adverse effects (e.g. skin injuries) or concern about radiation doses. There is a need to optimise these procedures so that they can become commonplace leading to the wider availability of interventional radiology. It is hoped that these initiatives will reduce hospital waiting lists.

At present European manufacturers are world leaders in the production of X-ray equipment, contrast media and guidewires/catheters. Whilst the manufacturing of X-ray equipment may be undertaken outside of the European Union, software and information technology developments are undertaken in the Union. In a digital imaging world, it is the latter which is particularly important. The DIMOND III project has supported the position of European manufacturers on a world-stage by contributing to the standardisation process, especially with respect to the DICOM header. In rapidly evolving innovative fields such as those covered by the DIMOND III project, manufacturers need research results to base their commercial decisions on equipment and technological developments.

An objective of the DIMOND III project is to support the legislative agenda of the European Union. In addition, at a recent meeting in Luxembourg[3], an international group of experts identified various priorities. The DIMOND III project addresses virtually all of these priorities:

(1) It has established quality criteria for interventional radiology and digital imaging and thereby addresses the problem of the proliferation of inappropriate equipment for the clinical task. It ensures the citizens of Europe have access to safe, more cost-effective health care.
(2) Acceptability criteria for interventional and digital imaging equipment have been developed.
(3) The issue of justification for a wide range of digital and interventional procedures has been considered.
(4) Referral criteria have been developed.

*Corresponding author: keith.faulkner@nhs.net

(5) Reference levels have been developed.
(6) Design criteria for equipment have been produced.
(7) Various practical training issues have been addressed.

APPROACH

The precise details and actions associated with the work content of the DIMOND III project is summarised in six separate, but interlinked, work packages. In turn each comprises a series of subprojects.

The research undertaken within DIMOND III may be considered to be subdivided into two separate subgroups of projects. The first subgroup covers the basic underlying and clinical research necessary to achieve the objectives. This group comprises work packages 1–3 covering clinical quality criteria and technical parameters (WP1), physical aspects of image quality (WP2) and reference values and justification (WP3). The second subgroup of work packages is intended to bring this basic research into direct clinical practice. This group of clinical evaluation projects covers specific interventional radiology procedures (WP4), cardiology (WP5) and digital mammography (WP6).

In the first work package the development of clinical image quality criteria and technical parameters for digital radiology (including both digital diagnostic and interventional procedures) has been studied. It is a natural follow-up of the previous EC research programmes in conventional radiology. This basic research is complementary to and essential for the satisfactory completion of the clinical evaluation projects in interventional radiology, cardiology and digital mammography covered in the clinical research work packages.

The second research work package, concerning the physical aspects of image quality, is fundamental to the complete comprehensive and rigorous scientific evaluation of any digital imaging system.

Reference values may be regarded as a radiation protection tool to indicate where optimisation studies would be most useful. Any investigation in to high radiation doses must consider the two basic principles of radiation protection that apply to medical exposures (i.e. justification and optimisation). In interventional radiology the concept of justification is a complex issue and has been subject to evaluation within the DIMOND III project. Justification and patient dose evaluation in digital radiology and interventional radiology are also essential to underpin the application of radiation protection in this important field of medical exposures. Work packages 4–6 cover the application of quality assurance and the use of reference values in three specific clinical areas.

RADIATION PROTECTION IMPLICATIONS OF NEW TECHNOLOGY

Interventional radiology is a relatively new subspeciality dating back just 30 y. The progress of interventional radiology has been rapid, with many current therapies being pioneered by interventional radiologists before migrating to other clinical specialities. From the patient's perspective, interventional radiology is a minimally invasive technique, with lower morbidity, a short convalescent time and lower cost. Interventional radiology presents a number of scientific and social issues.

Specifically, many other clinical specialities other than radiology perceive these procedures as being easy to perform on almost any item of X-ray equipment. As interventional radiology migrates to other clinical specialities, where self-referrals with no overall oversight occur, then a number of radiation protection issues arise. Within the DIMOND III project there must be justification and optimisation studies have been undertaken to complement these developments. In addition, there are substantial training needs. Moreover, the risk of deterministic injuries if inappropriate equipment is injudiciously used is significant[4,5]. This demands the development of equipment specifications for interventional procedures.

Interventional radiology presents a number of challenges for the future, particularly given the introduction of direct digital detectors for fluoroscopes:

(1) There is a continuous need for improved image quality at lower doses (optimisation studies).
(2) Interventionalists continue to want to expand their techniques and wish to see smaller, lower contrast objects.
(3) There is a continuing need for improved imaging devices.
(4) Referral criteria and justification studies must match these developments.

Digital projection radiology (either with phosphor plates or with 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 a number of work packages that address 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, hardcopy 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 online 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[2] with respect to justification, optimisation, reference leads, acceptability criteria and referral criteria in an area at the forefront of radiology. These radiation protection tools are described in these proceedings and will transpose to other areas of radiology.

Similar issues have arisen with the development of digital mammography[6]. This has two main applications, the first for routine screening/imaging of symptomatic women, and the second in the assessment of suspected lesions. Whilst the former has the greater potential impact for the population of Europe, it is the latter application that 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[7]. 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. It is likely that every centre in Europe, which assesses women for breast lesions, will demand digital mammography within the next two years.

Clinical image quality criteria have been developed for conventional radiology, paediatric radiology and computed tomography examinations. These criteria were based on expert opinion of a group of radiologists and scientists. This approach has been adapted for digital and interventional radiology procedures[8]. 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[9].

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[10]. 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 online data on quality criteria and dose[11].

Subjective image quality assessments have 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[10].

Measurement of reference values for interventional radiology is reliant on achieving a consensus on a minimum patient dosimetry dataset[12]. 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[13]. 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 there are risks from radiation, contrast media complications, etc. Benefits that 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 should be monitored. This very important social discussion must be addressed if European citizens are to be given an informed choice about alternative techniques.

CONCLUSION

The DIMOND project has been particularly productive given the numerous scientific papers, a sample of which is contained in these proceedings, scientific presentations and protocols/guidelines published. The impact of DIMOND into key areas, such as the development of standards and proposals for new standards has been remarkable. Its impact at a clinical level has been important, as for example audits of practice in cardiology can be undertaken, where procedures of similar capacity may be compared. The use of the DICOM header for dose surveys leads the way in contributing to patient dosimetry. Risk/benefit studies in mammography have informed government policies[14]. These proceedings illustrate the impact of DIMOND on current and future practice.

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