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FOREWORD

The extent of the radiation exposure of patients has increased dramatically in recent times. The major part of the exposure now arises from practices that barely existed two decades ago. In some countries, the population dose from medical exposures now rivals that from the natural background. For practitioners and regulators, it is evident that this innovation has been driven both by the imaging industry and by an ever increasing array of new applications generated and validated in the clinical environment.

Because of these increases, the radiation protection of patients has assumed much greater importance. The doses involved are large compared with those from occupational exposures. Much work has been done to optimize these doses, and much of what is required is well understood. However, more remains to be done to ensure that routine day to day practice throughout the world is well optimized.

The other cornerstone of the radiation protection of patients is the justification of exposures as recommended by the International Commission on Radiological Protection (ICRP) and required by the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS), jointly sponsored by the IAEA and a number of other international organizations. The justification process must ensure that only those who can benefit from medical exposures will receive them. In practice, the benefit must be balanced against the risk. The theory of the radiation protection of the patient relies on this balance being struck in a way that ultimately favours patients and does not expose them to unnecessary risk. With the increase in the dose per examination, the issue of justification has acquired a new urgency to which the IAEA has responded vigorously over the last few years.

The IAEA response initially involved two consultations with groups of experts. The first established that there is a prime facie case to be concerned that the implementation of justification is not all it should be. The second established that there is a robust set of tools that can greatly improve justification. These are mature enough to be deployed for clinical use in various parts of the world, although further refinement and nuancing is required.

Arising from these initiatives, the IAEA and the European Commission (EC) organized a joint workshop on the justification of medical exposures in Brussels with a view to consolidating these conclusions and broadening the interest groups involved in considering the problem. These proceedings report the work and conclusions of this workshop. Over 40 countries and several international organizations were involved, and concluded that there are major issues to be addressed in the implementation of justification in practice. A concerted global campaign to improve ‘awareness, appropriateness and audit’ (the three A’s campaign) is required, as set out in the conclusions. The campaign will necessarily involve all the key players in the field.

The International Action Plan for the Radiological Protection of Patients was approved by the General Conference of the IAEA in 2002, and its implementation has been the subject of a resolution at succeeding General Conferences. Recently, the IAEA Secretariat was encouraged to “develop further guidance on justification of medical exposures and optimization of protection, taking into account, inter alia, the outcomes of the September 2009 workshop hosted jointly with the European Commission”. These proceedings are prepared and issued in response to this.

The IAEA thanks J. Malone (Ireland), who had a major role in organizing the workshop and in preparing the proceedings for publication. The IAEA officers responsible for this publication were O. Holmberg and R. Czarwinski of the Division of Radiation, Transport and Waste Safety.

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CONTENTS

SUMMARY

BACKGROUND

The International Conference on Radiological Protection of Patients held in March 2001 in Malaga, Spain led to a major outcome: the development of the International Action Plan for the Radiological Protection of Patients. Coordinated by the IAEA and kept under review by international organizations, professional bodies and international experts, the Action Plan seeks progress in the radiation protection of patients as a whole. While dose limits are not applied in medical exposure, the principles of optimization and justification of medical exposure are central to patient protection. Data published by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and the National Council on Radiation Protection and Measurements (USA) clearly indicate a trend of rising radiation burden from medical exposure.

In the early years of the Action Plan, much progress was achieved in the area of optimization, but evidence that a substantial fraction of radiological examinations may be inappropriate has focused attention on justification. On one hand, there are basic ethical considerations involving autonomy and patient consent, while on the other hand the question of overutilization of medical imaging begs examination because of radiation exposure and economic implications.

THE WORKSHOP

The International Workshop on the Justification of Medical Exposures in Diagnostic Imaging was held from 2 to 4 September 2009 in Brussels, Belgium. It was organized in cooperation with the European Commission.

The members of the Programme and Organizing Committee, and the Editorial Committee were: J. Malone (Ireland); O. Holmberg and R. Czarwinski (IAEA); and G. Simeonov (European Commission).

The session Chairpersons were: J. Mayo, University of British Columbia and Vancouver General Hospital, Canada; C. Dora, World Health Organization; R. Chhem, IAEA; A. Janssens, European Commission; P. Smeesters, Federal Agency for Nuclear Control, Belgium; and R. Czarwinski, IAEA.

The session Rapporteurs were: G. O'Reilly, St. James Hospital, Ireland; D. Regulla, GSF-National Research Centre for Environment and Health, Germany; W.R. Hendee, Medical College of Wisconsin, USA; E. Picano, Institute of Clinical Physiology, Italy; P. Horton, Royal Surrey County Hospital, United Kingdom; and K. Faulkner, Quality Assurance Reference Centre, United Kingdom.

The topics addressed in the workshop were:

— Referral guidelines;
— Communication and risk;
— Audit and justification;
— Special problems.

Appropriateness criteria and referral guidelines are tools available to a physician when deciding whether or not a particular imaging study is justified for a patient with a specific set of conditions. Experience in the USA and the United Kingdom underscore the advantage of using such tools to arrive at the correct choice of imaging, and indicate that the number of radiological investigations can potentially be reduced by up to 44%. In Canada, a patient dose registry is being proposed to provide patients and health care providers with information that should help prevent duplicate imaging, thereby reducing unnecessary radiation exposure. Electronic decision support tools can also play a significant part in this reduction, if widely adopted. In Brazil, the uneven distribution in the numbers and types of radiology equipment in the different regions has a detrimental effect on the quality of service offered to the population. At least one-third of imaging tests performed are cardiovascular in nature, underscoring the role that cardiologists can play in reducing radiation doses globally by using appropriate tests for the appropriate indication in the appropriate patient.

Inadequate communication about the risk of medical exposures has led to news media interest that, if not properly addressed, could lead to a dramatic loss of public faith in the benefits deriving from the use of radiation in

medicine. Not only is it important to embark on an outreach programme targeted at journalists and the public (including patients, and patient advocate organizations) but it is vital to raise awareness about safety among radiation protection professionals and health professionals. The experience in France and Belgium in implementing European Union radiation protection regulation has led to the conclusion inter alia that more efforts are needed in education. Studies undertaken in several countries indicate that knowledge among referring physicians regarding dose and risk from ionizing radiation is inadequate, and patient awareness also needs to be increased.

The European Union requires its Member States to implement clinical audits, and provides relevant guidance addressing objectives, coverage and standards of good practice. Justification should be among the top priorities in an audit programme. In the United Kingdom, clinical audits are actively encouraged. A study of the justification of computed tomography (CT) examinations in Sweden identified areas needing improvement. The situation in several Latin American countries regarding regulation of the principle of justification was reviewed, and a need for harmonized efforts to address an overlap between medical and medico-legal exposures identified.

Finally, the Workshop considered the practice of justification in such specific areas as medico-legal exposures, dental cone beam CT, medical exposures for women of child bearing age, CT examinations in young patients, mammography and health screening.

CONCLUSION

The workshop concluded the following:

(1) The benefits of diagnostic medical exposures are not in doubt. They contribute greatly to the care and management of patients.

(2) There is a significant and systemic practice of inappropriate examination in radiology. Much of this arises from deficiencies and lack of knowledge within health systems. This is occurring in a context of greatly increasing medical usage, increased reliance on technology, and increased doses. In addition, it is occurring during a time of social change and increasing emphasis on openness, transparency and accountability.

(3) This problem is global and regional and requires international bodies to address it proactively to provide supra national/global solutions that can be of assistance to nations and regions.

(4) In some countries, cardiology is a major contributor to increasing doses and special problems concerning justification in cardiology must be recognized.

(5) In the European Union, as well as in some other parts of the world, a solid legal framework regulating medical exposures has been in place for over a decade. However, there are many indications that the legislation has not been effectively implemented in practice, particularly in the area of justification.

(6) The tools examined, i.e. the 3 A's (awareness, appropriateness and audit), are viewed as likely to facilitate and enhance justification. They are mature enough to introduce and apply in some regions and need further differentiation and development in others.

(7) The importance of guidelines in improving referral patterns, and thereby enhancing compliance with justification, was highlighted. Much work is needed to further the involvement and participation of both referring and radiological practitioners, clarification of their respective roles, development and dissemination of guidelines suitable for wider application, and provision of support for their implementation. Concern was expressed to ensure that commercial or intellectual property issues do not inhibit this process and to ensure patient involvement with it.

(8) The importance of clinical audits to improve justification in diagnostic radiology was highlighted. It was recognized that it is desirable and achievable. Its adoption should be encouraged/reinforced through the use of statutory measures where necessary, through measures encouraging dissemination of effective audit, through the support of professional and regulatory bodies, and through the use of payment systems, contractual arrangements and accreditation programmes.

(9) The need to break out and differentiate the communication tasks facing professions involved with radiation protection in medicine was highlighted. The issues involved should be highlighted and programmes should be developed around them, including educational programmes and the deployment of information and communication technologies.

(10) The traditional approach to communication of dose and risk by radiation protection professionals to health professionals and patients has been ineffective. New, simple and effective approaches in these areas should be identified, explored and promoted.

(11) A publication reviewing the contribution of ethics, law, health economics and communication on justification should be produced. Its level should be such that it can be used as a primer and reference source for education/training programmes in the area.

(12) Qualified radiographers may contribute greatly to improved justification with particular examinations. Ways of giving effect to this should be explored.

(13) The part patients must play in a successful justification process should be explored and this should involve patients and patient advocate organizations.

(14) Areas in which there are specific justification problems include, among others: special issues with younger patients and children; CT opportunistic screening and related problems; screening programmes; pregnancy issues; non-medical human imaging; dental radiology; and problems with mobile and portable equipment.

(15) Research on risk with appropriate medical populations is required. Evidence for guidelines from practice based research should be prioritized. There is a need to consider whether research budgets should be re-balanced to recognize the fact that >90% of human exposure to human made radiation is now medical.

(16) In view of the above, it is deemed important that a series of actions to address the justification problems in medical exposures from diagnostic imaging be undertaken. Some of these actions will be specific to certain regions, and others will be global/international. All will require cooperation between international organizations, professional bodies and other key players. The framework of the International Action Plan for Radiation Protection of Patients will greatly facilitate these actions.

OPENING ADDRESSES

OPENING ADDRESS — IAEA

E. Amaral
Division of Radiation, Transport and Waste Safety,
International Atomic Energy Agency,
Vienna

I am honoured to welcome you to the workshop on justification of medical exposure in diagnostic imaging, sponsored jointly by the International Atomic Energy Agency and the European Commission, and I would like to thank the European Commission for hosting this workshop here in Brussels.

Diagnostic imaging has seen many developments as it has evolved over the years, and in the last 30–40 years the pace of innovation has increased, starting with the introduction of computed tomography in the early 1970s. During the last decade, the rate of change has accelerated even further. Most patient exposure now arises from practices that barely existed two decades ago. These developments are evident in technology such as multi-detector CT scanning. However, this advance is achieved at the cost of a radiation burden to the individual patient and to the community. Contrary to other exposures to ionizing radiation, which have remained constant or decreased over the past decades, medical exposures have increased at a remarkable rate.

It is of interest to note that in the 1990s, a patient had to remain in a CT gantry for a period of 10 minutes for a chest CT, whereas now it takes a few seconds to scan the entire chest. This may give the impression that the radiation dose in CT is small, which is not the case. A typical chest CT can impart a radiation dose equivalent to hundreds of chest radiographs. However, the radiation dose to individual patients and the population can be reduced significantly through careful application of optimization and justification of medical exposures. Over the last 20 years, much successful work has been devoted to developing and consolidating approaches to optimization. Less effort has been committed to justification and the limited amount applied has not yet been as successful.

We should recognize that the use of ionizing radiation in medicine has brought tremendous health benefits to the global population, even though these benefits are not evenly distributed around the world. We should also take note of the very rapid growth of medical radiation technology, increasing access for patients every year. But we must always remember that the use of ionizing radiation has an associated risk. There are many advocates for the first two points, for example ‘big industry’ and ‘big medicine’, but perhaps a shortage of serious well considered advocates for the balanced management of the risks involved. In many cases, regulatory oversight of medical exposure is lacking, even in highly developed countries, and the sharing of experience among practitioners needs to be further developed. This technology is now increasingly reaching developing countries with less developed infrastructure, making the issues even more crucial.

Joint efforts by the IAEA, along with WHO, the EC and other organizations within the framework of the International Action Plan for the Radiological Protection of Patients is a good example of cooperation for the benefit of patients. This Action Plan has been in effect since 2002, and has enabled coordination of international efforts and the provision of guidance on the radiation protection of patients. We should remember that medical exposure is a massive global activity and that every day, throughout the world, radiation is used in an estimated more than ten million diagnostic procedures and one hundred thousand nuclear medicine procedures, while more than twenty thousand radiotherapy courses are started.

For those of you who might not be aware of the work of the IAEA, I would like to share some fundamental facts. The IAEA is part of the United Nations family of organizations, functioning under its own statute as an autonomous international organization in a working relationship with the United Nations. The UN recognizes the IAEA as the agency responsible for international activities concerned with the peaceful uses of atomic energy, which includes the application of ionizing radiation in medicine. We are working closely with other United Nations Organizations on this issue and I would like to highlight our close cooperation with the World Health Organization.

