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THE HISTORICAL DEVELOPMENT OF REFERENCE DOSES IN DIAGNOSTIC RADIOLOGY

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INVITED PAPER

Abstract — National surveys of patient doses from X ray examinations in Europe and the USA since the 1950s have demonstrated wide variations in doses between hospitals and the need for quantitative guidance on patient exposure. Subsequent national advice on patient protection in the USA and the UK included dosimetry protocols and reference doses in order to prompt local critical review of potentially poor practice. The concept of *investigation levels* for diagnostic medical exposures was first proposed by ICRP in its 1990 recommendations and further developed into *diagnostic reference levels* in ICRP Publication 73. At the European level, the Medical Exposure Directive of 30 June 1997 requires Member States to promote the establishment of *diagnostic reference levels* and for national regulations implementing this requirement to be in place by May 2000. Meanwhile, reference dose values have been incorporated into European Guidelines on Quality Criteria for Diagnostic Radiographic Images and for Computed Tomography and are being developed for Paediatric Radiology. The development of reference doses in Europe over the past decade is reviewed, appropriate dose quantities described and the philosophy behind the selection of suitable reference dose values discussed.

HISTORY OF PATIENT DOSE MEASUREMENTS

Measurement of the doses received by patients in diagnostic radiology did not begin in earnest until the 1950s. At that time the predominant biological effects of ionising radiation exposure were thought to be the induction of genetic effects and leukaemia. Consequently the anatomical sites which featured in national patient dose studies, such as the 'Adrian Survey'[1] in the UK, were the gonads and the red bone marrow, with testes doses being measured directly with a special design of ionisation chamber dosemeter. This was probably the first major national survey in which the very wide variation in doses to patients from the same type of X ray examination became evident. For example, as seen in Figure 1, the testes dose to individual patients was found to vary by a factor of 10,000 for lumbar spine examinations at a large sample of hospitals around the UK.

Later national surveys concentrated on measuring entrance surface doses in the centre of the X ray beam with or without backscatter for common radiographic projections. The variations in dose were not as wide as those seen for testes doses in the Adrian Survey since the dosemeters were always in the centre of the beam. However, the Nationwide Evaluation of X-ray Trends (NEXT) in the USA in the 1970s[2] measured entrance skin exposure (ESE) free-in-air for average exposure technique factors (or for a standard phantom, if automatic exposure control was used) and still found variations of a factor of 20 between hospitals in the typical ESE used. Figure 2 shows the typically wide and skewed distribution for simple antero-posterior (AP) radiographs of the abdomen.

The NRPB national patient dose survey in the UK in the 1980s[3], measured entrance surface dose (ESD) directly on the surface of the patient (including backscatter) using thermoluminescence dosemeters (TLDs). A range of a factor of 30 was observed in individual measurements and of a factor of 5 between the mean value for a representative sample of patients at 20 randomly selected hospitals, again for AP abdominal radiographs. A European trial in support of the Quality Criteria for Diagnostic Radiographic Images in 1991[4] used the same dosimetry technique and found, for example, a range of a factor of 10 between the mean ESD for each hospital, for AP lumbar spine radiographs.

One of the main reasons why such wide variability in patient doses occurred was the fact that X ray department staff did not have the means of knowing precisely what doses they were delivering to patients with the procedures and equipment which they employed. The first essential requirement to reduce this wide variability and to eliminate doses at the high end of the distribution was to provide X ray departments with a method for monitoring their performance and for identifying where corrective action was most urgently required. A set of reference or guidance dose levels for common diagnostic procedures, expressed in a manner that could be easily checked by the department staff, fulfilled this requirement.

HISTORY OF DOSE GUIDELINES

Dose guidelines began to appear in late 1980s in those countries which had extensive survey data, as indicated in Table 1. First was in the USA, promoted by the Centre for Devices and Radiological Health

(CDRH) in conjunction with the Conference of Radiation Control Program Directors Inc (CRCPD)[5]: then in the UK, led by NRPB in collaboration with the professional bodies of radiologists (RCR), radiographers (CoR) and medical physicists (IPSM)[6,7]. These initiatives were closely followed in Europe where reference doses were incorporated into Working Documents giving Quality Criteria for Diagnostic Radiographic Images for adult and paediatric patients by EC Study Groups of radiologists and physicists[8,9].

