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Justification of diagnostic medical exposures: some practical issues. Report of an International Atomic Energy Agency Consultation

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Objectives: The Radiation Protection of Patients Unit of the International Atomic Energy Agency (IAEA) is concerned about the effectiveness of justification of diagnostic medical exposures. Recent published work and the report of an initial IAEA consultation in the area gave grounds for such concerns. There is a significant level of inappropriate usage, and, in some cases, a poor level of awareness of dose and risk among some key groups involved. This article aims to address this.
Methods: The IAEA convened a second group of experts in November 2008 to review practical and achievable actions that might lead to more effective justification.
Results: This report summarises the matters that this group considered and the outcome of their deliberations. There is a need for improved communication, both within professions and between professionals on one hand, and between professionals and the patients/public on the other. Coupled with this, the issue of consent to imaging procedures was revisited. The need for good evidence-based referral guidelines or criteria of acceptability was emphasised, as was the need for their global adaptation and dissemination.
Conclusion: Clinical audit was regarded as a key tool in ensuring that justification becomes an effective, transparent and accountable part of normal radiological practice. In summary, justification would be facilitated by the ''3 As'': awareness, appropriateness and audit.

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Radiation protection in medicine is underpinned by the concepts of justification and optimisation. Over the past 20 years much successful work has been devoted to developing and consolidating approaches to optimisation. There is now an extensive knowledge base and wide range of practical approaches to support its implementation [1–3].

Less effort has been committed to justification. This is not surprising, as historically it has not been seen as a problem. Radiology has been very successful in overseeing and delivering into the healthcare system a technology transfer of exceptional proportions in a relatively short time. However, recently, the extent of use of radiology has become a matter of concern for many reasons, including population dose, individual dose, budgetary and financial issues, and finally the appropriateness of the examinations or justification [4–9]. These are not all dealt with here; rather, the focus is primarily on justification. It is of interest that authoritative sources suggest that a significant fraction (20–50% in some areas) of radiological examinations may be inappropriate [10–12]. Also, experience and the published literature suggest that, in clinical settings, both referring and radiological medical practitioners often have limited awareness of the actual doses and risks involved. For example, a number of publications have identified that few practitioners from these areas are familiar with the units used to specify the amount of radiation (and risk) received [4, 13–15]. In these circumstances, it is hardly surprising that patients frequently do not know, or are confused about, the risks involved [10, 16]. This is unlikely to continue to be

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This report presents the consensus of the views of the group of experts who were invited to take part in the IAEA Consultation on Justification of Diagnostic Medical Exposures: Some Practical Issues, held in Vienna on 10–14 November 2008. It is published to provide information to those who are interested and to stimulate feedback on these views.

acceptable, where imaging patients can routinely receive doses that are large compared with occupational exposures, and the focus of much radiation protection has shifted from workers to patients [14, 15]. These developments are happening against a background of worryingly increasing medical radiation doses, with the American College of Radiology (ACR) White Paper noting [8, 9]:

> The rapid growth of CT and certain nuclear medicine studies may result in an increased incidence of radiation-related cancer in the not-too-distant future.

Added to the above, the report of a consultation held by the IAEA in Vienna in December 2007, dealing with the nature of justification, was illuminating [4]. It particularly emphasised the need to be aware of the patient and his or her wishes in the justification process. The consultation achieved progress in identifying achievable pathways to effective justification. Its deliberations have implications for many aspects of medical irradiation. However, much more work will be necessary to develop practical, accountable and transparent approaches to implementation of justification. To take these forward, a number of additional initiatives are necessary [14, 15]. These include a consultation on practical arrangements that can improve implementation of justification in the day-to-day practice of hospitals and clinics throughout the world.

Practical issues identified in terms of reference

This consultation concerned itself with three practical issues that are key to the effective implementation of justification. They are the means of ensuring that those referred for radiological examinations really need them; the audit of the effectiveness of the referral and related processes; and finally devising means of effectively communicating about radiation risk to patients, physicians, surgeons, allied professionals and, of course, the radiologists who are generally responsible for performing them.

Ensuring that those referred for radiological examinations need them

A method of helping to ensure that patients are referred for procedures that are appropriate is to use referral (or appropriateness) guidelines, such as those issued by the Royal College of Radiologists in the UK [17], the ACR [18], European Commission the (EC) [19] and others. In Europe, such guidelines are required by the Medical Exposures Directive (MED), which specifies that Member States must ensure that referral criteria, including radiation doses, are available for medical exposures [20].

Some unsatisfactory aspects of referral patterns were noted in the report on the 2007 consultation, including self-presentation and self-referral (Appendix A), some types of screening programme, referrals arising from social, economic, legal and medicolegal or political pressures [4, 21, 22]. The level of uptake, use and effectiveness of referral guidelines is highly variable throughout the countries that have produced them and elsewhere in the world. This is an area requiring much more attention and the development of strong local evidence bases.

Clinical audit of the effectiveness of the referral and related processes

Within modern evidence-based medicine, clinical audit is a key component in all disciplines, but has not been widely accepted in diagnostic radiology. Notwithstanding this, there have been significant initiatives in the area. For example, the MED requires that clinical audits be carried out with respect to the procedures performed. Currently, processes of developing guidelines for clinical audit and useful tools for audit of radiology are becoming available [23–25]. These have excellent scope with respect to various aspects of optimisation, dosimetry and quality assurance programmes, and can provide a framework for audit of justification. The limited evidence available indicates that audit of compliance with guidelines can be a simple and effective tool for improving referral patterns [26]. There is also anecdotal evidence that a more rigorous regulatory approach may contribute to improving practice when it is out of step with socially acceptable values.

Clinical audit of justification in radiology and nuclear medicine should be part of ongoing continuous quality improvement activities. Audits may be internal or external and will share many features and data sets with other activities, such as accreditation and professional inspections. Its value includes reassurance of patients, the public, regulators and legislators. Equally important, it gives those being audited confidence that their work is appropriate, and often excellent. Where it is not so, audit provides an incentive and information to facilitate improvement.

Effectively communicating about radiation risk

With many (but not all) procedures utilising ionising radiation, the benefits are clear and well established and, to date, are generally well accepted within the medical profession and by society at large [4, 27]. When a procedure that uses radiation is proposed, the anticipated benefits to the management of the patient are almost always identifiable and are sometimes quantifiable. On the other hand, the risks of adverse consequences are often difficult to estimate, require statistical techniques to infer, and may be difficult to quantify and communicate. In its 1990 and 2007 recommendations, the International Commission on Radiological Protection (ICRP) stated as a principle of justification that ''Any decision that alters the radiation exposure situation should do more good than harm'' [28, 29]. The report on the IAEA 2007 Justification Consultation states that the ''good'' (*i.e.* the benefits) should substantially outweigh the risks that may be incurred, in part because of the uncertainty of the risks [4]. This consultation recognised that successive approaches to communication of radiation risks to various groups, including patients, practising physicians and surgeons, radiologists and allied professionals, have not been particularly effective

[4, 30, 31]. The importance of a more effective approach in this regard has been given additional weight by recent communications and debate both in the specialist medical literature and in the public press. While communication about risk is central to the above problems, the manner in which communication with patients and between professionals is undertaken is important also.