Three main pillars underpin the IAEA´s mission: the first is safety and security; the second is science and technology; and the third is safeguards and verification. Within the first two pillars, in safety/security and in science/technology, we carry out our work relating to the use of radiation in medicine. The IAEA helps countries to mobilize peaceful applications of nuclear science and technology, for example through providing Member States with equipment, training and expertise to help fight cancer, and the IAEA also helps countries to upgrade safety and

security in nuclear science and technology in order to protect people and the environment from harmful radiation exposure, for example through our programme on radiation safety.

A core element of safety is setting and promoting the application of international safety standards for the management and regulation of activities involving nuclear and radioactive materials.

It is a statutory function of the IAEA to establish standards of safety for protection of health and minimization of danger to life and to provide for their use.

I would here like to mention the key standards in this area: the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources. This is known as the International BSS, and marks the culmination of efforts that have continued over the past several decades towards the harmonization of radiation protection and safety standards internationally. Sponsoring organizations of the International BSS, in addition to the IAEA, are the Food and Agriculture Organization of the United Nations (FAO), the International Labour Organization (ILO), the Nuclear Energy Agency (NEA) of the Organization for Economic Cooperation and Development, the Pan American Health Organization (PAHO) and the World Health Organization (WHO). The Standards are presently being revised with participation from representatives of the sponsoring organizations and IAEA Member States. This will result in a fully revised edition. The International BSS is another example of cooperation which has a lasting impact on the radiation protection of people, including patients, as does the International Action Plan for the Radiological Protection of Patients.

The IAEA has a central role to play in efforts on minimizing unnecessary exposure and ensuring medical exposure is justified in diagnostic imaging. At a time when the medical radiation technology industry has gained a global presence, while the radiation regulatory framework is a national entity, it is important for intergovernmental organizations, such as the IAEA, the WHO and the European Commission, to continue to step up and show leadership and provide guidance for nations as well as for health professionals.

While dose limits are not applied in medical exposure, the principles of optimization of protection and justification of medical exposure are at the core of protecting the patient. There has been much progress in the area of optimization during the years of the Action Plan, but progress in the area of justification has been less successful. Authoritative sources suggest that a substantial fraction of radiological examinations may be inappropriate, from 20% to 50% in some areas. Key practical issues to the effective implementation of justification are first, the means of ensuring that those referred for radiological examinations really need them, second, auditing of the effectiveness of referrals and related processes and third, effectively communicating radiation risks to the relevant persons involved.

I hope that this workshop can be a step on the way to finding practical arrangements and tools that can improve the effectiveness of justification implementation in the day to day practice of hospitals and clinics throughout the world.

OPENING ADDRESS — EUROPEAN COMMISSION

A. Janssens
Directorate-General for Energy,
European Commission,
Luxembourg

The core principles of radiation protection are those of justification, optimization and limitation of exposures. In general these aim at the health protection of workers and members of the public by avoiding exposure to ionizing radiation through the prohibition of frivolous or unjustified uses of radiation or radioactive substances, the optimization of protective measures and restrictions on individual dose.

The application of these principles to medical exposures is not straightforward. Indeed, rather than avoiding exposures, the medical practice implies the deliberate exposure of individuals. In the case of diagnostic imaging, exposure of a patient should be commensurate to the desired quality of the image.

The deliberate exposure of an individual is justified only if there is a direct benefit to this individual, for instance the benefit of proper diagnosis and imaging for further health care or treatment of a patient, or a significant benefit to public health in the case of mass health screening or for the purpose or research, which indirectly may be to the benefit of the exposed individual as well, or if there is overwhelming societal benefit as may be the case for security screening.

This special feature of medical exposures results in the application of the principle of justification at three levels:

- At the first level, the use of radiation in medicine is accepted as doing more good than harm to a patient and is therefore taken for granted and not dealt with in regulations;
- At the second level, the justification of using ionizing radiation for specific medical purposes is dealt with, requiring justification of new types of practices involving medical exposure before being generally adopted;
- Finally, justification of each individual exposure is required, taking into account the specific objective of the exposure and the characteristics of the individual.

The second and third levels of justification were laid down in specific EU legislation: Directive 84/466, as updated in 97/43 and which is now being updated again as part of a major revision and recast of the Basic Safety Standards. While these directives were promptly and correctly transposed in national law, the implementation and enforcement of the principle by national authorities has proven to be difficult, particularly in the two following areas:

- The third level of justification is a matter to be decided upon by health professionals, be it the prescriber or the radiological practitioner, and the impact of the regulatory authority is very limited;
- The Directive requires steps to be taken to avoid the unnecessary proliferation of medical equipment.

The latter point reflects societal reality. Despite the responsibility of health professionals to apply only individually justified exposures, if the, often expensive, equipment is available it is likely to be used more often. Unfortunately, while it is obvious that different national health policies and health security regimes have an impact on the frequency of medical exposures, there seems to be little room for authorities to use this requirement of the Directive to change undesirable trends.

These deficiencies rightly receive new attention in view of the technological revolution, which in particular diagnostic imaging has experienced over the last decades. Earlier technological developments, such as image intensification for fluoroscopic examinations and the introduction of photographic film allowed for a reduction in exposures while preserving image diagnostic quality. Digital imaging and computerized tomography meant a revolution in the processing and quality of imaging, but did not reduce exposure to patients. On the contrary, doses can be very high, and while in many cases these may be justified by the quality of the image and the subsequent

treatment, the proliferation of CT equipment and its possible overuse have caused a significant increase in overall population exposure, medical exposures now approaching those of the natural background.

In view of these developments, the IAEA initiative to launch this series of workshops on justification of medical exposure in diagnostic imaging was important and timely. The EC is very pleased to host the present workshop here in Brussels and is grateful for this opportunity to involve EU stakeholders more closely, in particular our medical working party of the Article 31 Group of Experts. I also welcome the representation of WHO in this workshop, WHO being obviously a major actor in the development of health policies.

This workshop will be an outstanding event which I am sure will look into the fundamental aspects of the principle of justification as well as into specific aspects such as radiological imaging for asymptomatic patients, children and pregnant women, into the further development of tools such as referral guidelines, the clinical audit, into the role of professional societies, etc.; all matters in which the Commission is very active as well, both in my unit, the RP unit of DG TREN, as well as in the research programme of our colleagues in DG RTD.

The workshop is also timely with regard to the ongoing revision of international standards. The EC is deeply involved in these in order to ensure full coherence between the international standards and the EURATOM standards, in view of our eventual co-sponsorship of international standards.

This workshop is of course only one of many initiatives in the medical area, and it is only one of the areas of cooperation between the EC, the IAEA and WHO. The EC plans the adoption of a communication next year elaborating our long term policy in this area. No doubt this communication will receive fair media attention and raise the awareness of stakeholders. The results of this workshop will of course be reflected in this communication.

SETTING THE SCENE

(Session 1)

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J. MAYO
Canada

Rapporteur

G. O'REILLY
Ireland

JUSTIFICATION: THE IAEA INITIATIVE

O. HOLMBERG
Radiation Protection of Patients Unit,
Division of Radiation, Transport and Waste Safety,
International Atomic Energy Agency,
Vienna
Email: o.holmberg@iaea.org

Abstract

A substantial percentage of medical procedures using ionizing radiation are lacking in justification and optimization, rendering unnecessary a substantial fraction of the effective dose per capita from medical exposures, and thereby causing an unnecessary radiation burden to the global population. The paper presents data published by the United Nations Scientific Committee on the Effects of Atomic Radiation, and information about relevant actions being taken by the IAEA through its International Action Plan for the Radiation Protection of Patients.

1. INTRODUCTION AND BACKGROUND

The use of ionizing radiation in medicine is an activity of enormous size and global distribution. It is estimated that every day around the world, ionizing radiation is being used for the imaging of patients in more than ten million diagnostic radiology procedures and one hundred thousand diagnostic nuclear medicine procedures, while twenty thousand radiotherapy courses are started along with many therapeutic nuclear medicine procedures. Since its discovery, ionizing radiation has brought mankind tremendous benefits when used in medicine. While the use of radiation in medicine is increasing rapidly overall, it is unevenly distributed around the world.

As a result of this massive activity, the world's annual per capita effective dose is increasing rapidly, almost exclusively due to increasing medical exposures, which is now equal to or exceeds that from natural background in some countries. The global figure for the effective dose per capita from medical exposure was estimated by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) to have increased from 0.3 mSv (1993 Report) [1] to 0.4 mSv (2000 Report) [2], reaching a current value of 0.64 mSv (2008 report) [3]. The corresponding present figure for the United States of America is 3.0 mSv (NCRP Report 160, 2009) [4], indicating clearly the trend of rising radiation burden from medical exposure (Fig. 1). In themselves, these figures are not a problem, but can be seen as an indication that access to radiation in medicine is increasing for the global population. There is, however, evidence that a substantial percentage of medical procedures using ionizing radiation are lacking in justification and optimization, and thereby that a substantial fraction of the effective dose per capita from medical exposures is unnecessary and thus is bringing an unnecessary radiation burden to the global population.

2. ISSUES IN RADIATION PROTECTION OF PATIENTS

Patients subjected to medical exposure need to be protected from unnecessary and unintended exposure. Unnecessary exposure of patients can arise from medical procedures that are not justified for a specified objective, application of procedures that are not justified for the individual's condition (Fig. 2), and medical exposures that are not appropriately optimized for the situation in which they are used, leading to unnecessary risks due to stochastic effects. Unintended exposure of patients can arise from the unsafe design or use of medical technology. Accidents arising from unintended exposure can lead to deterministic effects or loss of tumour control.

An issue relating to the radiation protection of patients is the rapid clinical introduction of new medical technology, including the increased use of computed tomography (CT) scanners for radiological imaging procedures, with relatively high associated patient doses. CT contributed less than 15% to the global collective dose from medical X ray examinations in the time period 1985–1990 [2]. This figure rose to more than 30% in the time

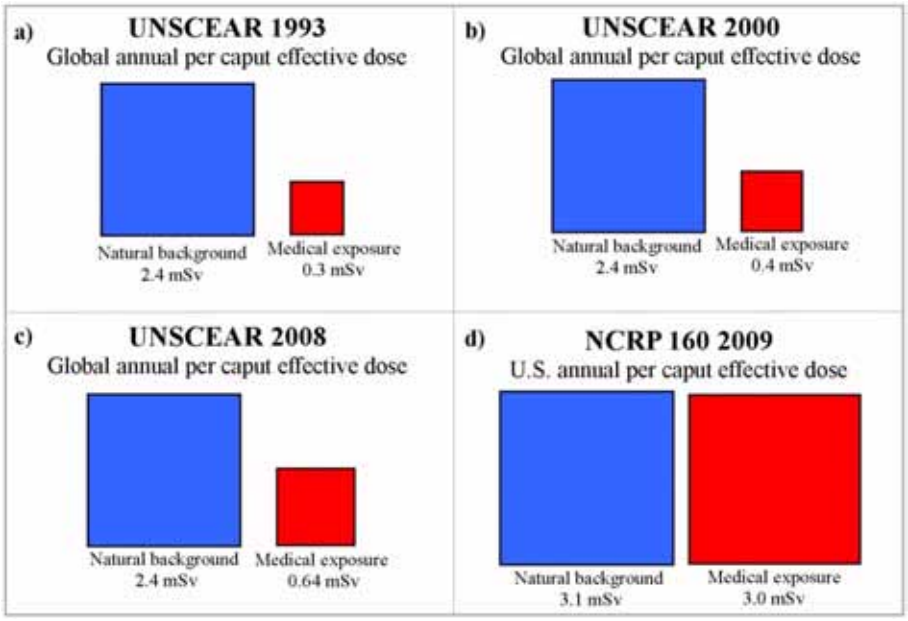

FIG. 1. Annual per caput effective doses from natural background (size proportional to blue square) and medical exposures (size proportional to red square) reported by UNSCEAR (globally) a) in 1993 [1], b) in 2000 [2], c) in 2008 [3] and d) by NCRP (USA) in 2009 [4].