Prior to 1996 dose guidelines were referred to variously as 'exposure guides', 'guideline doses' and 'reference doses' but they were all expressed in terms of directly measurable dose quantities at the entrance surface of the patient for a few of the more common X ray projections or examinations. After these national initiatives, international recommendations appeared which progressively provided more detailed advice on how to measure and set reference dose levels, but they basically followd the concepts pioneered in the USA and the UK. The most complete current international recommendations on *diagnostic reference levels* as they are now called, are to be found in ICRP Publication 73[10] and in the EC Medical Exposure Directive of 30 June 1997[11], the latter requiring Member States to promote the establishment of *diagnostic reference levels* and for national regulations implementing this requirement to be in place by May 2000. These documents provide some, but not complete, guidance on the two important fundamental issues concerning diagnostic reference

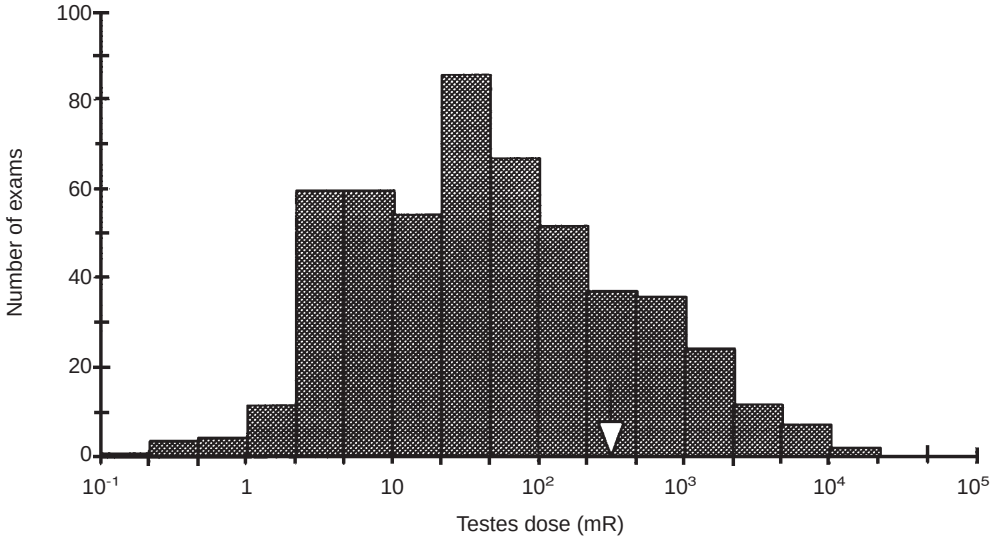

Figure 1. Distribution of testes doses for lumbar spine examination seen in UK Adrian survey in 1950s (note logarithmic scale).

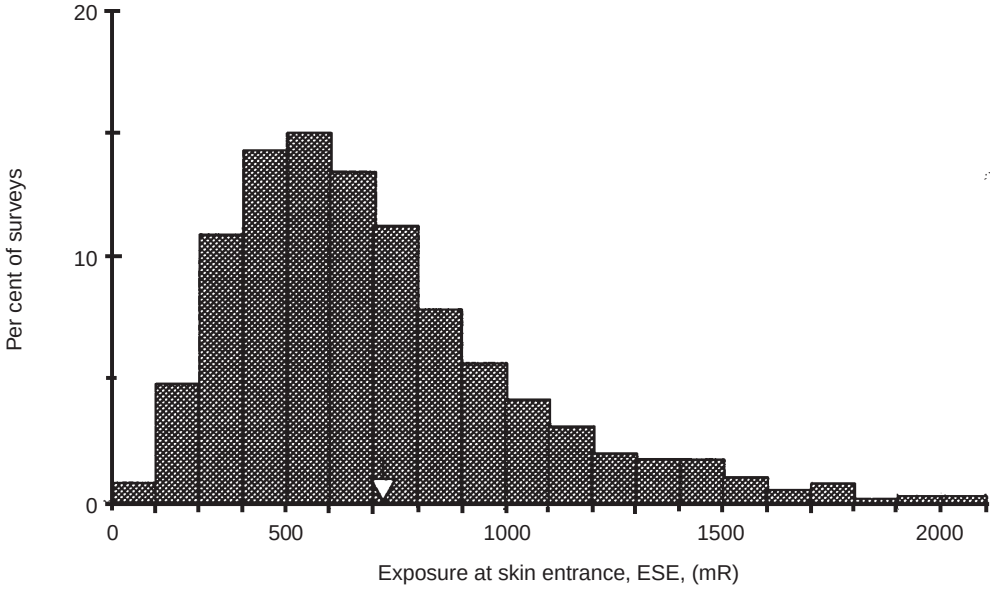

Figure 2. Distribution of entrance skin exposure for AP abdomen seen in USA NEXT survey in 1970s.

levels: which dose quantities should be measured and how should the reference levels be set?