Concerns about risk and its communication have been a major preoccupation of this consultation. Patients and professionals need trusted sources of information to be clearly communicated. In some parts of the world, it is clear from press reports that, both in medicine and in the radiation/nuclear industries, there may be an overhead of distrust. This can require a proactive approach to communicating information and matters of fact, so that both the public and the professions can reach good decisions in the interests of healthcare. Reaction to advice about risk depends on whether the person trusts the source and whether or not it is conveyed in terms which are relevant to the rest of the life of the recipient [32, 33]. Thus, the importance of knowledgeable and skilful communication with both patients and healthcare professionals cannot be overestimated. Good communication will be damaged by use of arcane or politically correct scientific and medical language, which tends to hide or obfuscate issues and meaning [34] (the term ''subprime lending'' is a good example of a term that hides meaning). These issues are raised and discussed here, and were more fully addressed at the joint European Commission (EC)/IAEA Justification Workshop held in Brussels [35].

Objectives and scope

The scope of the consultation from which this publication derives included:

- all aspects of diagnostic and interventional radiology using ionising radiation
- diagnostic imaging examinations in nuclear medicine.

It excludes non-medical human exposures (*e.g.* medico-legal exposures, age determination exposures, defensive medicine exposures, security and crime detection exposures etc., and detailed consideration of screening programmes, self-presentation or self-referral; medical exposures are defined in Appendix A). Within the defined scope, the terms of reference were to evaluate and make recommendations for activities in respect of:

- existing approaches to communication with patients and professional groups with a view to better disseminating information and improving understanding of the risks involved
- the development of referral/acceptability criteria and the nature/extent of their application in diagnostic medical procedures
- alternative approaches where referral/acceptability criteria may not be effective
- approaches to clinical audit which are likely to be effective in improving compliance with the requirements for justification.

The report is divided into the major sections dealing with the background to the IAEA consultations on justification, communication issues and tools for implementing justification, including referral guidelines and clinical audit. Conclusions and recommendations are summarised towards the end.

Background to justification consultations

The consultants' recommendations are made in light of some background issues that were discussed at length. These include the ICRP definitions of justification, related social trends in the practice of medicine as noted in the SENTINEL project and elsewhere, the culture of professions and some of the more significant difficulties with the present approaches to justification.

Justification and the ICRP definition

The ICRP identifies justification as one of the cornerstones of radiation protection in medicine [5, 6, 16, 28, 29]. In medicine, justification has well-accepted differences from other situations where it is also important (*e.g.* in a nuclear power plant or industrial radiography). These differences include the following:

- the process of justification is evaluated with each individual (*i.e.* each patient)
- the consent of the individual is required for each and every radiation procedure
- exposures are not subject to regulatory dose limits.

These differences acknowledge that medical exposures are used to help manage the patient and that the justification process ensures that the benefits to the patient substantially outweigh any short- or long-term risks that the patient may incur. In medicine, the ICRP notes that there are three levels at which justification operates [4, 27, 28]. The following definitions and comments summarise ICRP's exposition of this area.

Level 1: Justification of use of radiation in medicine

At the first and most general level, the use of radiation in medicine is accepted as doing more good than harm. Its overall justification is taken for granted.

Level 2: Justification of a defined radiological procedure

At the second level, a specified procedure with a specified objective is defined and justified (*e.g.* chest radiographs for patients showing relevant symptoms). The aim of the second level of justification is to judge whether the radiological procedure will improve diagnosis or provide necessary management information for the benefit of those exposed. A summary of the ICRP exposition of Level 2 justification, based on [27, 28], is as follows. The justification of the radiological procedure is a matter for national professional bodies, in conjunction with national health authorities and with national radiological protection regulatory authorities. It should be noted that the justification of a medical procedure does

not necessarily lead to the same choice of the best procedure in all situations. Thus, the justification for routine radiological screening for some types of cancer will depend on the national incidence and on the availability of effective treatment for detected cases. National variations are to be expected. The possibility of accidental or unintended exposures should also be considered. The decisions should be reviewed from time to time, as more information becomes available about the risks and effectiveness of the existing procedure and about new procedures. The justification of investigations for which the benefit to the patient is not the primary objective is problematic and is treated extensively elsewhere.

Level 3: Justification of a procedure for an individual patient

At the third level, the application of the procedure to an individual patient must be justified (*i.e.* the particular application should be judged to do more good than harm to the individual patient). Hence, all individual medical exposures should be justified in advance, taking into account the specific objectives of the exposure and the characteristics of the individual involved. A summary of the ICRP exposition of Level 2 justification, based on [27, 28], is as follows. Beyond checking that the required information is not already available, no additional justification is needed for the application of a simple diagnostic procedure to an individual patient with the symptoms or indications for which the procedure has already been justified in general. For complex diagnostic and fluoroscopically guided interventional procedures (*e.g.* some cardiac and neurological procedures), the second level of justification may not be sufficient. Individual justification by the practitioner and the referring physician (the third level) is then even more important and should take account of all the available information. The ICRP provides further discussion of both levels [27]. In undertaking justification exercises, it is important to note that the ICRP advises that the total benefits from a medical procedure include not only the direct health benefits to the patient but also the benefits to the patient's family and to society. Perhaps more controversially, it also suggests that the doses to staff and the public should be taken into account when reckoning the detriment. At Level 3 this could be viewed as being inconsistent with longstanding medical practice.

In practice, the second and third levels of justification are those that come into play in the day-to-day operation of diagnostic imaging, and are the main concerns of this document. However, the term can also take on additional sociopolitical meanings [4, 30, 31]. This report focuses on the two ICRP levels, but it occasionally uses justification in a broader sense.

Related social trends in the practice of medicine

As noted in the SENTINEL project, the social context for the practice of medicine has radically altered in recent decades [5, 6, 30, 31]. Some of these changes have a profound impact on how justification is or can be implemented. For example, the view of the person in general, and more specifically in a medicolegal context, can greatly affect how justification might be implemented. Likewise, the prevailing consumerist culture and media-driven aspects of society have a bearing.

In terms of the view of the person, there is now a high level of consensus in most political, social and legal systems respecting the dignity of individuals, their autonomy and their right to respect [4, 30, 31]. Where this has been recently tested in the courts, judges tend to favour tests of reasonableness based on the concept of the ''reasonable person'' rather than the ''reasonable doctor'' [36–38]. These decisions, and the general social consensus on the view of the person, give a high level of authority to the opinions and wishes of the individual. This, in turn, raises the requirement for consent to a more demanding level. This trend underlines the move, in some countries, towards removing from medicine its privileged position with regard to self-regulation. In the UK, for example, the medical profession no longer enjoys a majority of the membership of its statutory regulatory body, the General Medical Council [39]. This trend is also evident elsewhere and in other aspects of public behaviour [40].

Another feature of the social context of medicine and radiology is the extent to which medicine is adopting a consumerist approach. This is frequently encouraged by governments, industry and the professions. Medical tourism is now commonplace in many holiday locations. In radiology, the growth throughout the world of clinics is widespread; the feeling among ''customers'' of these clinics may be that, if they want an examination, they should be allowed to have it. This feeling is encouraged by promotional websites, leaflets, brochures and related materials from clinics. Arising from this, two types of patient referral or presentation, not traditionally encountered in radiology, now occur (see Appendix A):

- Patients may refer themselves for a procedure and appeal to a radiology service to have it undertaken. This is referred to as self-presentation.
- A physician (*e.g.* a cardiologist) who has radiological facilities within his/her own clinic may perform a procedure on a patient instead of referring on to a third party, such as a radiologist. This is referred to as self-referral.