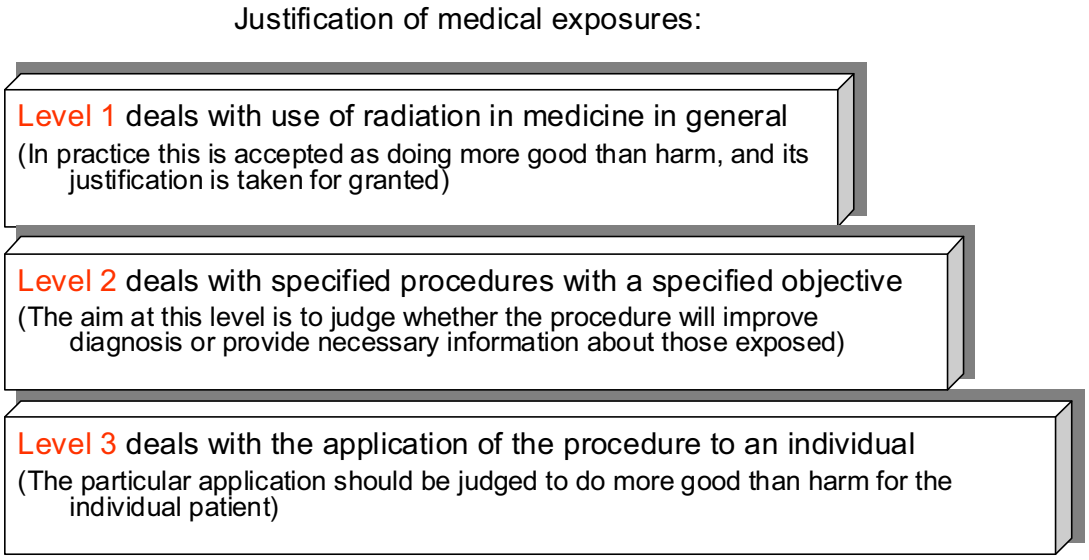

FIG. 2. Justification of medical exposures operates at three levels, as identified by the International Commission on Radiological Protection (ICRP) [5, 6] (from HOLMBERG, O., MALONE, J., REHANI, M., MCLEAN, D,. CZARWINSKI, R., "Current issues and actions in radiation protection of patients", Eur. J. Radiol. Jul 16, 2010).

period 1991–1996 [2], while according to the latest global data, CT scanning accounts for 42% of the total collective effective dose [3]. Patient surveys reveal a wide range of doses for the same examination, indicating lack of optimization. Other investigations also show the significant and systemic practice of inappropriate examination in radiology, indicating a lack of justification. These issues require effective solutions.

Reports of unintended exposures in radiotherapy also continue to appear, involving overexposure of patients as well as the systematic underexposure of large groups of patients. This highlights the need to continue to strengthen international efforts to find effective solutions for the radiation protection of patients.

3. THE INTERNATIONAL ACTION PLAN FOR RADIATION PROTECTION OF PATIENTS

In March 2001, an International Conference on the Radiological Protection of Patients was held in Malaga, Spain. A major outcome of this conference was a request to the IAEA to formulate an action plan for future work relating to the radiation protection of patients. The International Action Plan (IAP) for the Radiological Protection of Patients was prepared and approved by the IAEA's governing bodies in 2002. The overall objective of this action plan is to make progress in the radiation protection of patients as a whole, noting that the involvement of international organizations and professional bodies is crucial to performing the actions and achieving the goals outlined in it. The IAP is ongoing, coordinated by the IAEA and kept under review by a steering panel consisting of individual experts and representatives of international organizations and professional bodies including WHO (World Health Organization), PAHO (Pan American Health Organization), UNSCEAR (United Nations Scientific Committee on the Effect of Atomic Radiation), EC (European Commission), ESTRO (European Society for Therapeutic Radiology and Oncology), ICRP (International Commission on Radiological Protection), ICRU (International Commission on Radiation Units and Measurements), IEC (International Electrotechnical Commission), IOMP (International Organization for Medical Physics), IRPA (International Radiation Protection Association), ISRRT (International Society of Radiographers and Radiological Technologists), ISR (International Society of Radiology), ISO (International Organization for Standardization), and WFNMB (World Federation of Nuclear Medicine and Biology).

Many actions are being taken under the IAP. The types of actions include: 1) providing standards; 2) providing training; 3) providing guidance; 4) facilitating knowledge exchange; 5) providing direct technical assistance; and 6) building awareness. Much progress has been made over the years in addressing the optimization of medical exposures and increasing safety in medical exposure. There has been less progress made in addressing the justification of medical exposure over the years. It is the aim of this workshop to investigate the issue, and find practical solutions to improve this situation.

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JUSTIFICATION AND TOOLS FOR CHANGE: SCENE SETTING

J. MALONE*
International Atomic Energy Agency,
Vienna

Abstract

The paper seeks to set the scene by providing a summary of some key points in the social, legal, philosophical, medical radiological and radiological protection background to this meeting. In addition, it identifies the hopes and expectations held by the organizers when they took the initiative to organize the meeting.

1. INTRODUCTION

The immediate precursors of this workshop were two consultation initiatives held by the IAEA in Vienna. These, in turn, arose from growing concerns on a number of fronts, including increasing doses, ongoing research and related projects in the EC. In addition, many practitioners of radiation protection in the medical field doubted the efficacy of justification, but suspected that there was little that could be done in practice to improve it.

The reports of formal activities in these areas, cited below, speak for themselves. They provide many insights, and it is hoped that by bringing them together here a more coherent overview of the problem will emerge and the initiatives that might be taken to address it will become clearer. This, among other objectives, is the intention of this workshop.

2. JUSTIFICATION

The Compact Oxford Dictionary indicates the noun *justification* has its origins in the Latin verb *justificare* 'do justice to' [1]. The verb is defined as follows:

- **verb** (**justifies**, **justified**) **1.** Prove to be right or reasonable. **2.** Be a good reason for. **3.** Printing adjust (text) so that the lines of type fill a given width exactly, forming a straight right edge.

The dictionary identifies a special resonance for the noun with its usage among the Lutheran and Protestant Christian Churches founded on Martin Luther's teaching of "justification by faith alone" [1]. The sense in which the concept is used in radiation protection is based on the first and second definitions. However, it is not without baggage from its origins and it continues to suggest a high moral tone with ethical as well as scientific/medical resonances.

In radiation protection, the development and use of the concept of justification has been promoted by ICRP as a cornerstone of its system, together with optimization 'as low as reasonably achievable, economic and social factors being taken into account' (ALARA) and dose limitation. Justification has, accordingly, been introduced into the legal systems of numerous countries, and has been key to the International Basic Safety Standards (BSS) published by the International Atomic Energy Agency (IAEA) and the radiation protection directives of the European Commission (EC) [2, 3, 4, 5].

ICRP explicitly identifies justification as critical to radiation protection in medicine [2, 3]. Some of its key features include the following:

* Permanent address: Professor of Medical Physics, Trinity College, Dublin, Ireland. Email: jifmal@gmail.com or jfmalone@tcd.ie

FIG. 1. Harrowing of Hell, Fra Angelico, with trapdoor for those failing justification.

- Justification in medicine is established, in theory, for each individual patient;
- Consent of the exposed individual is inherent in the justification process;
- Medical exposures are not subject to regulatory dose limits.

These features acknowledge that medical exposures are to help and benefit the patient. The process of justification ensures that the benefits to a patient substantially outweigh any short or long term risks incurred [6]. The manner in which consent is expressed is not detailed by ICRP and is subject to active consideration and ongoing development [7].

In medicine, ICRP notes that there are three levels at which justification operates. The following definitions and comments summarize ICRP's exposition of this area and have been considered in more detail elsewhere [6, 7]:

- **Level 1: Justification of use of radiation in medicine**

At the 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 specific procedure with a targeted objective is defined and justified (such as chest radiographs for patients to whom an anesthetic is to be administered). The aim of the second level of justification is

to establish if the identified procedure will improve diagnosis or provide necessary management information for the benefit of the group of patients involved. It may be possible to improve justification by sharpening the definition of the group to be exposed.

- **Level 3: Justification of a procedure for an individual patient**

At the third level, the application of a procedure to an individual patient is justified (i.e., the particular application should be judged to do more good than harm to an 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.

ICRP and recently published IAEA consultations provide further discussion of the levels and the background to the use of the concept of justification. In practice, the second and third levels of justification are those that come into play in the operation of diagnostic imaging, and are the main concerns of this workshop. However, the term can take on additional socio-political meanings [6, 8, 9]. Finally, it is clear that the processes and practices of medical justification cannot adequately deal with situations involving deliberate human exposures for non-medical purposes, e.g. drug searches, security and many other applications [10].

3. GENERAL BACKGROUND

The philosophical framework for the current approach to justification lies in ICRP 60 [11]. This publication carries much baggage from an earlier era. While it served the system of radiation protection well, it requires updating to bring it into line with contemporary philosophical, social and legal thinking. Valuable work in this regard has been undertaken and addressed elsewhere [6, 7, 9, 12]. Here it is enough to note that the post-WW II paternalism of the professions no longer provides an acceptable guide to appropriate actions. There are also many other shifts in how basic value systems and social concerns are expressed [8, 9, 13]. Here is a short list of areas in which there has been profound change since the concept of justification was formulated and introduced by ICRP: euthanasia, assisted suicide, marriage, divorce, single parents, disability, gender, mistrust of authority/professions, the right to life and the autonomy of the individual.

In many cases these changes are reflected in the law, social policy and practices of society. This is particularly so in medicine, where there has also been substantial shifts in practice, often driven by social or legal developments and often, initially, resisted by the health professions. In particular, there have been significant developments in the areas of patient status and consent. Sometimes these are easiest to visualize by referring to extreme examples. These might include a changed model of access to hospital facilities which function more or less on a consumer basis as can be the case in some instances of medical tourism. Likewise the Stark Law in the US illustrated an extreme problem in regulating health care providers and their charging patterns [14].

It is further evident that the concept of justification must now be applied in health care systems that are very different to those that prevailed a few decades ago. The influence of health economics and special interest groups on decision making has become very important and may on occasion override individual clinical decisions [15]. Examples include the fact that interest groups may divert resources to benefit their group; health professionals may be under pressure to optimize revenue; bureaucracies, including regulatory agencies, can be self serving to the detriment of the common good; politicians need to deliver things for the public at large, e.g. screening programmes; and the level of provision to the underprivileged and marginalized can be distorted. These problems and many more have given rise to a more formal approach to Health Technology Assessment (HTA). Arising from such studies there is now in these proceedings, and in wider literature, a strong sense that there may be significant overutilization of some technologies in medicine, including imaging [16, 17].

The final area in which the prevailing environment has radically altered since the introduction of the concept of justification is in the level of openness, accountability and transparency expected of professionals and the institutions in which they serve. This is obviously different in different parts of the world. However, the direction in which external pressures are applied is invariably more in favour of openness, accountability and transparency. This imposes a new burden on professions not accustomed to this type of oversight. In medicine, enquiry into serious problems may start with a peer review process. Where this fails, enquiry by a professional body, in former times, often yielded acceptable results (such as the Medical Council in the UK). However, it is now common for the

findings of such groups to be regarded as unsatisfactory and self-serving. When this is the case, formal tribunals of enquiry follow to determine the pertinent matters of fact and resolution comes through the courts. Determining facts and guilt/punishment has become a much more common feature of the lives of health professionals [7, 9].

4. MEDICAL ISSUES

Medical practice in general and radiology/medical imaging in particular necessarily takes place within the context of the above general developments in society and expectations of its citizens [9]. This, and its consequences for radiation protection in the medical sphere, have been reviewed at some length elsewhere, and a few of the more important points vis-á-vis justification will be summarized here [7, 9].

Perhaps the defining characteristic of medicine in recent times has been its immense scientific and technological success coupled with an iconic repositioning in the public consciousness. This has been accompanied by a growth in the level of expectation placed by the public on hospitals and medical institutions, to a level where these are probably unrealistic and place an undue burden on the health care system and those working in it. This also, inevitably, creates public disappointment and anger when expectations are not met.

On the down side, the model for the provision of medical services continues to harbour a strong paternalist approach. It is not uncommon to encounter evidence of desensitization of professions to the concerns of the public [18]. The health professions frequently fail to recognise that growth in individual autonomy, a consumer culture, transparency and accountability are dominant influences in the way social (including medical) transactions are expected to take place. This has led to a distrust of the authority of professions, and can ultimately lead to the collapse of professional self-regulation [19]. Examples of these phenomena can be studied in the history of various medical scandals, such as blood products issues, infant organ retention stories and many others [8, 9].

Echoes of these problems are evident in radiology and arise in any critical evaluation of justification in the area of medical imaging. As will be seen during this workshop, there are serious concerns that imaging is overutilized and not justified in many circumstances [16,17] and that the consequences include both the significant consumption of resources with little return in outcome, as well as possible harm to patients [16, 17, 20, 21, 22 23]. Perhaps this is well captured in the following extract from the New York Times in a piece following publication of a paper in the New England Journal of Medicine [24, 25]:

“ ‘I think the central driver is more about culture than anything else,’ Dr. Krumholz said. ‘People use imaging instead of examining the patient; they use imaging instead of talking to the patient.’ — ‘Patients should be asking the question: ‘Do I really need this test? Is the information in this test going to help in the decision making process?’ — ‘In many cases, there is little evidence that the routine use of scans helps physicians make better decisions, especially in cases where the treatments that follow are also of questionable efficacy.’ ”

This reinforces a view earlier expressed that much professional behaviour in the area is effectively ritualized and will be difficult to change. However, in the area of justification and closely related aspects of practice there is a growing realization that this will be necessary [6, 7, 12, 26, 27].

With respect to radiation protection professionals in the medical services, similar concerns apply, even though the defining characteristics of the profession are somewhat different. These include a relatively strong base in the hard sciences. However, it has been developed mainly outside medicine, and as it is used mainly within medicine, there is some level of mismatch. One of its greater problems is that the radiation protection system employs an arcane language and units which are impenetrable to those outside radiation physics. This compromises the possibility of its message being received, understood and acted on by health professionals. This language is protected by physicists and will not be easy to change.