APPROPRIATE DOSE QUANTITIES AND TECHNIQUES

To achieve widespread use, diagnostic reference dose quantities need to be unambiguously defined and easily measured with readily available dosemeters of sufficient precision and accuracy. They should provide a measurement of the typical dose received by patients examined in a particular facility from either a particular type of individual radiograph or a particular type of complete X ray examination.

ICRP Publication 73 recommends that 'diagnostic reference levels apply to an easily measured quantity, usually the absorbed dose in air, or in a tissue-equivalent material at the surface of a simple standard phantom or representative patient. They should be related only to common types of diagnostic examination and to broadly defined types of equipment.' The 1997 EC Medical Exposure Directive reinforces the concept of reference dose applying only to 'standard' or 'representative' patients by saying 'diagnostic reference levels are dose levels for typical examinations for groups of standard sized patients or standard phantoms, for broadly defined types of equipment'.

Not surprisingly, these recommendations encompass the protocols already established in the USA, UK and Europe. However, the 'absorbed dose at the surface of a standard phantom or patient' requires more precise definition. In the USA the exposure (R) at the skin entrance (ESE) measured free-in-air in front of a standard phantom was the quantity used. In the UK the entrance surface dose (ESD) including backscattered radiation, which increases the free-in-air dose by up to 40%, was preferred since it can be readily measured on actual patients using TLDs without obscuring the image. The UK *National Protocol for Patient Dose Measurements in Diagnostic Radiology*[7] describes methods for monitoring patient doses from routine X ray examinations which can easily be carried out by radiographers with advice and assistance from medical physicists. The recommended dose quantities are Entrance Surface Dose (ESD) for individual radiographs and the Dose-Area Product (DAP) for complete examinations. ESD can be directly measured with TLDs or estimated from X ray tube output measurements made during routine quality assurance tests as long as an appropriate backscatter factor is applied. DAP is conveniently measured with a specially designed ionisation chamber DAP meter which can be attached to the X ray tube diaphragm housing. The total DAP from a complete examination, even when it involves fluoroscopy as well as radiography, can be accumulated by the DAP meter and compared with the appropriate reference level. This provides a measure of the degree of patient protection afforded both by the imaging equipment and the examination procedures (e.g. collimation, number of images taken, duration of fluoroscopy, etc.) that are adopted in a particular facility.

Since doses are critically dependent on patient size, it is recommended that measurements be made on a representative sample of about 10 patients with mean weight close to 70 kg. The average dose to such a sample for each particular type of radiograph or examination should provide a good indication of typical clinical practice in each room of an X ray department. The average doses can then be compared with national reference doses to assess local performance.

The European Quality Criteria documents (now published as updated Guidelines[12,13]) also recommend using the average ESD measured on a representative sample of patients for common types of radiograph. Different dose quantities are needed for CT where the exposure conditions are quite different from those in conventional radiography. Patient doses from CT examinations are relatively high, making the establishment of

Table 1. History of dose guidelines for medical exposures.

	Professional/ Advisory bodies	Nomenclature
USA		
1985	CDRH	Technique/exposure guides
1988	CRCPD	Average patient exposure guides
UK		
1990	NRPB/RCR	Guideline reference doses
1992	IPSM/CoR/NRPB	Reference doses
Europe		
1990–97	EC Study Group	Quality Criteria
1997	EC Directive	Diagnostic reference levels
The world		
1990	ICRP 60	Investigation levels
1994	IAEA BSS	Guidance levels
1996	ICRP 73	Diagnostic reference levels

diagnostic reference levels for CT particularly important. The paper by Shrimpton *et al* in these proceedings[14] describes the latest EC guidelines for CT reference doses using a weighted CT Dose Index ($CTDI_w$) and a Dose-Length Product (DLP) analogous to DAP for conventional X rays.

Both ICRP Publication 73 and the EC Medical Exposure Directive recommend that diagnostic reference levels in nuclear medicine should be expressed in terms of the quantity 'administered activity'. The only published reference levels for common nuclear medicine procedures at the present time appear in the IAEA *et al* Basic Safety Standards[15] as *Guidance Levels*, based largely on the 'maximum usual activities' (MUAs) quoted by the UK Administration of Radioactive Substances Advisory Committee (ARSAC)[16]. However, the derivation and purpose of these MUAs has not been formally established and they have not been officially recognised as diagnostic reference levels in the UK.