Both tend to increase the use of ionising radiation over and above that which prevails in the traditional approach, which involves referral by a medical practitioner to a third party such as a radiologist. In practice, the service provider can inadvertently, or otherwise, be diverted from his main focus, *i.e.* the well-being of the recipient. In particular, financial interest in maximising use of a clinic's resources may interfere with an objective risk–benefit evaluation. When a physician has such a financial interest, it should be disclosed to the patient [4].

Implementation of good justification practice is important for the individual patient, and also has an important societal dimension. In the case of the individual, it will result in examinations which are appropriate to his/her presenting features, circumstances and wishes. In addition, it will dramatically reduce individual doses through the elimination of unnecessary or inappropriate examinations. In the case of its social impact, it may reduce the unnecessary medical radiation burden to the population where this is becoming a matter for concern.

Equally important, it will have the effect of removing unnecessary work from departments and services that are often already hard pressed. The consultation group was of the opinion that the net outcome could be the reduction of waiting lists and improvement of patient access. Some members of the group speculated that the effect of eliminating unnecessary and inappropriate referrals might be that waiting lists could be eliminated.

Culture of professions

In the nineteenth and early twentieth centuries, anthropologists commonly visited ''newly discovered'' countries and/or tribes and reported on the ways of life and the different cultures they encountered. This approach has been extended to subgroups of Western society by social scientists, ethnographers and anthropologists [41, 42]. Studies of the way of life and culture of disadvantaged subgroups are commonly described. However, a similar methodology can be applied to any identifiable group to expose the culture out of which it operates. The group might be, for example, clerics, doctors, software workers or other professions, including radiation protection specialists.

In studies of this type, use of the term culture is not limited to some aspects of the arts. Wilson [43], cited by Malone [31], in a study of the decline of a highly identifiable group (clergymen), describes culture in this sense as follows:

> [It] involves very concrete patterns of behaviour and ways of thinking that give shape to a particular body of people – whether we can put names on those features or not. … It has its shape because of a deep and commonly held set of standards and expectations which come to expression in the behaviours of the collection of players.
>
> Living out a culture, with its innumerable assumptions and expectations, inevitably evokes in us a challenge when we come face to face with persons operating in a different one: we find it difficult to understand their behaviour because we don't know where it is coming from. …
>
> The expected attitudes and behaviours of [those involved in] a particular culture can be so powerful that it becomes all but impossible for its members to even conceive of other ways of being.
>
> Finally, cultures cling to existence tenaciously, for [several] reasons …. The first lies precisely in the fact that much of their causation is unacknowledged. … For the individual who risks acting out a different paradigm, the cost in terms of rejection by the players who want to continue with the reassuring story may be high.

It is clear that these characteristics can be applied to many groups, including doctors, health professionals, radiation protection professionals and the general public. Each group has, to some extent, the characteristics described by Wilson and many other workers in the area [31, 41, 42]. The individual, while functioning as a member of the group, will adopt the norms and approaches of the group, *i.e.* will live according to the culture of the group. The present approach to dealing with justification in radiology is clearly part of the culture of the groups involved. While this has many commendable features, it is at least arguable that parts of this culture might be unacceptable to other groups in society—particularly the courts, the general public, politicians and most of all patients—were these groups to subject the culture to critical examination. Divergences of cultures of this type can be at the heart of the lack of trust of the medical profession that has become prominent in some countries.

Reasons for problems with the existing approach to justification

The reasons why the principle of justification is not more successfully applied in diagnostic radiology and nuclear medicine at present include [44]:

- a historical legacy of inadequate methodology inherited from an era of much lower frequency of patient examination in radiology
- carrying forward practices of justification appropriate to an era of much lower dose examinations;
- a feeling among many professionals that there is little practical action that can be taken to improve the situation
- a failure to recognise and adjust to important aspects of social, ethical and other changes (*e.g.* continuing a paternalistic approach to justification)
- the widespread use of radiology for the purpose of defensive medicine, even when it will be of little or no benefit to the patient
- economic and political drivers favouring continuation of weak justification (including target-driven processes, clinical pathways, self-referrals, reimbursement patterns and financial models for the development of radiological services)
- consumerist trends in the patterns of use and referral for radiological services
- the inertia arising from the culture of professions
- significant and systematic communication failures between healthcare professionals, and between healthcare professionals and both patients and public (in common with other areas of medicine) over a long period.

While these factors are all understandable, it is not justifiable to continue to expose patients to the consequences of unnecessary risks.

Communication and awareness issues

Intuitively, it seems appropriate that both the referring and the radiological medical practitioners share different aspects of the responsibility for justification (Appendix A). It also, and this is frequently neglected, requires participation of the patient. As patients normally do not know the risks, individual justification requires an explanation of the benefits and the risks of the investigation as part of the informed consent process. This will prove problematic in practice when, as noted elsewhere, physicians (referring medical practitioners) and radiologists, cardiologists and others (radiological

medical practitioners) lack knowledge and awareness of the risks. Recent studies indicate that less than 50% of physicians in two well-established teaching centres were aware of the referral guidelines for many common examinations, and few if any doctors in another study were aware of the doses and risks involved. Most underestimated dose and risk from CT scans. This pattern is generally reproduced when studies are performed [8, 13, 30, 31, 45–47].

Active participation of the patient requires knowledgeable doctors and healthcare professionals. They must assist the patient in balancing the immediate risks of their presenting condition against the long-term risk of the radiation dose involved in the procedure that they are being advised to undergo. Ensuring that this is effective requires a team approach to the communication difficulties involved, with a view to ensuring good justification practice. For success, from the patient's point of view, it is essential that the team be conscious of the great power imbalance that prevails between them and the patient in these transactions.

The view of justification taken in the first IAEA consultation report was that the ''good'' (*i.e.* the benefits) should substantially outweigh any risks that may be incurred, in part because of the uncertainty of the risks [4]. The framework for justification and related communication should be constructed so that this is the case, provided that the indication is appropriate. Effective communication will assist risk management and will improve perception of the long-term risks, and thereby lead to a healthy and reassuring view of appropriateness among both patients and health professionals.

Good communication should be facilitated by picture archiving and communication systems (PACS) and radiology information systems (RIS), in which due consideration is given to justification, communication and audit of both, in electronic requesting of investigations from the introduction of such systems.

The current position and clinical, ethical and legal requirements

Research has demonstrated a high rate of inappropriate or unnecessary examinations (figures range from 20% to 77%), even for those examinations with a high effective dose [10–12, 17, 48, 49]. There is also the low awareness of dose–risk on the part of patients and clinicians, as noted elsewhere. Consequently, there is, frequently, little or no mention of radiation risk, or the approach adopted provides little information. This is complicated by the fact that the units used to quantify radiation exposure, effective dose and risk are specialised, complex and have an arcane quality that renders them unsuitable to effective communication with the public and health professionals. Many now feel that, although they are scientifically correct within the culture of the professions, their net impact is to hide or obfuscate the issues involved [34]. This problem is at its most extreme for patients in radiology. Nuclear medicine patients usually fare somewhat better. Many nuclear medicine services also have a well-developed system, including leaflets and explanations, for the provision of information to patients and third parties, such as comforters/carers and members of the public.