In practice, many physicists working close to the coal face know that justification does not work as it should, but feel there has not been much that could be done about it. A rigorous analysis is unlikely to find this position defendable. Finally, radiation protection professionals have special problems in coping with social and media perceptions of radiation, an area which requires a new approach.

5. INCREASES IN DOSE

A central issue in setting the scene for this workshop is the increase in dose from medical procedures, both in terms of the frequency of examinations and the dose per examination. These are discussed at some length in recent publications [28, 29] and will not be reviewed in this paper other than to note their central importance and to note the summaries of the values involved presented elsewhere in these proceedings [20, 30, 23].

6. CONCLUSIONS FROM TWO IAEA CONSULTATIONS

Concerns about the practice of justification in medicine led the IAEA two organise two carefully framed consultations, one each in 2007 and 2008. Each involved 10 to 12 participants, including IAEA staff. The consultants were drawn from many disciplines and once nominated acted as experts making judgements in their own right without reference to a nominating constituency. Reports on both consultations have been published [6, 7].

6.1. IAEA consultation 1 (Dec 2007)

This was a broadly based group consisting of a cardiologist, radiologist, health economist, lawyer, philosopher, physician and physicists. It defined a philosophical and legal basis for medical exposures in terms of the:

- **Agent** responsible for and performing the exposure;
- **Act** of the exposure; and
- **Recipient** of the exposure (or patient).

The issues involved were revisited and grounded in contemporary philosophical, legal and social thinking. Among the dominant themes emerging was the need to give more attention to the autonomy and dignity of the individual patient [6, 13, 31]. In this context, the questions of communication and consent take on a new importance. Additionally, accountability to the public and to patients was viewed as being as important as, if not more important than, accountability to professional peer groups [6].

This consultation also reviewed the then limited evidence on the level of knowledge of dose and risk that physicians and radiologists use in making justification decisions. They concluded that it is probable that physicians seldom know how to assess the risk and radiologists often do not. This was deemed a matter for immediate concern requiring attention. They further concluded that there are a series of practical and special issues requiring attention, including the use of arcane language and symbols in education and training that health professionals and the public do not relate to; tools such as referral/appropriateness guidelines which though available are not widely used, and the potential of clinical audit as a tool for justification [6].

6.2. IAEA consultation 2 (Nov 2008)

This was also a broadly based group but its remit was much more focused. The first consultation established that it was probable that there are serious problems with justification. This one concentrated on possible approaches to remedying the situation. Apart from some important general conclusions, consultation concentrated its suggested remedies around three areas, the three A's: **awareness, appropriateness and audit** [6, 7].

The conclusions included a strong feeling that there is a significant, systematic practice of inappropriate examination in radiology. Further, the group were fully aware that their recommendations on communication of risk, use of referral guidelines, and audit would impact on the operational life of a department. In addition, they asserted that effective training, in communication, the social function of departments, referral/appropriateness guidelines and clinical audit are essential.

In respect of the first of the three A's, **awareness,** it was felt that a physician or radiologist requires a working knowledge of risk to be able to justify imaging procedures. However, there are serious deficiencies in the communication of risk and dose among health professionals that make this difficult. In particular, the system of radiation units is not suited to communication with the public, patients or health professionals. With respect to

consent, it is a non-negotiable requirement that radiological procedures and communication with patients must be skillful, nuanced and well understood.

Great improvement in the second A, **appropriateness** can be achieved through the use of referral or appropriateness guidelines [32]. These have the potential to lead to a rapid dose reduction of 20% with a potential 40% reduction. To achieve this, it is likely that local and regional guidelines will have to be developed. The uptake and use of guidelines throughout the world depends on access to them and their presentation. In this area it was felt that further attention is required on issues associated with self-referral, self-presentation and screening programmes.

The third A, **audit (clinical),** should be undertaken in a fashion that accords a priority to justification. It should assess compliance with referral guidelines and the quality of communication with patients. The outcomes from audit must be integrated in a department's operating life. Both internal/external audits were encouraged on the basis advised by both the EC and the IAEA [26, 27].

7. EXPECTATIONS, CONCLUSIONS AND PROBLEMS WITH JUSTIFICATION

From the above it is clear that there are significant knowledge and communication issues regarding justification. Perhaps one of the more dramatic illustrations of this is the investigation described by Shiralka et al. in 2003. In this, 130 doctors, including 40 consultants, and some radiologists were studied. Practically nobody from the group knew the dose quantity (or the unit in which it is expressed) for a chest X ray, and almost all underestimated risk [33]. These findings and those in closely allied areas are confirmed in these proceedings [20, 23, 34].

The organizers of this workshop had a number of expectations. In particular, they were concerned about improving awareness of the ongoing work in justification and concerns about it in the European and world radiological and regulatory communities. They were also anxious to expose what they felt to be a sound, contemporary philosophical, legal and social basis for policy, regulatory and practice development to the critique of a widely based audience from both the developed and the developing worlds.

It is hoped that high quality reference material and publications will be produced on the basis of the material presented at the workshop.

With respect to the tools identified at the second consultation, the desire was to get a clear account of the state of development of the three As, and to identify whether they are mature enough to begin a campaign to have them or similar approaches more widely adopted. In particular, it was hoped the workshop would provide useful advice on their development, adaptation and dissemination.

The findings in respect to knowledge, communication, evidence, accountability, and legal issues all give cause for concern. However, as illustrated in the concluding and overview papers in these proceedings, it is also clear that there are paths that allow the problem to be dealt with in what is likely to prove to be a satisfactory way [35, 36, 37].

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RE-EXAMINING ETHICAL ISSUE: PHILOSOPHICAL CONSIDERATIONS

S. SIA
Milltown Institute,
Dublin, Ireland
Email: ssia@milltown-institute.ie

Abstract

The paper reflects on the current trend among radiologists to move away from what is regarded as a paternalistic attitude existing among practitioners and to place more emphasis on the rights of individual patients with regard to the issue of justification. The ethical discussion addresses the autonomy and rights of the patient, as well as the question of consent on his or her part.

1. THE ETHICAL CONTEXT

There is some move on the part of radiologists to re-think the issue of justification as it applies to their profession [1]. This gathering, as well as similar ones in the past, attests to this. The move appears to be in the shape of a shift in emphasis from what has been regarded as a rather paternalistic attitude of practitioners to one which stresses the rights of the individual patients. There are several implications, some of which have already been noted. Since my contribution to this workshop is meant to be philosophical, rather than scientific or medical, my concern here is to reflect on this current move on the part of the profession by offering certain philosophical considerations which are relevant to the present discussion on this topic [2].

In an earlier paper I discussed what is involved in the ethical task and its challenges and in the search for ethical justification [3]. More recently, I had also offered an ethical framework within which the discussion on justification in radiology could be facilitated [4]. To contextualize what I should like to offer now, it is useful to be reminded that the ethical task — in the present context, the search for an ethical criterion to justify the practice — is much more than just following or implementing agreed guidelines. In fact, what makes such a task more challenging is that it is rather complex because it involves so many factors. This is as true in a professional context (like radiology) as it is in daily life. And yet, one is expected to act — and to act ethically — despite this complexity. This is really the nature of the ethical task: it is ultimately a human judgement on the part of the agent (that is to say, the ‘doer of the action’). At the same time, however — and this is a crucial consideration, contrary to the views of many — the judgement made by the agent is not a completely subjective or arbitrary one. It is based on a criterion that has been seriously and fundamentally considered (that is to say ‘an ethical norm rather than a scientific fact’). For this reason, the discussion on justification differs from the related discussion that deals with the issue of optimization. The ethical framework that I had previously offered focused on the agent, the act and the recipient and the need to take all three into account.

2. AUTONOMY AND CONSENT OF THE RECIPIENT

This paper aims to advance the ethical discussion on this topic by the profession — it would therefore be useful for the reader to have read the previous papers — by commenting on the shift in emphasis towards the recipient of the act (and away from the agent), since this strategy brings to the surface some important and fundamental philosophical issues such as the autonomy and the rights of the patient as well as the question of consent on the patient’s part.

The current focus on human individual autonomy — even in contemporary philosophical thinking — is actually rooted in a long tradition that claims that each and every human individual is, to use Immanuel Kant’s terminology, an ‘end to itself’ [5]. That means that the individual’s ability to exercise his or her freedom comes from within oneself, rather than from outside. It is not, therefore, conferred, but acknowledged. It is, to adopt business-speak, non-negotiable. It is the basis for the fundamental rights of the individual which all others have a duty to respect. It is for this reason that, as Kant would put it, every human individual has dignity and not just

value.[1] Unlike the worth of, say, a work of art or a material possession[2], it is invariable and cannot be taken away without doing an injustice to that human individual. For Kant (and for the vast majority of philosophers) the human individual is therefore itself the source of one's law, and therefore is truly free and has inalienable rights. This autonomy is what marks the human individual off from every other creature.

But the affirmation of human autonomy is complicated by the fact that such an exercise of freedom takes place within a social context. In other words, since every human individual is autonomous and since every such individual needs to exercise its autonomy in human society, a conflict of rights takes place. There is a fundamental need to recognize and acknowledge that other human individuals are themselves centers of autonomy whose rights must also be respected. It is for this reason that Kant's view has been modified by others: the suggestion has been made that one must not regard human autonomy or human rights in absolute terms. A number of contemporary philosophers have talked therefore of prioritizing human rights. However, this is much more than just putting rights on a sliding scale — an impossible task in itself — but rather of putting the onus on those who wish to override the fundamental status and rights of the human individual to provide reasons which can legitimately and justifiably be accepted. In other words, the autonomy of the human individual remains intact until and unless there are good and solid reasons to affirm otherwise. To a large extent, this is where utilitarianism, particularly as developed by the philosopher JS Mill [6] and nuanced by a number of contemporary philosophers, can be helpful in that it does supply us with a way towards reconciling competing claims. Despite the ambiguity of both the criterion itself and the difficulty of its implementation, the need to reckon with the consequences — benefits and risks in the present context[3] — of our actions and to evaluate them in terms of the kind of impact and the number of affected parties provides a more tangible and manageable way out. However, it should be added that among others, this philosophical ethical theory is also criticized for sacrificing the individual good — and not always in a laudable way — by pushing forward what some may claim to be the common good. Moreover, it can be accused — at least, in certain versions of utilitarianism — of prejudging both the kind and extent of consequences while ignoring the basic rights.

This philosophical discussion, despite the seemingly theoretical air about it, has practical implications, not least in our present context. The move by radiological practice towards affirming patient autonomy is, in fact, a recognition of the dignity of every patient as a subject, rather than an object. In other words, the patient is not a thing to be worked on but rather a unique individual. For this reason, such a recipient of one's action is not a receiver of one's action in the way that an object in an assembly line is but rather one that requires individual personal attention[4]. Thus, the re-thinking of justification in radiological practice is not merely a move away from what was regarded as paternalistic, but is rather an awareness of the status and the role of the recipient. This is where the call for soliciting the informed consent of the recipient is particularly relevant. What justifies the need for informed consent is based on the nature of the recipient. As a subject (in the ethical sense), that human individual must be respected as a human individual, and not just the recipient of someone else's action. Informed consent is based on his or her nature as a being with intellect and free will and the need to be treated as such. Paternalism can be rightfully accused of promoting heteronomy — although it must be noted it may not always be questionable in some cases, but is so in this instance — inasmuch as the decisions are being made on behalf of the recipient by others who believe that decision making should be relegated to those who 'know best', namely, themselves.

But we do need to qualify all this. Just as there are difficulties with the Kantian emphasis on the autonomy of the subject, we must also be aware that soliciting the consent of the recipient is not always nor necessarily acting in the best interests of the recipient. The usual way of dealing with this issue is to turn to the phrase 'informed consent' or 'valid consent'. Having the relevant information and communicating it to the recipient of the action is of course of primary importance in acknowledging the recipient as a human individual. As has been noted already, this is to acknowledge that he or she is entitled to such knowledge as befits his or her nature. However, as Aristotle has

[1] Some contemporary philosophers have introduced in their ethical discussion the distinction between the concept of 'human being' (a descriptive term) and that of the 'person' (a prescriptive term). The latter term implies a certain moral attitude or response on our part.

[2] Given the present economic situation in the world, a more relevant comparison would be shares, stocks or pension funds!

[3] The accepted phrase in radiology seems to be 'benefits and risks'. Strictly speaking, however, if one were referring to consequences, it should be 'benefit and harm (including possible harm)'. This is because taking risk itself can be justified since it is necessary for our development as human beings.