PHILOSOPHY BEHIND THE SELECTION OF REFERENCE VALUES

The method for selecting reference dose values depends critically on a clear understanding of their intended purpose. Both the ICRP recommendations and the Medical Exposure Directive state that reference doses are intended to act as *investigation levels* triggering a local investigation if the typical dose for a specific type of diagnostic procedure is found consistently to exceed the relevant reference level. Unless this can be justified by sound clinical judgement, appropriate corrective action should be taken to improve practice; this could involve changes in procedures or equipment to reduce doses to below the reference level without compromising the quality of the diagnostic information. Essentially, diagnostic reference levels act as a simple test for identifying situations where patient doses are becoming unusually high and action is most urgently required. With this function in mind, they should not be set at an 'optimum' or 'minimum achievable' level but more at the borderline between acceptable and unacceptable practice. A pragmatic way of setting this level, and one which has been adopted in the earlier USA exposure guides and in the UK and European protocols, is to use the third quartile values observed in widescale surveys of typical doses for common procedures.

Indeed, ICRP Publication 73 recommends that '...initial values (be chosen) as a percentile point on the observed distribution of dose to patients. The values should be selected by professional medical bodies and reviewed at intervals that represent a compromise between the necessary stability and the long-term changes in the observed dose distributions.' Tables 2 and 3 show the current UK national reference dose values of ESD per radiograph and DAP per examination for standard adult patients based on rounded values of the third quartile of the distributions of mean hospital doses seen in the NRPB national survey of the 1980s. The same ESD reference dose values appear in the *European Guidelines on Quality Criteria for Diagnostic Radiographic Images*[12] since the 1991 European trial[4] showed similar mean dose distributions to the 1980s UK survey. Different reference levels are required for paediatric radiology due to the large differences in size between neonates and adolescents. A system of age/size-related reference doses is being developed by an EC Study Group as discussed in the paper by Schneider *et al* in these proceedings[17].

Table 2. Reference values of entrance surface dose per radiograph.

Radiograph		Reference entrance surface dose (mGy)
Lumbar spine	AP	10
	Lat	30
	LSJ	40
Abdomen	AP	10
Pelvis	AP	10
Chest	PA	0.3
	Lat	1.5
Skull	AP	5
	PA	5
	Lat	3

CURRENT DEVELOPMENTS

Periodic monitoring of patient doses following the national protocol[7] has become widespread throughout the UK with hospital physicists sending the results of their local surveys to NRPB for national collation. By the end of 1995 the national patient dose database contained the results of over 50,000 patient dose measurements made at 375 hospitals. A review of these data by NRPB[18] revealed that, by then, only about 10% of hospitals were exceeding the reference doses for common conventional X ray examinations and that the mean

Table 3. Reference values of dose-area product per examination.

Examination	Reference dose-area product ($Gy.cm^2$)
Lumbar spine	15
Barium enema	60
Barium meal	25
Intravenous urography	40
Abdomen	8
Pelvis	5

and third quartile values of the dose distributions had dropped by about 30% since the earlier national survey in the 1980s. This could be regarded as clear evidence of the successful implementation of recommendations on patient dose reduction over the past few years, encouraged by the heightened awareness of patient doses through widespread periodic dose monitoring and comparison with national reference levels. However, although the distributions of typical doses have shifted downwards, the variability between hospitals remains as high as before, indicating a continuing need for (perhaps lower) reference doses to help identify and bring more into line those hospitals at the top end of the dose range. Some UK X ray departments are already using the more recent survey data to set lower reference doses for local use. The national levels have, so far, remained unchanged but are under review by NRPB and representatives of the professional bodies in radiology in the UK, within the further development of a general framework for quantitative guidance on patient doses.

Proposals for national reference doses in some other European countries appear in these proceedings and are listed in Table 4. The dose quantities used in each proposal are indicated and are mostly the easily measured quantities discussed above with the exception of The Netherlands where image intensifier and phantom entrance dose rates are advocated for interventional fluoroscopic procedures and effective dose for all types of X ray examination including CT and paediatric radiology. Moreover, not all these proposals are following the concept of using 3rd quartile values of widespread surveys as the basis for an 'investigation level'. The concept used is not always apparent but some appear to be re-defining the purpose of diagnostic reference levels as a guide to optimum performance or minimum achievable doses compatible with the diagnostic need, rather than as a simple means of identifying those situations well away from the optimum where corrective action is most urgently needed. This is probably the next sensible step to be taken in the development of patient dose guidelines in diagnostic radiology, but to avoid confusion with the already well established concept of 'reference dose' as an investigation level, it might be better to give such guides to optimum performance a different name.

Table 4. New national reference dose proposals at this Workshop.

Country	Author	Quantities	Concept
Germany	Bernhardt	ESD, ESAK, DAP DLP (CT)	3rd quartile
Netherlands	Gelijns	Dose rate (fluoro.)	?
Netherlands	Zoetelief	Effective dose	?
Sweden	Leitz	?	Optimum
Nordic	Saxebol	ESD, DAP	?
Europe	Shrimpton	$CTDI_w$, DLP (CT)	3rd quartile
IEC	Leitz	?	Diagnostic need

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