Thus, the current situation is one in which communication is incomplete and/or unsuccessful. Simple matters of fact are not transmitted in an effective, enduring way to those who need to know them and have confidence in them. There is practically no worthwhile nuanced dialogue on balancing benefits and risks with patients whose perceptions and requirements must surely, on many occasions, contribute to and alter the equation. This situation, inevitably and with time, will undermine the social acceptability of justification as it is presently practised, and needs to be remedied.

When the appropriate investigation involves ionising radiation, the clinical risk–benefit assessment should include the long-term risk of malignancy. Patients have the right to know of this risk, and physicians have the duty to inform them. Physicians must empower their patients to make informed decisions about their treatment [50]. In practice, achieving this will require the development of new operational approaches. However, especially with high-dose procedures, this will be best facilitated by open discussion and shared decision-making [51].

The need to obtain the patient's consent is underpinned in a number of legal instruments and many judicial decisions [52]. It is now a feature of most legal systems to encourage and enable patients to make decisions for themselves about matters that intimately affect their own lives and bodies. [The present draft of the revised IAEA Basic Safety Standards (BSS) requires that a procedure not be carried out unless ''The patient has been informed, as appropriate, of the potential benefit of the radiological procedure as well as radiation risks.'']

In this connection, the trend in evaluating if a process to obtain consent is reasonable is towards disclosure of information based on a ''reasonable patient test''. This bases judgment on what a ''reasonable person in the patient's position'' would want to know. Obviously this could differ sharply from what a ''reasonable physician'' thinks a patient should or might want to know. This is notably different from earlier legal approaches, which tended to work on the ''doctor knows best'' approach.

Finally, there are many special situations, some already mentioned, such as pregnancy or self-presentation/referral. The particular requirements of these situations will not be addressed here, but will be taken up elsewhere in due course.

Template for effective communication of risk

The requirements for good and effective communication of information involve:

- due attention being paid to previous examinations and their relationship with this one
- information normally being provided to the patient, in advance, to allow for assimilation and afford an opportunity for questions; preparatory leaflets may help
- use of clear, straightforward language, with tables or illustrations, as appropriate
- a consistent, clear, non-technical approach to presenting the dose and risk
- avoiding arcane scientific and medical jargon
- the message being presented in a form that is likely to be understood by patients/physicians

- information to patients being provided by a person (or means) the patient is likely to find trustworthy; thus, the person(s) entrusted with communication roles will need knowledge of the procedure, training and experience in effective communication, and the capacity to relate to patients' needs
- recognition that amplification of risk occurs, and is to be expected, particularly in respect of radiation
- appreciation of the wider social context of the understanding of risk—use of other familiar risks (*e.g.* smoking, air travel, driving etc.) as comparators
- due regard for experience in other fields of medicine, particularly public health, and the findings of the social and behavioural sciences, with respect to effective communication.

Figure 1 and Table 1 provide approaches to communication of dose and risk that have been developed by Picano [14, 15] and by the Royal College of Radiologists (RCR) in the UK, respectively [17]. They provide alternatives to the arcane and impenetrable approaches commonly used. The ''mSv'' is still present in the RCR approach, although Picano found it possible to present the matter without recourse to it. The RCR expression of dose in terms of chest radiographs, or equivalent periods of natural background radiation, has advantages in contextualising the amount of dose involved in terms of experience that most patients and health professionals easily relate to. Some radiologists have objected to the use of the chest radiograph scale in situations when it exceeds several hundred. However, this may not be all bad as it may encourage a more considered use of CT.

Likewise, the manner in which the risk of fatal and non-fatal cancer is expressed should be simplified and be consistent. It should preferably be expressed as the lifetime additional risk of cancer per investigation in the format of 1 in *X*. There should not be changes in the denominator, or the way in which risk is expressed (*e.g.* as fractions, percentage values or probabilities). Figure 1 and Table 1 are used to illustrate this approach. The values presented were calculated by reference to BEIR VII (Seventh Report on Biological Effects of Ionizing Radiation) [56] for the main patient subsets, *i.e.* male and female adults, children under the age of 15 years and the elderly. Some workers also value comparative risks, such as those of smoking or air travel. Care needs to be exercised with these to retain the same risk quantity and scale in which it is expressed. It is also well to note that, although now widely used, this approach has not yet fully resolved the problem.

Operational considerations

The consultation group was of the view that improved communication of risk and other aspects of justification and audit will result in changes in practice, and will have a substantial impact on the operational load in an imaging department. For example, it is possible that a significant burden of communication and a series of processes to obtain valid consents may arise with each patient in particular categories following from the recommendations here. When this is the case, it is important to remember that the department and its operational systems exist, ultimately, to provide good medical practice. Sound justification is an inevitable part of this.

Considerable effort was devoted to the problem of lower doses (arbitrarily considered as those below 1 mSv). The risk at this level is generally regarded by professionals as very low. It was recognised that, although communication and consent are always required, below this level risk is sufficiently low that it may be reasonable to simplify the operational arrangements for it. General information, for example by way of leaflets or notices, should be provided. These should encourage questions to be raised, which should be answered, and any further information sought should be provided. Provided these conditions prevail, the patient's acceptance of the examination should be sufficient to constitute implied consent to the examination. At higher doses and risks, the need for more formal and explicit consent becomes essential.

Opportunities and special concerns

There are many additional and special concerns in the communication areas. Some of these relate to the special information needs of specific groups or arise from specific problems. For example, we recognise the special communication issues in respect of pregnant patients [53, 54], but, as with the particular issues that arise with carers and children, they are not addressed here [55]. The problem of dealing with previous exposures, in terms of both diagnostic impact and cumulative effects, is also well recognised, but is not taken up here.

On the other hand, clear advice is offered in some cases. For example, in the event of uncertainty in the referral information, best practice requires consultation between the referring medical practitioner and the radiological medical practitioner. Use of forms for consent purposes promotes the patient's understanding and reminds the physician of his or her responsibilities. Retention of the form in the patient record facilitates audit of justification. The use of specific forms for particular examinations should be considered. Mandatory use of such forms for higher dose investigations (*e.g.* >10 mSv) is suggested.

The problems of risk communication are not confined to medical radiology and have a wide provenance throughout medicine and in the nuclear industry. In both of these, it is now well recognised that communication of accurate comprehensible information, while essential, does not fully deal with the issues involved. Failure to recognise this, or if the information is not accurate and comprehensible, leads to social amplification of risk. In the public health area, Alaszewski and Horlick-Jones [32], dealing with incidents arising from the measles, mumps and rubella vaccination crisis, derived lessons pertinent to the problems noted here. These include the importance of the social context of the persons receiving the message, their context, as well as the importance of the message being communicated by a person who is likely to be trusted [32].