[4] A purely 'clinical approach' therefore ignores the humanity of the patient.

rightly pointed out, having the right knowledge is merely one aspect to being able to make the right judgement. The situation is aggravated by the complexity of the data. We have become aware of the enormity and complexity of the information that is thrust upon us by all the developments in the scientific and technological world in which we live. 'Informed consent' should therefore not merely mean 'being in possession of the relevant information' but more crucially 'being able to process correctly all the information that has been given'[5]. This presents the agent of the action[6] with a difficulty and may account for the paternalistic practice of withholding some information or of relegating decision making to those who do have the expertise to make the right judgement. Worse, providing all the information to the recipient could lead to unacceptable consequences for the recipient, including damaging that individual's well-being[7]. 'Being able to process correctly all the information that has been given' therefore means more than just being able to understand the data but also being able to correctly act on the information. This is where the 'consent' part of the phrase 'informed consent' is crucial. For 'consent' in the ethical sense — as distinguished from other contexts — is not simply agreeing on the basis of one's knowledge but 'being in a position to agree'. And that differs from individual to individual and from case to case. Moreover, 'consent' refers to the recipient as one who has not just an intellect but also free will. This complicates the matter even further, since the question could be asked how freely given the consent is. Outside pressures, as well as both individual and social circumstances, do limit the amount of freedom an individual has in decision making, including medical treatment. The keyword here is 'voluntary'. In short, just as excluding the recipient from the decision process is ethically questionable, putting the onus of decision making on him or her is not always the best way forward either in our attempts to re-think the ethical issue of justification in radiology, since the recipient may not after all be in a position to really exercise his or her autonomy.

Earlier I had referred to the notion of autonomy as indeed highlighting the dignity of the human individual. At the same time I stated that this has to be understood in context. It is important, therefore, to keep in mind that in the present context, what is really more crucial is not autonomy as such but the exercise of that autonomy. The distinction between the two is conceptual of course, hence abstract, but its reality is concrete and therefore has practical implications. That is to say, while we must indeed respect the autonomous nature of each human individual, we must also be alerted to the factual situation regarding its exercise. This is because the exercise of autonomy is always social: it is always over another. And that other, especially if it is also autonomous, has rights which must also be respected[8]. And that is what leads sometimes to a conflict of rights, a situation which needs to be resolved. For this reason, one should not overplay the 'autonomy of the recipient' card — without considering that it cannot and should not be 'absolutized'. Otherwise, one could be accused of 'reverse paternalism' whereby we offload responsibility on the recipient without taking into serious consideration whether indeed the recipient — and I am not necessarily talking of extreme cases — is in a position to make the decision.

3. THE MORAL SENSE OF THE AGENT

From what has been said so far, it seems that I am in fact returning to — rather than moving away from — the agent in re-thinking the issue of justification in radiology. To an extent this is true but only because in ethics ultimate responsibility rests with the agent, that is the doer of the action. Nonetheless, it is not a simple return to the paternalistic attitude that has incurred some justified criticism and has prompted re-thinking. In other words, it is not the claim that 'the practitioner knows best' that is being advocated here; rather, it is that the practitioner, who is the agent in this case, must ensure that he or she is 'acting from a sense of responsibility'. Needless to say, that includes 'having the right knowledge base', or ascertaining that one has the most informed basis on which to act

[5] The issue of communication, already identified in the current discussion on justification in radiology, is particularly relevant. It is not simply 'imparting data' but dealing with a human situation.

[6] The 'agent' is not merely a reference to the individual practitioner, but to the entire professional body. There is such a thing as 'corporate responsibility'.

[7] For this reason, clarity and accuracy of communication are not sufficient as the human situation also calls for sensitivity on the part of the agent.

[8] This point is particularly pertinent to specific cases like self-presentation, self-referral as well as the distribution of scant commodities. It also raises the issue of balancing public and individual interests, a topic that I will address further in a paper for the International Symposium on Non-Medical Exposures in Dublin in October 2009.

from a medical and scientific point of view. It would certainly be regrettable and even irresponsible if that were lacking[9]. But just as important in this context is developing what I call 'the moral sense of the agent'. Nurturing moral sense — as we should do in all aspects of life — and at times relying on it when faced with new situation, as we may have to at times in medicine and science and elsewhere, is a difficult task indeed. But ultimately, since we have to, and indeed do, make moral judgements, it is essential that we are guided by a moral sense that has been deepened and strengthened by continuous ethical reflections not just in day-to-day living but also in our professional endeavours. In this respect, the early education of practitioners in this area is truly crucial. Since they are dealing with human subjects, they have to face up to the human situation and not just to the medical, clinical or technological side of their training.

Moral sense is much more than just moral sentiment or feeling. Nor is it an intuition or an intellectual ability that enables one to distinguish between right and wrong. Moreover, it is not simply a hunch that one follows when one exercises one's free will. And yet all of these come into play since moral sense is ultimately based on our very humanity[10]. As human beings, we possess feelings, intellect and free will, and when we ask what is ethical and what is not, and draw a conclusion, we make use of all these gifts.

The word 'sense' carries different meanings, each of which we can avail of to shed light on 'moral sense' (as used in the present context). 'Sense', of course, means our five senses that enable us to be in contact with the outside world. The word is also used to refer to someone having 'sense'; and we mean that that person does not just know but has the right knowledge. It can also mean simply, 'in a particular instance', as when we qualify a statement or a claim when we say 'it is true in this sense'. But 'sense' can also have a stronger meaning as a more or less coherent overall view as when we talk of 'life making (or not making) sense'[11].

The phrase 'moral sense' draws on these meanings. It is through our senses that we accumulate experience, including moral experience, about the world around us. We require the right knowledge, and not just any knowledge, to enable us to act ethically. We need to be aware of the particularity of a situation to enable us to judge the appropriateness of our judgement or decision. More importantly, we ought to be informed by an overall perspective that helps us not just to situate the particular moral situation or context but also to judge it consistently[12].

The various uses of 'sense' and their applicability to the phrase 'moral sense' means that ethics should not be interpreted as an instinctive, wilful or even a cerebral activity. It is a rational activity, by which I mean that it involves all the abilities that human beings possess, including the use of our intellect[13]. And since it takes place in concrete situations and particular individuals, it is an activity that draws on various sources, including gender, culture and religion, and so on, whenever we resort to it.

Moral sense has a particular role to play in our ordinary and professional lives. The will to act must be spurred by our moral sense to ensure that we are indeed acting ethically. This is because the pursuit of ethics should lead not just to knowing what is right and wrong — in the broad sense indicated above — but ultimately to doing that which is right, and avoiding that which is wrong. For this reason, there is a justified expectation that ethics should facilitate our becoming more responsible, more civic-minded, and better behaved. This is a greater challenge. On the other hand, while ethics itself may not necessarily lead to ethical conduct of the individual agent, it nevertheless promotes and sustains it, at least indirectly. While knowledge of what is right needs other factors to make us want and pursue the good, ignorance of relevant information, including what is involved in making the ethical judgement or decision, can easily lead to irresponsible or unethical conduct. Since acting ethically is dependent on our knowledge of a situation, the more we know the relevant factors, including our moral norms, the less we are in danger of acting unethically.

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[9] In ethics, one talks not just of 'commission' but also of 'omission'. One is accountable not just for what one has done but also for what one should have done but has not done.

[10] There is a close association of 'moral sense' with 'conscience', but I am distinguishing the two because certain connotations associated with one would not necessarily apply to the other.

[11] Contemporary philosophy, influenced by the postmodern trend, has shied away from pursuing the so-called 'biggest picture' of life. However, there are signs that such a trend is being reversed.

[12] Contemporary ethical philosophers, like John Rawls in his A Theory of Justice, have moved away from pursuing merely meta-ethical issues to construct ethical theories.

[13] I am therefore distinguishing between 'reason' (usually associated with the use of the intellect) and 'rationality' (referring to the whole of human nature).

In decision making or the pursuit of an action, it is important once again to note that it is not simply a matter of deciding and then acting but of situating it against a wider background. Situation ethics, which focuses almost exclusively on the particular situation or circumstance as dictating the morality of an action, ignores the need not only to be consistent in our ethical judgements — a lesson that can be learned from Kant — but also to be right in our judgement. In ethics, what is appropriate or even what is legal is not only always the right ethical decision. We have to guard ourselves against making simply ad hoc decisions[14]. In this respect developing a moral sense — a sense of responsibility that is spurred on by what we can do but is constantly guided by what we ought to do or not do — is particularly crucial. This underlies the need for the larger picture — as well as ethics education generally.

4. CONCLUDING COMMENTS

Ethics challenges us to provide a more consistent and more systematic answer. In some cases the answer to the question "what ought I do?" has to be a quick and even instinctive one. But in the ethical context, one's answer should be much more thoughtful. This does not mean that every time we find ourselves in an ethical situation, we cannot and should not act until we have undergone a prolonged and thorough process of thinking about the matter. Many cases, particularly medical ones, do not allow us that luxury for every problem. But ethics — and the role it can play in one's training and education in the professions — can be of paramount importance as it can provide us with a 'theoretical framework' that enables us to work out an ethical solution to a problem. The basis for one's judgement, even those made in a hurry, can be more firmly grounded. What ethics education does is to expose underlying theoretical assumptions and subject them to a critical evaluation, thus giving us an 'early lead' as it were in urgent cases. Ethics education — which nurtures one's moral sense — can be described thus as bringing to the fore, with a view to scrutinizing more critically, not just the questions we are asking but also and more importantly disclosing the underlying assumptions behind those questions. And I believe that it has an important role in re-thinking the issue of ethical justification in radiology as much as in every facet of life.

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[14] Here ethics committees, audits (both internal and external) and agreed guidelines have an important role to play. The term 'clinical audit' may raise suspicions, however, despite the explanations of their purpose and status. A less contentious term is probably 'quality assurance' since the intended outcome is assurance that best practice is in place.

OVERUTILIZATION IN MEDICAL IMAGING

W.R. HENDEE
Medical College of Wisconsin,
Milwaukee, Wisconsin,
United States of America
Email: whendee@mcw.edu

Abstract

The most important contributing factor to the higher cost of health care in the United States of America is the overutilization of services, including a growth in medical imaging that reflects advancements in imaging technologies and their contribution to improved detection and diagnosis of disease and injury. A fraction of imaging studies, perhaps as much as one-third, may be inappropriate. Several approaches to addressing overutilization of medical imaging procedures are being explored, including the development of appropriateness criteria and referral guidelines for imaging procedures. This can help in the selection of procedures judged to be in the best interests of patient care, and requires improved communication and cooperation among practitioners.

Expenditures for health care in the United States of America exceed those in any other country by a substantial margin. In 2005, the United States spent US $6401 per person on health care, 2.4 times the average expenditure (US $2759) on health care in developed countries. In spite of these expenditures, health outcomes (e.g. life expectancy, disease specific mortality rates, and other variables) for US residents compare unfavorably with those for residents in many other countries [1].

Several factors contribute to the higher cost of health care in the United States of America. One factor is the expense of providing a plethora of health insurance programmes, each of which has a different administrative process for paying for health care services. The complexity of billing and collecting for health care services, and for keeping individuals insured under a variety of insurance programmes, creates extraordinary administrative costs not experienced in other countries, especially those with a single payer system for health care coverage.

Another factor is the steeper price for health care goods and services in the United States of America compared with other countries. Physician incomes are considerably higher in the United States of America, and goods such as pharmaceuticals and hospital supplies cost much more as well [2]. Also, health care in the USA offers amenities such as private hospital rooms, ancillary services and more individuals involved in patient care than is found in many other countries. These and other factors contribute in large and small ways to the greater cost of health care in the United States of America compared with other developed countries.

An additional factor is the ‘moral hazard’ of a payment system for health care services in which the recipient of the services does not pay directly for the services [3]. Instead, the services are paid for by a third party, usually an insurance company to which the recipient has paid a periodic fee for some period of time. As a consequence, many recipients have little interest in the cost of health care services they receive, and often feel they are entitled to the services irrespective of the cost.

The most important contributor to the high cost of US health care, however, is overutilization of services. Overutilization can be either higher volumes or higher costs of services, or both, where services include items such as office visits, hospitalizations, tests, procedures, and prescriptions. In the United States of America, it is the cost as well as the volume of services that accounts for a substantial fraction of the higher expenditures for health care compared with other countries. In particular, the use and overuse of health care services, especially those that employ medical technologies, help make health care in the United States of America more expensive than in comparable developed countries.

Medical imaging, especially ‘high tech’ imaging procedures such as computed tomography, positron emission tomography, and magnetic resonance imaging, is one of the principal drivers in the growth of health care spending. Medical imaging is reported to be the fastest growing area of medical technology, with spending approaching US $100 billion in the US and with the expectation that this amount will double over the next four years [4].

Much of the growth in medical imaging reflects advancements in imaging technologies and their contributions to improved detection and diagnosis of disease and injury, and to more effective treatments through

image guided interventional procedures. Computed tomography is today a mainstay in hospital emergency departments to detect acute conditions such as pulmonary emboli and appendicitis and to rule out heart attacks [5]. Magnetic resonance imaging provides exquisite images of low contrast tissues in all areas of the body, and is essential to the detection and diagnosis of soft tissue abnormalities, including tumors. Positron emission tomography is widely used for staging cancer and for monitoring the response to cancer treatment with radiation and chemotherapy. Ultrasound and X ray imaging are ubiquitous in the health care arena and are used by many medical specialists including, but not limited, to radiologists.

Advancements in imaging technologies are occurring at an ever increasing rate, leading to shortened product life cycles, spiraling capital costs for equipment purchases, and high reimbursement charges needed to offset the financial investment in imaging technologies. Over seven years, total imaging costs paid to physicians by Medicare increased more than two-fold, from US $6.89 billion in 2000 to US $14.11 billion in 2006. The compound annual growth rate in costs for medical imaging over this period was greater than 14% [6]. Unless drastic measures are taken, Medicare expenditures for medical imaging will certainly be higher in the next few years as a greater fraction of the population (the ‘boomer’ effect) reaches the age of Medicare entitlement.