In addition, it has recently been noted in the *IAEA Bulletin* that [33]:

> It was believed that clear, understandable information was all that was needed to make people see that the risks were lower than many feared. To this day, many still believe risk communication is just a matter of

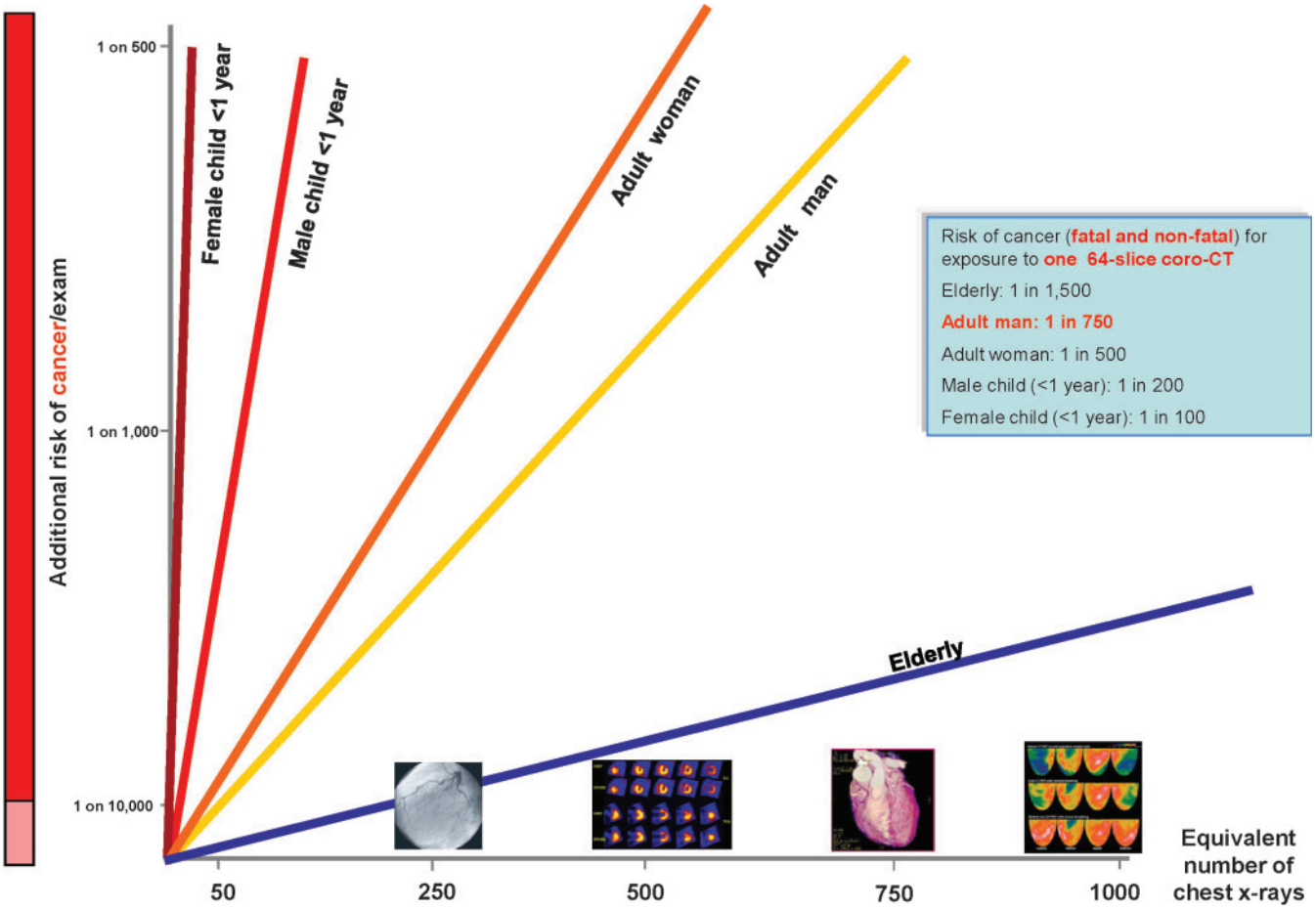

Figure 1. Equivalent number of chest radiographs (on *x*-axis) and risk (on *y*-axis) for male and female children, for adults (men and women) and the elderly. To illustrate how the graphs might be used, icons designating some cardiac procedures are placed on the *x*-axis at the number of chest radiographs corresponding to that procedure dose. The first one on the left illustrates a typical coronary angiogram dose at roughly 250 chest radiographs. The associated risk can be read from the *y*-axis. Based on Picano [15] with data updated from BEIR VII [56].

making information understandable. This is particularly true in fields … strongly influenced by people with scientific … backgrounds.

For decades this approach has failed, and most risk communication experts say it is inadequate. The perception of risk, and the behaviours that result, are a matter of both facts and our feelings and instincts and personal circumstances. Communication that offers the facts but fails to account for the affective side of our risk perceptions is simply incomplete.

We can learn much from looking at how other disciplines handle these issues and thereby, hopefully, improve the effectiveness of our communication with patients and other health professionals. At present, in practice, we are failing to hear what they may have to offer [32, 33].

Table 1. Dose–risk communication: the Royal College of Radiologists (RCR) approach [17]

Investigation	Effective dose (mSv)	Equivalent no. of plain chest radiographs	Approximate equivalent period of natural background radiation[a]	Additional lifetime risk of fatal and non-fatal cancer[b]	RCR symbolic representation[c]
Plain postero-anterior chest radiograph	0.02	1	3 days	1:1000000	▲
Thyroid scintigraphy (^{99m}Tc)	1	50	6 months	1:10000	▲▲
CT chest (non-contrast)	8	400	3.6 years	1: 1200	▲▲▲
CT abdomen	10	500	4.5 years	1:1000	▲▲▲
Multidetector CT cardiac (64 slice)	15	750	7 years	1:750	▲▲▲▲

[a]Average background radiation is 2.2–2.4 mSv per year.
[b]These examples relate to a 50-year-old man. Multiply by 1.38 for women, by 4 for children under 1 year of age, and by 0.5 in an 80-year-old man.
[c] ▲, <1 mSv; ▲▲, 1–5 mSv; ▲▲▲, 5–10 mSv; ▲▲▲▲ >10 mSv.

Referral guidelines and tools for clinical justification

In view of the difficulties outlined above, which reflect the state of practice in 2008, the EU Medical Exposure Directive of 1997 was prescient in requiring [20, Article 6.2]:

> Member States shall ensure that recommendations concerning referral criteria for medical exposure, including radiation doses, are available to the prescribers of medical exposure.

This section focuses on the question of justifying particular medical radiological procedures and loosely corresponds with Level 3 justification as defined by the ICRP (section 2.1). There are now excellent tools to support justification at this level. Referral guidelines have been produced in the UK [17], the EU [19], the USA [18], Canada [57], Australasia [58], Far East Asia [59] and probably other countries and regions. They are produced with a view to promoting evidence-based good medical practice; expediting the appropriate investigation of patients; and reducing the radiation burden to individuals and the population. These can either be part of an agreed investigation protocol or used for individual cases.

Some guidelines have a remarkable level of sophistication in terms of the evidence content and user accessibility, both in hard copy and online [17, 19]. For example, the most recent version of the RCR guidelines makes every effort to ensure a sound evidence base and consensus agreement for its recommendations. Notwithstanding this, there is inevitably a significant number, possibly one in four of the guidelines, which relies on expert opinion, usually through consensus [60].

Guidelines will find greater acceptance among referring and radiological practitioners and by patients when:

- a robust system for guideline synthesis has been used
- the evidence base is strong
- bias has been avoided
- wide consultation has been carried out
- clear and simple dose and/or risk classifications are provided.

Great care must be taken with the precise wording of guidelines as this has a strong impact on how they are implemented [61].