However, not all of the growth in the use of medical imaging reflects advancements in medical technologies. Some fraction of imaging studies, perhaps as much as one-third, may be inappropriate. These studies represent the overutilization of imaging services. Examples of inappropriate imaging procedures include the use of MRI to assess low back pain in the first 30 days after the onset of symptoms without evidence of serious cause, the employment of whole body computed tomography in asymptomatic individuals who desire reassurance that they are not at risk for cardiovascular disease and X ray examinations acquired as evidence to defend against possible future legal actions brought against a physician. These types of examinations contribute to the overutilization of imaging services, excess costs to payers for the services, and unnecessary exposure of individuals and the population to ionizing radiation.

Several factors drive the overutilization of services in the arena of medical imaging. These factors include the referring physician’s lack of knowledge about imaging procedures, the strong and growing practice of self-referral to imaging facilities owned or partly owned by physicians, the prevalence of procedures requested for purposes of defensive medicine rather than patient welfare, the absence of the radiologist in decision making about preferred procedures for individual patients, the demand of some patients for imaging studies they have read or heard about, and fundamental flaws in the health care system, particularly those associated with fee-for-service medicine. These factors, all of which contribute to the overutilization of imaging services, are discussed in some detail in a recent report of a medical summit in Washington, DC, entitled Addressing Overutilization in Medical Imaging [7].

The referring physician is usually the individual who decides whether an imaging study is required for a particular condition and a particular patient. In making the decision, the referring physician can look to a number of sources of information for guidance. These sources include appropriateness criteria and referral guidelines prepared by professional organizations, radiology colleagues who have expertise in imaging procedures and their appropriate utilization, decision support algorithms that may be embedded in electronic radiology order entry systems and improvements in general referral knowledge that can be acquired through continuing education programmes, professional meetings, and journal articles. These sources of information are described in greater detail in a companion article [8].

In addition to concern over the financial costs associated with the overutilization of medical imaging, there is considerable worry about the contribution of inappropriate imaging procedures to the radiation exposure of individuals and to the population as a whole. Recently the National Council on Radiation Protection and Measurements reported that in the USA medical radiation constitutes slightly more than half of the average exposure of individuals to radiation [9]. Averaged over the population, the annual dose from medical exposures in 2006 was 3.0 millisieverts (mSv), compared with 2.4 mSv from natural background radiation. In 1980, the natural background level was the same, but medical exposures averaged only 0.54 mSv. From 1980 until 2006, the average dose to individuals from medical exposures increased 560%. When this increase is applied to the larger US population in 2006 compared with 1980, the population dose in person sieverts increased from 124 000 to 800 000, an increase of 710%.

These values of individual and population doses are a bit misleading, because they cannot be used directly to evaluate the risk of individuals for the induction of cancer caused by radiation exposure. The reason is that while background radiation is distributed relatively uniformly across the population, medical exposures are concentrated in the upper decades of individuals’ lives where the cancer risk is diminished because of the shorter expected

lifespans of the exposed individuals. In addition, risk estimates of cancer incidence and mortality caused by medical exposures do not include lives saved through effective radiation based medical procedures. Nevertheless, the increased exposure of the US population caused by medical radiation is of concern, especially since some of the exposure is unwarranted because it originates from inappropriate imaging procedures.

Several approaches to addressing the overutilization of medical imaging procedures have been examined. Some of the causes of overutilization, including self-referral and defensive medicine, are not solvable by medicine alone. They will require legislative action leading to restraints on self-referral and on malpractice claims resulting from less than satisfactory medical results, whether or not the physician is at fault. But there are other causes that can be addressed by medicine, including closer cooperation between radiologists and referring physicians concerning the selection and performance of imaging procedures, the development of user friendly decision support systems to aid the referring physician in selecting imaging procedures, and the use of appropriateness criteria and referral guidelines in choosing specific imaging procedures for specific patients. Also, public education programmes should be developed to help individuals understand the limitations of imaging procedures, such as CT whole body scanning, that currently are being marketed directly to patients.

Appropriateness criteria and referral guidelines for imaging procedures currently are developed principally through a consensus process involving the opinion of many experts. Although this process is certainly defensible, a better approach would be to build criteria and guidelines from hard data on the comparative effectiveness of various imaging approaches to yield the needed results in a cost and dose efficient manner. Admittedly, comparative effectiveness research has its difficulties, especially when one particular imaging approach is considered by most experts to be superior to all others in yielding the desired results. Nevertheless, such an approach would be helpful, especially in those cases where the preferred selection of an imaging modality is unclear.

As the burden of financial and radiation costs of imaging procedures continues to mount, medicine can expect increasing restraints on the selection of procedures judged to be in the best interests of patient care. Medicine has an obligation to protect these interests, and therefore should act on its own wherever possible to request and conduct imaging procedures in the most efficacious manner possible. This, in turn, will require improved communication and cooperation among referring physicians, radiologists, and medical physicists who are responsible for the quality and efficient deployment of imaging devices. With enhanced communication and collaboration, the welfare of patients can be preserved while imaging procedures are used in a more efficient and cost effective manner.

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REFERRAL GUIDELINES

(Session 2)

Chairperson

C. DORA
WHO

Rapporteur

D. REGULLA
(Germany)

REFERRAL GUIDELINES: WHY, HOW AND FOR WHOM?

D. REMEDIOS
Chair, RCR Guidelines Working Party,
Northwick Park Hospital,
Harrow, United Kingdom
Email: denis.remedios@imperial.ac.uk or denis.remedios@nwlh.nhs.uk

Abstract

Referral guidelines for diagnostic and interventional radiology are useful in the avoidance of unnecessary ionizing exposures. Referral guidelines have been in existence for over 20 years and have been published in several countries and regions. They provide guidance toward the correct choice of investigation for an individual patient rather than being prescriptive. This paper provides a comparative overview of the guidelines and their application in the United Kingdom and the United States of America.

Referral guidelines for diagnostic and interventional radiology have been in existence for 20 years and have been published in the United Kingdom (the Royal College of Radiologists' Making the Best Use of Clinical Radiology Services [1]), the United States of America (American College of Radiology's Appropriateness Criteria [2]), Europe [3], Australia and New Zealand [4], Hong Kong [5], Canada [6] and other countries. Early versions were intended to guide referring medical practitioners to select the most helpful investigation for a particular clinical problem and were based on expert opinion. The methodology for guideline development has evolved to avoid bias and allow for regional variations; it is increasingly based on published and validated evidence. The intention is to provide guidance towards the correct choice of investigation by clinician and radiologist for an individual patient rather than to be prescriptive. Referral criteria have also been used to produce referral pathways and protocols with algorithms designed and agreed upon by relevant stakeholders (clinicians, radiologists and health organizations) for use within a defined community or health organization. The value of referral guidelines in justification is to avoid unnecessary ionizing exposures when an investigation without ionizing radiation is of greater or equal diagnostic efficacy.

The strategy for ensuring that investigations are helpful to management can be summarized from the Royal College of Radiologists' (RCR) Making the Best Use of Clinical Radiology Services [1]:

(1) Avoid repeat investigations. This can take place due to similar investigations being performed at different centres separated geographically or a repeat of the same investigation due to non-availability of images. This important cause of unhelpful and unjustifiable radiology is not directly addressed by referral criteria and requires an additional strategy;
(2) Avoid investigations when results are unlikely to affect patient management. This applies to investigations which cannot discriminate disease for a particular clinical problem. Diagnostic efficacy and impact are prerequisites for an appropriate test;
(3) Avoid investigating too early. Some chronic conditions such as headache or low back pain not associated with sinister features can be managed without imaging as most will improve within weeks. Investigation would be appropriate should symptoms persist;
(4) Avoid the wrong investigation. Evidence based guidance as to the most effective investigation should ensure an appropriate test but choice will be influenced by local availability and expertise, particularly in less well resourced regions;
(5) Ensure adequate and appropriate clinical information is available with a defined question to be answered by an investigation. The value of an imaging report is proportional to the clinical information provided;
(6) Avoid over-investigation. Although some patients and referring medical practitioners are reassured by multiple examinations of dubious cumulative value, this practice is not helpful and may carry an unjustifiable radiation burden.

Guideline development has evolved and matured to incorporate a more evidence based approach. For the published 6th edition of referral guidelines and the 7th edition in preparation, the methodology used by the RCR includes:

- Centralized literature searches with inclusion and exclusion filters and with an electronic 'hand search' of seven journals with high impact factors;
- Expert panels from special interest groups which are system based, age based (paediatrics) or modality based (especially for nuclear medicine);
- Delphi consensus to agree on recommendations, comments and grading of evidence. These Delphi groups comprise approximately 10 experts and may have a mix of specialty and modality base. Consensus is reached with 75% participation and 75% agreement at 5, 6 or 7 on a 7-point Likert scale. Expert bias is avoided by anonymizing data and geographical bias is avoided by use of Delphi experts from different centres;
- Wide consultation with colleges and organizations;
- Editorial consideration of additional evidence through consultation and with due regard to web and paper publications;
- Ordering of recommended investigations is based on:
  (1) Evidence based diagnostic impact. Selection of the best test is ensured for the clinical indication;
  (2) Radiation effective dose. Low or no dose investigations are promoted;
  (3) Cost effectiveness;
- Particular consideration has been made for guidance in the paediatric population, recognizing the different spectrum of diseases and the increased sensitivity to radiation in this age group.

The 6th edition of the RCR Referral Guidelines published in 2007 contains 315 guidelines, 43 of which are new. The evidence base has been strengthened with less than a quarter reliant on expert opinion alone.

The American College of Radiology's Appropriateness Criteria were first published in 1993 and the current version was released in October 2008. These imaging referral criteria are intended to offer guidance for common clinical problems to radiologists and referring physicians and also to hospitals and payers. Guideline development is based on attributes from the Agency for Healthcare Research and Quality:

- Validity;
- Reliability/reproducibility;
- Clinical applicability;
- Clinical flexibility;
- Clarity;
- Multidisciplinary process;
- Scheduled review;
- Documentation.

It is recognized that data from scientific studies is frequently insufficient and consensus for the ACR Appropriateness Criteria was reached using a Delphi technique with a maximum of three rounds, scoring 1 to 9 for appropriateness of an examination. Consensus is reached with 80% agreement. Guidance for initial imaging is offered with caveats that the availability of equipment and personnel will influence choice and that a final decision will be reached together by the referring physician and the radiologist. The aim is for quality and cost effectiveness.

Development of referral criteria on both sides of the Atlantic have converged in a reasonably similar methodology summarized in the table below.

Referral criteria are globally aimed at directing referring medical practitioners to select the best choice of investigation for their patients. In the UK, the RCR guidelines are specifically targeted at general practitioners and doctors-in-training. Additionally, since 2006, imaging referrals have been accepted from appropriately trained, experienced health care professionals who are not medically qualified. Referral guidelines are also helpful to radiological practitioners for ICRP level 2 [7], generic justification of investigations especially to avoid ionizing exposures where a suitable and effective non-ionizing alternative exists. Whereas ICRP level 3 justification on an

TABLE 1. SIMILARITIES BETWEEN THE ROYAL COLLEGE OF RADIOLOGISTS' REFERRAL GUIDELINES AND THE AMERICAN COLLEGE OF RADIOLOGY'S APPROPRIATENESS CRITERIA

Features	ACR	RCR
Evidence based	+	+
Based on common clinical problems	159 (800 var.)	315 (647 var.)
Cycle of review	1 yr selective	4 yrs
Expert panels	18	16
Consensus technique	Delphi	Delphi
Level of agreement for consensus	80%	75%
Involvement of other organizations	15 through consensus	100 through consultation
Dose information	Rel. radiation level (= ED)	Effective dose (ED)
Publication	Web	Paper and restricted web

individual basis can only be made with dialogue between referring and radiological practitioners, guidance incorporating an up-to-date knowledge base informs this process of both efficacy and radiation dose. Such guidance must include choices where appropriate, to enable the best test within resource constraints.

Health care organizations and national departments/ministries of health will find referral criteria helpful to plan and resource departments of radiology. However, guidelines should not be used to limit helpful investigations and procedures. Patients may be reassured that a procedure recommended by their doctor using recognized guidelines is appropriate but should not feel that referral criteria are a substitute for advice from their doctor. Radiographers who act as the justifying practitioner as well as the operator will also find referral criteria useful. In the UK, RCR referral guidelines have been adopted by the Department of Health for distribution throughout the National Health Service. Private hospitals also use these guidelines for effective and efficient imaging. Promotion of good medical practice and clinical/radiation risk reduction are elements of clinical governance for any hospital and imaging centre.

There is evidence that justification is lacking for many radiological procedures and that the number of such procedures may be reduced by use of referral guidelines.