Need for guidelines

At the legal and social level, compliance with the EU Medical Exposure Directive places an obligation on the Member States to produce guidelines. The need for them also arises, more generally, in connection with the trend towards transparency and accountability in public life and in the practice of medicine. Within radiology, the need for guidance stems from a wide variation in referral practice, particularly with high-dose and expensive procedures. Improving the appropriateness of investigation has clear advantages. The patient benefits from improved access to the correct procedure and reduced waiting lists, with consequent diagnostic, therapeutic, health and economic benefits. The service benefits from not performing unnecessary and inappropriate examinations. This improves both morale and efficiency.

In terms of the day-to-day operations of a department, the need for guidelines arises to help eliminate the more common causes of unnecessary medical exposures. These are often due to the following (based on a list developed by the RCR) [17]:

- repeating investigations which have already been done;
- undertaking investigations when results are unlikely to affect patient management
- investigating too early
- doing the wrong investigation
- failing to provide appropriate clinical information and questions that the imaging investigation should answer;
- overinvestigation
- poor knowledge of the dose levels involved (particularly in CT).

Guidelines are intended to support but not constrain practice or remuneration. They may be used to formulate investigation pathways and protocols [62]. There is a particularly strong need for guidelines when investigations with equivalent diagnostic benefits, not involving the use of ionising radiation, should, where possible, be considered first. Local expertise, health infrastructure and availability of resources must be taken into account when using guidelines to construct a protocol. Adoption of guidelines and adaptation to local disease patterns and levels of health-service provision may prove particularly important [63].

At the other end of the spectrum, the approach to both justification and optimisation of high-dose procedures, such as interventional radiology, cardiology and single photon emission computed tomography or positron emission tomography CT, may not be satisfactory in practice [64, 65]. Where referral criteria are not available, justification will be on a case-by-case basis and, thereby, relies exclusively on the knowledge/experience of the referring and performing medical practitioners. Additional guidance is also needed with alternative, lower dose strategies. Self-referral and self-presentation of patients (Appendix A) for radiological investigations is frequently associated with unnecessary investigations, radiation burden and cost. This area needs further consideration.

Intended users of guidelines

Guidelines are used by:

- referring medical practitioners in hospitals
- referring medical practitioners in primary care
- doctors in training
- allied health professionals who are entitled to request radiological examinations
- radiological medical practitioners
- technologists/radiographers
- hospitals, healthcare organisations, health ministries and governments
- patients.

Guidelines are not primarily directed towards radiological medical practitioners, but they will generally find them helpful in dealing with requests. When they have been developed with a strong evidence base, they will also be of value to this group where there is a substantial variation in clinical practice without demonstrable differences in outcomes. Technologists/radiographers find guidelines useful for justification and in assisting with obtaining patient consent. Patients can find it reassuring to see that the information and recommendations in guidelines confirm that an appropriate investigation strategy is being planned for them. Hospitals, healthcare organisations, health ministries and governments, among other things may find guidelines both informative and useful in service planning and in many other ways. Effective use of guidelines is highly dependent on their widespread dissemination and how they are presented and integrated into the culture of an organisation.

Dose reduction achievable through use of guidelines

A significant 13% reduction in the referral rate of patients for radiography by general practitioners was shown following the introduction of the first (1989) edition of the RCR guidelines [66]. A randomised controlled study [67] showed a significant reduction in referrals for spinal radiographs. However, it was not sustained in a later study [68], indicating that providing guidelines alone may not be adequate to ensure a sustained reduction in referrals for radiography. A 20% reduction in referrals for investigations regarded as being of limited value resulted from a strategy employing the use of educational reminders on radiological reports in a randomised trial [26]. Further studies with this feedback strategy showed a sustained reduction [69]. Scandinavian audits have demonstrated a generally high rate, approximately 20% or over, of inappropriate or unnecessary examinations, and a very high rate, up to 77%, in the case of some specific examinations [48, 49]. In paediatrics, a recent straw poll among specialist radiologists suggested that up to 30% of CT examinations may be inappropriately undertaken [12, 56].

A reduction in referral rate and improved quality of investigations has been shown by application of the ACR guidelines [70]. Higher effective dose investigations, including CT in the emergency room, demonstrated a potential for up to a 44% dose reduction. These findings reinforce the importance of the Scandinavian audits and the impressions of paediatric practice in respect of the potential of audit to reduce individual and population doses [10, 11, 48, 49, 60]. To achieve the potential gain, there is an urgent need to improve awareness of, and compliance with, guidelines [45–47, 70–73].

Practical approaches to good referral systems

Optimal justification that is refined and nuanced to take account of local situations will inevitably be constructed around the strengths (and weaknesses) of local clinical teams. These should, ideally, be integrated with respect to the guidelines deployed. Guidelines are most effective when they are developed and adapted to the local situation by teams that include both referring and radiological medical practitioners and their departments. It will be important to further develop, refine and appropriately nuance the role of both the radiological and referring medical practitioners to achieve success with the development, deployment and use of guidelines in practice. This needs to be achieved at local, national and international levels and is among the subjects addressed at the joint EC/IAEA Workshop on Justification [35]. Good referral documentation and clinical information optimise the choice of investigation and improve patient throughput. They do much to reduce the significant and systematic practices of inappropriate examinations which often arise from systems failures. Guidelines should be reviewed regularly with a defined cycle of renewal, *e.g.* 4 years [17, 18]. When there is a change in the evidence base supporting a guideline, review and update should be performed sooner. This is facilitated when publication and protocols are online.

A clinical problem-based approach to guidelines has been used for 20 years by the RCR and has proven helpful for referring clinicians (see sections on referral guidelines and audit). It has the advantage of offering the best choice of appropriate imaging modality for the clinical question in the absence of specialist knowledge. Alternative approaches based on appropriate indications for specific investigations have also been used by others. This has been found to have advantages for the radiological medical practitioner, but is less helpful for clinical problem-solving. However, it was favoured in the EU and widely disseminated through both the EC website [19] and in revised form from the RCR. A third approach, flow chart protocol based, gives guidance beyond the first step of investigation but is often too rigid for widespread acceptance. This approach meshes well with clinical pathways for a limited number of common conditions.

It is important that those shaping the process become attuned to the importance of multi-organ, multisystem disease, and the repeated exposures inevitably associated with longevity and chronic diseases. These will almost certainly require new approaches to justification and to guidelines. For example, when multiple examinations are required for a patient with possible disease in several vascular areas, it is imperative that they are justified as a group and that investigations are undertaken and reviewed in an appropriate order [4, 22].

Finally, use of, and compliance with, guidelines can be improved using continuous quality improvement techniques such as clinical audit.

Clinical audit of justification, including referral

Background and purpose

For a variety of reasons—professional, public, financial and political—most countries seek to establish visible systems for managing quality in healthcare. One of the key elements in this is the establishment of clinical audit. This concept is not new and has long been applied to many healthcare fields [74–76]. More recently, audit is

being introduced into radiology on a widespread basis. For example, in Europe the MED requires that [20, Article 6.4]: ''clinical audits shall be carried out in accordance with national procedures'' in Member States. Article 2 of the MED defines clinical audit as:

> a systematic examination or review of medical radiological procedures which seeks to improve the quality and the outcome of patient care, through structured review whereby radiological practices, procedures, and results are examined against agreed standards for good medical radiological procedures, with modifications of the practices where indicated and the application of new standards if necessary.

It is obvious from this definition that clinical audit is a multidisciplinary, multiprofessional activity integrated with the operational management of the healthcare environment. Its general purpose is to improve the quality of patient care, to promote the effective use of resources, to enhance the provision and organisation of clinical services and to further professional education and training in a healthcare team environment. Within this general framework, clinical audit is a potentially valuable tool for improving justification worldwide. Its aims include assessing the quality of the justification process, including correct application of the referral guidelines, in order to avoid unnecessary, inappropriate and unjustified medical exposure.

Clinical audit is an essential tool for continuous quality improvement. It is imperative for its application that standards of good practice have been defined. Further, it should be ensured that the audit cycle is completed. This consists of selecting the standard of good practice, assessing the local practice, comparing it with the standard, implementing change when necessary and re-auditing after a certain time.

Specific guidance for clinical audits of radiological practices is published by the EC [23, 24]. Guidance for practical procedures in audit of X-ray diagnostic practices has been published by the IAEA, including advice on justification as a part of the diagnostic process [25].

Scope of clinical audit of justification and good practice

Radiologists, physicians and technologists have argued that both the implementation and audit of justification are hampered by a lack of appropriate tools, benchmarks, professional/institutional commitment and training etc. [23–26, 68, 69]. The opportunity to reverse these obstacles now presents itself, particularly in the light of the type of developments noted in the sections on referral guidelines and clinical audit noted above.

Clinical audit can be comprehensive and cover the whole clinical pathway or partial and target-selected components of it [24]. Justification is one of the cornerstones of radiation protection and is a crucial part of radiology and nuclear medicine diagnostic practice. Therefore, ensuring its implementation should be among the priorities of clinical audit.

A good practice, against which the justification process is audited, should be based on:

- education and continuous professional development of the referring and performing physicians on referral guidelines, advantages and limitations of different examination options, their complementary nature, risk–benefit considerations including adverse effects and contraindications
- communication with patients and communication between radiological and referring medical practitioners
- due consideration of patient and information/consent issues
- use of referral guidelines or appropriateness criteria;
- adequacy and timeliness of the referral requests
- identified responsibility for justification (*e.g.* with radiological and referring medical practitioners)
- level of availability of each modality
- availability of the report and how it is used.

The features of a good referral request are presented in Appendix B. The net impact of clinical audit of justification should a reduction of the significant and systematic practice of inappropriate examinations, particularly those arising from systems failures.

Clinical audits should generally cover the structure, process and outcome of the radiological or nuclear medicine procedure. Clinical audit of justification mainly addresses the selection and decision process, but should also cover the necessary structure (clinical responsibilities, training) and outcome (feedback processes, how the radiological or nuclear medicine procedure affects the management of the clinical problem and patient care).

Methods for audit of justification

When radiology departments identify a specific problem, it is most effectively addressed internally through clinical audit. Frequently, local problems and solutions are most easily identified by those working within a motivated department. External audits may help identify other, unrecognised areas for improvement. Thus, internal audits, self-assessments and external audits have a role to play, should be part of the life of a department and are recommended [23, 24]. For more formal external audits, two basic approaches can be applied:

- assessment through a site visit
- collection of samples of referrals and other relevant information by mail with central assessment by designated auditors.

The first option provides a more comprehensive review of the justification process owing to the direct access to all relevant documents, including the referrals, and the possibility of holding interviews of responsible practitioners. The second option can be used to audit the quality of the referral documents and also appropriate selection of examinations. However, its value for the latter purpose is dependent on the success of the former, because the judgement on the appropriateness requires that adequate clinical information is available from the referral documents [77].

To attain a comprehensive audit of the justification process, the second option should be supplemented by a

specific questionnaire based on the audit programme [25, 77]. Such a questionnaire can also provide helpful additional material for the first option and should be completed in advance of a site visit.

Compliance of referrals with referral guidelines has been classified on a scale ranging from full to no compliance. It is unlikely, in the real world, that 100% compliance with guidelines will be achieved in practice. Some work needs to be undertaken to establish the level that is achievable, and how it might best be presented. Pending the outcome of such studies, it has been suggested that 90% be regarded as the best achievable, but, to date, there is no evidence base for this value.

For assessing the output, or the impact of the radiological procedure on patient management, the audit should include review of examination reports.

Comprehensive audit of the justification process should include reviews of the following:

- referral guidelines and other guidance documentation;
- adequacy of the requests/referrals
- repeat examinations, to ensure that they are optimised to be purposeful and dose efficient
- the processes to ensure that justification is transparent, accountable and well adapted to current social values
- confirmation that referrals and procedures are authorised in accordance with agreed institutional roles, authorisations and alignment of responsibilities in respect of individual practitioners and groups of practitioners
- involvement of the referring and performing medical practitioners, as appropriate in:
  - review of referrals (by radiological practitioner)
  - review of patient records, including earlier examinations;
  - checking contra-indications and limitations (pacemaker, allergy etc.)
  - checking information on typical radiation doses to the patient
  - having appropriate awareness and knowledge of benefits, dose and risk
  - application of referral guidelines including possibility for alternative examinations
  - evaluating timeliness of the examinations
  - checking or giving information and advice to the patient;
  - obtaining consent in appropriate form.

Table 2. General recommendations

General
Radiology departments and their operational systems exist, ultimately, to provide good medical practice, and sound justification is an essential part of this
There is a significant and systematic practice of inappropriate examination in radiology. Much of this arises from systems failures and lack of knowledge
The published literature demonstrates significant deficiencies of knowledge of risks, dose and benefits among patients, referring medical practitioners and radiological medical practitioners
Consideration should be given to the design of PACS and RIS systems with electronic request facilities that support justification, particularly referral guidelines and clinical audit
Communication of risk, use of referral guidelines and audit will have a substantial impact on operational aspects of a department
The approach advocated here requires endorsement by professional bodies and the support and involvement of government departments and agencies
Effective training (undergraduate, postgraduate and CPD), with respect to communication, the social function of departments, referral guidelines and audit, is essential
We note the ACR White Paper view that ''The rapid growth of CT and certain nuclear medicine studies may result in an increased incidence of radiation-related cancer in the not-too-distant future''. Justification may therefore be an effective tool for cancer prevention
Further actions and publications on various aspects of the initiatives proposed are essential

ACR, American College of Radiology; CPD, continuing professional development; PACS, picture archiving and communication systems; RIS, radiology information systems.

Table 3. Awareness

Awareness: communication and consent
To understand why justification is necessary, one must be aware of the risk
To give effect to justification, it is necessary to have a good practical knowledge and awareness of the risks involved
There are serious deficiencies in communication and communication strategies in respect of risk and dose among practitioners and health professionals
The system of radiation units is not well suited to communicating on dose and risk with the public, patients or health professionals. An alternative effective global strategy is desirable
Due attention should be paid to findings of the social and behavioural sciences on the importance of achieving effective communication of emotional response, social context and the trustworthiness of the communicator
Due account should be taken of experience in the public health area of communication with the public, patients and professionals (*e.g.* MMR, BSE, AIDS, road accidents, smoking etc.)
Risk–benefit assessment of investigations involving ionising radiation should include the long-term risk of malignancy. Patients have the right to know of this risk, and physicians have the duty to inform them, so that they can make informed decisions about their treatment. This will facilitate shared decision-making
Consent is a fundamental requirement for all radiological procedures. The greater prominence of this issue needs to be brought to awareness in the practice of radiology. The level of formality associated with obtaining it will vary with the dose-risk involved, and the patient
A breakpoint, below which the risk can be ignored, would ease operational difficulties in justification (*e.g.* <1 mSv). To date, there is no consensus on such a breakpoint
Risk awareness and handling consent may be improved and/or facilitated by inclusion of relevant information and requirements, in electronic referral/ordering systems and RIS/PACS

AIDS, acquired immunodeficiency syndrome; BSE, bovine spongiform encephalitis; MMR, measles, mumps and rubella; PACS, picture archiving and communication systems; RIS, radiology information systems.