After publication of the first edition of the RCR referral guidelines in 1989, the RCR showed a reduction in referrals for plain radiographs by 13%, from 88.4 to 77.2 referrals per thousand patients [8]. The following year a randomized controlled study by general practitioners (GPs) in the UK showed significantly fewer referrals for lumbar spine radiography and a higher proportion of requests conforming to guidelines in the group of GPs to whom guidelines were distributed [9]. This early success by simple distribution of guidelines unfortunately was not sustained in a longer study over four years [10]. Additional strategies were clearly required. Feedback of audit data regarding unjustified referrals for lumbar spine and knee radiographs was ineffective at reducing referral rates but an educational reminder in reports for such incompletely justified investigations was helpful in producing a 20% reduction [11]. This effect was sustained [12].

In North America, application of ACR guidelines has been shown to reduce the number of radiological examinations performed by non-radiologists [13]. A study of computed tomography (CT) for trauma showed that there was the potential for a 44% reduction in the number of these high dose investigations if ACR guidelines were used to guide justification [14].

Improvement of compliance with guidelines for skull radiographs in children was shown when all specialties involved were included and agreed upon the guidelines. A subsequent reduction was noted in both the number of unnecessary radiographs and the total number [15].

Presentation of a guideline is important and a psychological study showed that the more precisely behaviours are specified (what, who, when, where, and how**)** the more they are likely to be carried out [16].

The challenge for the future is to present the right guideline(s) at the right time possibly as part of a clinical decision support system. Such systems are under development in North America and in the UK. The concept in the UK, that a referral for imaging is a request for a radiological opinion, concords with such guidance. Other challenges are:

- Difficulty with universal applicability and acceptance;
- Distribution;
- Use of referral criteria by payers to limit practice;
- Avoidance of repeat investigations. Use of centralized e-health records, patient held imaging records or a Smart Card [17];
- Self presentation for CT 'screening'.

The way forward for justification will involve:

- A joint approach between referring and radiological practitioners supported by the relevant health care organizations;
- Promotion of the principle that an imaging referral is a request for a radiological opinion both for the type of investigation and the findings therein;
- Use of referral guidelines to inform the decision to image and which investigation to choose possibly through a clinical decision support system.

CONCLUSIONS

(1) Referral guidelines help referring and radiological practitioners, health organizations and patients arrive at the correct choice of imaging and will inform the process of justification.
(2) Justification using guidelines can reduce the number of radiological investigations by 20% with the potential for a 44% reduction.
(3) Continuous quality improvement measures will influence referral patterns**.**

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MEDICAL RADIATION PROTECTION OF THE PATIENT: ISSUES IN CANADA

J. MAYO
University of British Columbia and Vancouver General Hospital,
Vancouver
Email: jmayo@vanhosp.bc.ca or john.mayo@vch.ca

J. CHEN
Radiation Protection Bureau,
Health Canada,
Ottawa, Ontario

Canada

Abstract

In Canada, the increase in CT utilization has led to substantially increased population radiation exposure. It is believed that a centralized electronic registry of all previous medical radiation exposure would allow better justification of imaging orders and better assessment of the benefits versus the radiation risk of contemplated examinations. Hence, the Radiation Protection Bureau of Health Canada has proposed the development of a Patient Radiation Dose Registry. Government funded projects towards this development are already underway.

Canadians are living longer and healthier than ever before as a result of healthier lifestyles and advances in the health care system. Advanced imaging technologies including computed tomography (CT), magnetic resonance imaging (MRI), and ultrasound (US) are essential, highly visible components of the Canadian public health care system. These high technology imaging modalities are used across the health care system from initial diagnosis through treatment to monitoring for disease recurrence. Recently, CT has been proposed as an autopsy tool [1]. Diagnostically, these non- or minimally invasive modalities provide rapid and accurate assessment of anatomic changes associated with disease. These exams have minimal associated patient pain or discomfort and in the case of CT can be acquired in virtually all clinical settings. Failure to identify an abnormality using high technology imaging is widely regarded as evidence of normality by both patients and clinicians, with the result that many scans are ordered to rule out statistically unlikely diagnosis. This increase in high technology imaging evaluation has greatly increased diagnostic imaging costs and in the case of CT examinations led to substantially increased population radiation exposure [2]. The high radiation exposure and consequent high dose of CT scans of the chest, abdomen and pelvis relates to the large number of views obtained using CT. Finally, studies in multiple jurisdictions have noted large variations in CT dose for the same examination without demonstrable difference in diagnostic accuracy or patient outcomes [3, 4].

Patient and physician demand for high technology imaging is illustrated by recent published data on CT utilization in Canada [5, 6]. These publications documented a nearly threefold increase in CT examination utilization per 1000 persons per year from 1991 (37/1000) to 2006 (103/1000), with an associated fourfold increase in the CT population dose in 1991 (0.19 mSv) to 2006 (0.74 mSv). The difference between the threefold increase in exam rate and the fourfold increase in CT dose is explained by the increased complexity and dose of CT examination protocols in that time. Compared to Canadian data, utilization data from the United States of America for 2006 [7] showed a threefold higher CT examination rate per 1000 persons per year (300/1000) and a twofold higher CT population dose (1.5 mSv per capita per year) [5, 6]. These radiation dose levels have created extensive commentary [8]. Studies in the USA have shown up to an eightfold difference in expenditures in medical imaging between states with no difference in health outcome [9].

Radiation is a known carcinogen, with definitive data existing linking radiation exposures above 100 mSv to increased levels of fatal and non-fatal cancers [8]. The increase in population radiation exposure from CT has raised questions regarding long term health effects [10]. Although the radiation dose from the majority of CT examinations is relatively low (less than 20 mSv), at the current rates of utilization, large numbers of Canadians will

receive multiple CT scans over their lifetime. It is currently believed that successive exposure to low dose radiation leads to a cumulative effect, with associated increased cancer risk. The risk of radiation induced cancers is strongly influenced by the age at exposure, being substantially greater in children than in older adults.

Radiology referral guidelines have been developed by multiple authorities [11–13], including the Canadian Association of Radiologists, to assist in the selection of imaging examinations that impact clinical management or add confidence to clinical diagnosis. It has been noted that guidelines have the greatest impact on imaging utilization when they are electronically available at the time the health care provider orders imaging tests. We believe that an additional tool would be useful at the time of ordering, a centralized electronic registry of all previous medical radiation exposure, documenting the number of exams, including the intensity of radiation exposure and the age at exposure. This information would allow better justification of imaging orders and better assessment of the benefit versus the radiation risk of the contemplated examination. With the current existing medical records, it is difficult for patients and health care providers to track the number of medical diagnostic procedures and practically impossible to measure the cumulative radiation exposure or dose. To be useful, a Canada wide 24/7 computer accessible record of medical radiation exposure and associated dose is needed.

To address this need, the Radiation Protection Bureau, Health Canada, has proposed the development of a Patient Radiation Dose Registry, designed to document the long term medical radiation exposure of individual patients. Such methodology has long existed for recording occupational exposures and has served to substantially reduce occupational exposures during the past decades [14].

The proposed Patient Radiation Dose Registry would track and maintain records of diagnostic medical exposures of individuals over their lifetime. This includes assigning radiation doses to individual diagnostic procedures with consideration of patient specific parameters where possible, and recording patient lifetime diagnostic exposure histories. To achieve this basic function, the registry will need to collect dose related parameters for radiological procedures from service providers. Data collection should be facilitated by the single payer health care system in place in Canada. Methods and software are currently available to compute typical patient doses for various diagnostic modalities. These tools will be used as the starting point to assign subject radiation exposure and dose records in the registry. As more accurate and Canadian specific tools are developed and become available, doses in the registry will be updated.

The primary goal of the proposed patient radiation dose registry is to provide patients and health care providers with diagnostic examination histories, associated radiation doses and cumulative dose information. This information should help prevent duplicate imaging, repeated imaging at too short a time interval and decrease the non-diagnostic examination rate. By reducing the prevalence of inappropriate imaging, the registry should decrease imaging costs and reduce wait times for indicated examinations. The registry will identify those persons who have received high radiation doses and facilitate decisions on the selection of future diagnostic procedures or follow-up imaging. In this fashion, the registry should reduce the risk of radiation induced cancers. Government funded projects towards this development are already underway [15].

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MEDICAL JUSTIFICATION OF CT IMAGING AND USE OF APPROPRIATENESS CRITERIA IN THE USA

C.H. McCOLLOUGH*, J.G. FLETCHER**, J.A. BRINK**

* Department of Radiology, Mayo Clinic,
Rochester, Minnesota
Email: mccollough.cynthia@mayo.edu

** Department of Diagnostic Radiology,
Yale University School of Medicine,
New Haven, Connecticut

United States of America

Abstract

Rapid technical developments and an expanding list of clinical applications that provide new diagnostic information or supplant less accurate or more invasive diagnostic tests have led to a dramatic increase in the use of CT imaging since its introduction in 1973. Our purpose is to discuss the medical benefit of CT imaging given the small risk associated with ionizing radiation used in CT in the context of medical justification, focusing on exam appropriateness, individualization of CT techniques, and decision support tools.

1. INTRODUCTION

In 2006, the estimated number of CT scans performed in the United States of America was approximately 62 million, up from 46 million in 2000 and 13 million in 1990 [1]. This increased use of CT is largely due to the tremendous contributions of increasingly powerful CT imaging methods to modern health care. We have previously addressed the risk and justification of body CT imaging, including the utilization of state-of-the-art dose reduction techniques [2]. We herein adapt this discussion to focus and expand upon the medical justification for CT imaging through the use of appropriateness criteria, individualization of CT acquisition techniques, and decision support tools. To minimize the radiation dose levels to persons from medical exposures, three guiding principles are applied:

(1) Justification: The exam or procedure must be medically indicated.
(2) Optimization: The exam or procedure must use doses that are as low as reasonably achievable (ALARA), without compromising the diagnostic or therapeutic task.
(3) Limitation: In medicine, upper limits to dose levels are typical only for occupationally exposed individuals (such as the radiologist or technologist). Limits are rarely established for medically necessary exams or procedures. One example where patient dose limits have been established is in screening mammography. However, when a screening mammogram, physical examination, or patient symptoms indicate the need for a diagnostic mammogram, no dose limits are applied. The philosophy of the US Food and Drug Administration (FDA) is not to establish dose limits because, as with any medicine or medical intervention, the medical practitioner must be able to tailor the exam to the particular patient and medical concern.

2. MAXIMIZING BENEFIT TO RISK RATIO

Any medical exam should be performed only when justified by the potential clinical benefit to the patient; the potential benefit should greatly outweigh any potential risk. An alternate way of stating this is that the risk of not performing an exam (such as delayed or inaccurate diagnosis or treatment) must exceed the risk associated with the examination. Medical justification includes a consideration of evidence based recommendations for relevant clinical scenarios and an understanding of the risk of disease for each patient. This is true for imaging exams of any

type, including those that do not use ionizing radiation, some of which have other risks associated with them. In the case of magnetic resonance imaging (MRI), uncommon risks include death or injury from magnetic objects being pulled into the magnet and striking the patient, burns, malfunction or damage to implanted electronic medical devices, and injury due to movement of internal metallic objects (such as aneurysm coils, surgical clips, or shrapnel) or trans-dermal patches [3–9]. In spite of this clear cause and effect relationship and considerable effort to prevent such incidents, many types of patient injuries from MRI still occur. In 2008, the Pennsylvania Patient Safety Authority received approximately 150 reports describing events in which the MR screening process was inadequate, and in some cases, erroneously permitted patients with pacemakers or other ferromagnetic objects into the MR scan room [10].

Unlike MRI, the cause and effect relationship with regard to potential risk from computed tomography (CT) is extremely controversial. Risks to patients are estimated from other populations of exposed individuals, most of whom were exposed to much higher doses or higher dose rates. At the low doses associated with CT, millions of individuals would be required to be studied over their entire life to prove a statistically significant increase in risk due to CT, taking into account the multitude of confounding factors in the exposed and control populations, not the least of which would be the potential injury or illness that led to the CT exam being performed [11–13]. To err on the side of being over-cautious, however, estimates of risk are made using the linear-non-threshold model of radiation risk and the consensus risk coefficient published by the National Academy of Sciences [14]. In spite of radiobiological evidence that these data markedly overestimate the risk from CT [15], it remains prudent to adopt BEIR VII estimates for the purpose of justification of medical exposures due to ionizing radiation.

In general, therefore, where health risks and the likelihood of a disease are high, increased risk from radiation and intravenous contrast media is justified if CT can detect the disease from which the patient suffers (for example, hospitalized patients with sepsis). Additionally, modifications of CT acquisition techniques such as the use of intravenous contrast, enteric contrast agents, multi-phasic scanning and higher tube currents (and radiation dose) are justified when they permit diagnostic quality images (such as in morbidly obese patients). Similarly and conversely, modification of CT techniques to decrease risk (and cost), such as low dose techniques or non-contrast scanning, is justified to maximize patient benefit when the patient is asymptomatic or when image quality does not require discrimination between structures with soft tissue attenuation (for example, in CT colonography, or repeat CT for renal stone disease). Justification should also take into account potential diagnostic alternatives, but also patient specific factors (such as claustrophobia, renal failure, hospitalized patient), and local practice specific factors (including local expertise and availability). Once the determination is made that there is an appropriate CT exam that can benefit the patient, CT parameters should be optimized and dose reduction techniques employed to perform the diagnostic task at the lowest level of radiation dose. These strategies are discussed elsewhere [16–31].