Table 4. Appropriateness

Appropriateness: referral/acceptability guidelines
Appropriateness criteria or referral guidelines can greatly assist the practice of justification
Use of guidelines can achieve an immediate dose reduction of 20% with a potential 40%, and even more in some areas and with some techniques. They can help eliminate categories of examination of little or no clinical value, *e.g.* skull radiographs for head injury
Guidelines are not only dose effective, but they also promote and foster good medical practice
Local and regional guidelines should be developed taking account of local epidemiology, institutional profile and levels of healthcare provision
Uptake and use of guidelines depends on access to them and presentation. Including them in an accessible way in electronic referral/ordering systems and RIS/PACS systems will help
National, regional and local studies on the dissemination, local adaptation, uptake and use of guidelines are essential
Further attention is required to issues associated with self-referral, self-presentation and screening programmes
Further attention is required to practice and guidelines for protection of pregnant or potentially pregnant patients
In some areas it will be necessary to further develop and refine the role assigned to both the radiological and referring medical practitioners to achieve success with the development, deployment and use of guidelines in practice

PACS, picture archiving and communication systems; RIS, radiology information systems.

Table 5. Audit

Audit: clinical audit of justification
Regular clinical audit is integral to good medical practice
Clinical audit in radiology is required by law in some parts of the world. Contribution to audit should be part of the contractual arrangements for radiological medical practitioners
Audit of justification should be a high priority; an indicator for the adequacy of justification should be a high-level marker for the quality of a radiological service. It should be recognised financially
Audit of justification should assess compliance with referral guidelines and patient communication requirements
Both internal and external audit methodologies should be encouraged as advised by the IAEA and the EC. Initially, internal audit will encourage ownership and promote change
Clinical audit must be realistically integrated into the operating framework of a department. It should influence work culture and the quality of the enterprise
Baseline studies on the level of compliance with justification that can be expected in a department functioning with best practice should be undertaken
Studies of the level of dose saving that may be realistically expected should be undertaken as part of following initiatives targeted on improvement of justification

EC, European Commission; IAEA, International Atomic Energy Agency.

All of the elements of audit may be greatly facilitated by PACS and RIS systems where consideration has been given to justification, communication and audit from the beginning of the project. National or regional audits will enable benchmarking and will identify departments in the lowest quartile of performance and those with special cause for variation [78, 79], for which strategies for improvement may be suggested.

More detailed guidance has been published by the IAEA [25]. Examples of practical audits have been published [*e.g.* 48, 49, 50, 77], and it is anticipated that many others will shortly become available. Information on the audit organisation, auditors, recommended audit frequencies, costs, financing and other aspects of practical implementation are available [24, 25].

Conclusions and recommendations

The recommendations of the consultation are set out under four headings (Tables 2–5). Following some general points, the operational findings are summarised under three headings, which can be summed up as the ''3 As'': awareness, appropriateness and audit.

In conclusion, while the innovations in medical imaging represent an exceptional success story, the operation of justification is unsatisfactory at present. There are now also real opportunities to greatly improve it. These arise from a combination of circumstances, which include the quality and level of experience with and availability of good contemporary referral guidelines. In practice, communication and distribution of responsibilities between the referring and radiological medical practitioners needs further nuanced discussion in the immediate future. In addition, techniques of clinical audit, suited to radiology including justification, are being developed and introduced into practice. Where these are combined with new and critically evaluated approaches to communication of dose, risk and benefit, there is every chance that routine implementation of justification can be greatly improved and the present unsatisfactory situation should become a thing of the past.

The need to improve justification arises directly from the changing patterns of practice in diagnostic radiology, particularly the routine introduction of relatively high-dose techniques, and because of changes in the social framework and individual rights/expectations in respect of how medicine is practised and delivered. It is likely that, following some initial reservations around operational problems, many doctors and the medical community will find that the approach advocated here engages and energises them. This is because practical approaches, which they can relate to and implement, are advocated. They are also assigned key roles that can be exercised within their accustomed competencies. Finally, while imposing some additional burdens, good justification will release the individuals and institutions from the burden of much unacceptable work of little benefit to patients.

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Appendix A. Some definitions adopted

A variety of terms are used to describe the roles of the different types of physician and health professional involved in the justification process. The IAEA, in the January 2009 draft of the revised BSS, uses the terms and definitions below. These were adopted for this document.

Radiological medical practitioner: An individual who: (a) has been accredited through appropriate national procedures as a health professional; (b) fulfils the national requirements on training and experience for performing or overseeing procedures involving medical exposure; and (c) is entitled in accordance with the relevant authorisation to perform or oversee procedures involving medical exposure.

Referring medical practitioner: A health professional who, in accordance with national requirements, may refer individuals for medical exposure to a radiological medical practitioner.

Health professional: An individual who has been accredited through appropriate national procedures to practise a profession related to health (*e.g.* medicine, dentistry, chiropractic, podiatry, nursing, medical physics, radiation and nuclear medical technology, radiopharmacy, occupational health).

Medical exposure: Exposure incurred by patients for the purpose of medical or dental diagnosis or treatment; by carers and comforters; and by volunteers in a programme of biomedical research involving their exposure.

The first two definitions correspond roughly to the prescriber and practitioner, as used in the EU.

Two types of patient referral or presentation, not traditionally encountered in radiology, now occur with increasing frequency, self-presentation and self-referral:

Self-presentation: Occurs when patients refer themselves for a procedure and appeal or apply to a radiology service to have it undertaken.

Self-referral: Occurs when a physician (*e.g.* a cardiologist), who has radiological facilities within his/her own clinic, performs a procedure on a patient (as opposed to referring it to a third party, such as a radiologist).

These terms are not used consistently throughout the world, but the sense in which they are employed here accords with these brief definitions.

Appendix B. Essential features of a good referral request

The essential features of a good referral system are set out in the aide-memoire notes:

- A good referral request provides sufficient information to allow the radiologist to:

– identify a clear clinical question
– justify the radiation risk *vs* potential clinical benefit of the examination
– determine whether an examination using no ionising radiation may be substituted
– determine the examination protocol
– provide supportive patient information to identify patient factors that may jeopardise the examination (*e.g.* delirium, dementia)
– be aware of the relevant clinical history.

- Essential data for a good referral request:

– date of request
– name of patient
– date of birth
– unique patient identifier
– patient address
– gender
– pregnancy status
– if age appropriate, last menstrual period
– weight
– height
– imaging modality requested
– body region to be examined
– clinical question
– supportive appropriate clinical information
– previous examinations with date(s)
– allergy status
– renal function status
– medication status
– medical device status
– infectious status
– ambulatory status
– name of referring medical practitioner
– contact information for medical practitioner
– clinical timeliness requested.