3. AMERICAN COLLEGE OF RADIOLOGY APPROPRIATENESS CRITERIA FOR SYMPTOMATIC PATIENTS

The American College of Radiology Appropriateness Criteria and others have provided evidence based criteria to help physicians recommend an appropriate imaging test [32, 33]. The Appropriateness Criteria are developed by expert panels composed of leaders in diagnostic radiology, interventional radiology, radiation oncology, and other relevant specialties. The Appropriateness Criteria are organized by topic and topic variants. There are 167 topics with over 800 variants in the September 2009 version. An array of possible imaging procedures are listed for each topic variant, and a relative rating is given for each imaging test on a scale of 1 to 9 (9 = most appropriate, 1 = least appropriate). For example, the topic ‘blunt abdominal trauma’ has three variants: unstable patient, stable patient, and stable patient with hematuria (Table 1). For stable patients, with and without hematuria, CT is the most appropriate imaging study. For unstable patients, focused assessment with sonography in trauma (FAST) and plain radiography are more appropriate than CT.

CT is included as a possible option in 931 of 7578 (12%) combinations of topics, variants, and imaging procedures. Of these, CT earned a rating of ‘7, 8, or 9’ in 285/931 (31%), and CT was the most appropriate imaging procedure with a rating of ‘9’ in 115/931 (12%). The Appropriateness Criteria also include the ‘relative radiation level’ (RRL) for each imaging procedure, based on the estimated effective dose (None — 0 mSv, Minimal — <0.1 mSv, Low — 0.1–1 mSv, Medium — 1–10 mSv, High — 10–100 mSv). The RRL is intended to provide the

TABLE 1. AMERICAN COLLEGE OF RADIOLOGY ACR APPROPRIATENESS CRITERIA FOR BLUNT ABDOMINAL TRAUMA

Variant 1. Unstable patient

Radiological procedure	Rating	Comments	Relative radiation level
X ray chest	8	To evaluate for fracture and abnormal air collection, patient condition permitting	Min.
US chest abdomen and pelvis (FAST scan)	8	Rapid assessment of free fluid, patient condition permitting	None
X ray abdomen and pelvis	8	To evaluate for fracture and abnormal air collection	High
CT chest abdomen and pelvis with contrast	7	Patient condition permitting	Med.
Arteriography with possible embolization abdomen and pelvis	5		NS
Ultrasound abdomen and pelvis	3		None

Variant 2. Stable patient

Radiological procedure	Rating	Comments	Relative radiation level
CT chest abdomen and pelvis with contrast	9		High
X ray chest	8		Min.
Arteriography with possible embolization abdomen and pelvis	5		NS
Ultrasound chest abdomen and pelvis (FAST scan)	5		None
X ray abdomen and pelvis	4	Information provided by CT	Med.
Ultrasound abdomen and pelvis	3		None

Variant 3. Hematuria >35 RBC/HPF (stable)

Radiological procedure	Rating	Comments	Relative radiation level
CT chest abdomen and pelvis with contrast	9		High
X ray chest	8		Min.
X ray abdomen and pelvis	7	To identify pelvic or spinal fracture	Med.
CT pelvis with bladder contrast (CT cystography)	6	Refer to text for indications	High
X ray retrograde urethrography	6	Refer to text for indications	Med.
Arteriography with possible embolization kidney	5	If CT identifies active site of bleed or arterial injury	NS
X ray cystography	4	CT cystography preferred	Med.
X ray intravenous urography	3		Med.
Ultrasound abdomen and pelvis	3		None

Rating scale: 1=Least appropriate, 9=Most appropriate

* NS = Not specified

ordering physician with a cursory understanding of the relative radiation exposure associated with each imaging procedure.

Table 2 delineates some of the indications for which the ACR Gastrointestinal (GI) Expert Panel considered CT the most appropriate imaging option (see Appendix 1 for a full listing). To illustrate their erudite considerations of justification and optimization, we consider two clinical scenarios—acute diffuse abdominal pain and Crohn's disease.

Acute diffuse abdominal pain with fever raises the clinical suspicion of an intra-abdominal abscess or condition that may need immediate surgical or medical attention. CT can help identify the cause of abdominal pain in 90–95% of such cases [34, 35], increases the clinician's level of certainty, and reduces hospital admissions [36]. Ultrasound tends to operate at lower sensitivity and specificity in this scenario [37, 38], likely owing to the potential presence of increased bowel gas or free air. In this situation, the use of CT is clearly warranted given the imaging alternatives and the potential to avoid life-threatening sepsis.

Crohn's disease has been associated with increased mortality rates and is a known cause of significant morbidity. CT enterography, unlike routine abdominopelvic CT, utilizes large volumes of ingested neutral contrast agent, intravenous contrast, and high spatial resolution imaging with reconstruction of thin multiplanar slices. CT enterography can detect mural inflammation, obstruction and penetrating complications of Crohn's with high accuracy [39–41], and has recently been shown to change management decisions in approximately 50% of patients with known or suspected Crohn's disease [42, 43]. Nevertheless, repeat imaging in younger patients can lead to relatively higher cumulative radiation doses [44–46] and may not be justified in the absence of symptoms. However, imaging is often desired in asymptomatic patients because of the risks associated with Crohn's therapies and the lack of correlation between symptoms and biologic activity [47]. The most beneficial exam for any particular patient in this setting will depend upon patient specific factors such as symptomatology, compliance, and local practice factors such as scanner availability and local expertise of CT, MR or US imaging.

TABLE 2. ESTIMATED LIFETIME RISK OF DEATH FROM VARIOUS SOURCES
*(adapted from Circulation **19** 7 (2009) 1056–65, with permission)*

Cause of death	Estimated number of deaths per 1000 individuals
Cancer (US American Cancer Society Data 2008)	228
Motor vehicle accidents	11.9
Radon in Home	
US average	3
High exposure (1–3%)	21
Arsenic in drinking water	
2.5 ug/L (US estimated average)	1
50 ug/L (acceptable limit before 2006)	13
Radiation induced fatal cancer	
Routine abdomen/pelvis CT scan, single phase, approximately 10 mSv (effective dose)	0.5
Annual dose limit for a radiation worker	
10 mSv (recommended yearly average)	0.5
50 mSv (limit in any single year)	2.5
Pedestrian accident	1.6
Drowning	0.9
Bicycling	0.2
Lightning strike	0.013

4. APPROPRIATENESS DECISIONS IN ASYMPTOMATIC PATIENTS

As discussed previously [2], asymptomatic patients should be considered separately from symptomatic patients as the risk for disease is much lower [48]. For example, justification of CT colonography (CTC) as a screening exam for colorectal neoplasia includes the mortality from colon cancer, the long preclinical course of adenomatous polyps, and the potential for polypectomy to eliminate the progression to invasive cancer [48]. Given the performance of CTC in multicentre screening studies [49–51], it was endorsed as an acceptable colorectal cancers screening test by the American Cancer Society in 2008 [52]. Risks of CTC include perforation, unnecessary treatment/workup of extracolonic findings, and potential risk of ionizing radiation. These must be balanced against the anticipated lifetime risk of colorectal cancer (5–6% [53]) and prevalence of advanced colorectal neoplasia (3–9% [54, 55]) in relation to the CTC perforation risk, estimated to be 0.001–0.02% [56, 57]. Extracolonic findings may be beneficial [58, 59], but may also increase financial burden or morbidity [60, 61], resulting in ongoing efforts to minimize these effects [62]. Brenner and Georgsson, using the conservative linear non-threshold model, estimated the potential risk of radiation induced malignancy from CTC to be 0.14% in a 50 year old and 0.07% for a 70 year old, with these risks falling further when optimized protocols are used [53], and determined that the benefit to risk ratio was positive. Further, a recent unpublished review of five peer reviewed studies [63–67] that looked at the complications, including death, associated with endoscopic colonoscopy, included over 173 000 patients (personal communication). There were 384 instances of significant bleeding and bowel perforation per 100 000 procedures, and 6.6 deaths per 100 000 procedures. Using the age/sex distribution of colonoscopy patients, the expected mortality attributable to X ray exposure calculated using the BEIR VII risk coefficients is about 7 per 100 000. Thus, the actually measured mortality rate of endoscopy is about the same as the hypothetical mortality rate of CTC.

5. INDIVIDUALIZATION OF CT TECHNIQUES

Given the rise of many new clinical CT applications, CT techniques must be adapted to individual patients, their co-morbidities and their suspected illnesses, in order to answer clinical questions and thereby maximize individual patient benefit. Individualization of CT techniques includes patient preparation (such as administration regimens for oral and intravenous contrast), CT acquisition methods (tube energy and current, collimation, automatic exposure control, technique charts, etc.), and reconstruction and visualization methods (including slice thickness, reconstruction kernel, 2D multi-planar images, 3D volume renderings, dual energy post-processing). Appropriateness criteria and decision support tools generally address the justification for CT imaging but only tangentially address the optimization and individualization of CT techniques, which greatly affects the benefit and risk associated with a CT exam. For example, a routine CT of the abdomen and pelvis with positive oral contrast in the portal phase of contrast enhancement may be sufficient to detect colorectal cancer metastases, but would be inadequate to detect hepatocellular carcinoma (which requires multi-phasic, thin section imaging [68, 69]) or Crohn's disease (which requires enteric distension and a neutral contrast agent [39, 40]). Moreover, locally available CT systems will have different ways to adapt radiation dose and preserve image quality, such as necessitating automatic exposure control, technique charts for tube energy and current selection, and/or noise reduction filters. Similarly, the optimum benefit of some CT applications is only realized when specialized computer post-processing is performed after image acquisition (including CT colonography, CT angiography, dual-energy for renal stone characterization or gout).

6. DECISION SUPPORT TOOLS FOR REFERRING PHYSICIANS

Eliminating non-beneficial and inappropriate CT exams likely represents the most important step towards reducing CT risk. Evidence based recommendations [33] or decision support tools [70] are gaining acceptance in many practices to facilitate appropriate referral for CT imaging. These electronic tools can significantly reduce the number of low utility exams [70] and have great promise for controlling utilization if adopted widely [71]. Computerized order entry with decision support provides the opportunity to guide the ordering physicians to the appropriate imaging test at the time that the order is placed. However, some ordering physicians may be reluctant to

use the system and will view it as another hurdle to overcome in caring for their patients. Others will be skeptical of the medical evidence on which the decision support engine is based. It is critical that practitioners from all medical disciplines have representation on the implementation team, and on the expert panels that review and rate relevant medical evidence on a regular basis.

In the United States, many insurance companies require pre-authorization for high end imaging tests (CT, MR, PET) before outpatients may be scheduled for these examinations. This process controls utilization by ensuring that the patient's clinical condition meets approved clinical criteria, as established by the insurance company. Physicians have the incentive to use decision support tools if they are exempted from this pre-authorization requirement, largely due to the time and effort needed to navigate the pre-authorization process. However, most insurance companies delegate utilization management to radiology benefits managers (RBM) who do not have incentive to participate in decision support programmes. This is because the revenue earned by the RBM is tied to the money that is saved for the insurance company through utilization management, and because of limited confidence that the decision support rules will mirror those of the RBM. In such markets, creative solutions will be needed to overcome the socio-economic barriers to widespread adoption of computerized order entry with decision support.

Non-beneficial CT exams ordered as a result of defensive medicine practices or self-referral are more problematic and unnecessarily increase both medical cost and patient risk [2, 72–74]). Successfully addressing these practices would likely require actions by third party payers or the government [75]. Because it is unrealistic to expect that all patients referred for CT imaging will have entirely appropriate indications, practices should establish mechanisms for transferring patients to MR or ultrasound when these exams are more appropriate.

7. CONCLUSIONS

In recent years, the media has focused on the potential danger of radiation exposure from CT while ignoring the potential for great individual benefit. To maximize benefit to the patient from CT exams, working to ensure appropriate referral goes hand in hand with individualizing an exam to achieve the lowest dose necessary for the specific diagnostic task, as well as with patient preparation and CT acquisition and post-processing techniques that maximize disease conspicuity while managing dose. Physicians must work together to ensure that the exams most likely to benefit patients are performed, taking into account the small potential risks associated with any diagnostic exam. Ongoing efforts to ensure that CT examinations are both medically justified and optimally performed must continue, and education must be provided to the medical community and general public that put both the risks — and benefits — of CT exams into proper perspective.

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APPENDIX

General clinical scenario	Scenario variants to which CT is the most appropriate exam (appropriateness rank, 1-9)	Scenario variants to which CT is not the most appropriate exam (Most appropriate modality, appropriateness rank, CT appropriateness rank)*
Acute abdominal diffuse pain and fever or suspected abdominal abscess in adults	Postoperative patient with fever (8)	Pregnancy (US abdomen, 8, 5)
	Postoperative patient with persistent fever and no abscess seen on CT scan within the last 7 days (8)	
	Patient presenting with fever, non-localizing abdominal pain, and no recent operation (8)	
Acute pancreatitis	Severe abdominal pain, elevated amylase lipase, 48 hours later assuming no improvement or degradation (assume no prior imaging) (8)	Etiology unknown, first episode of pancreatitis (US abdomen, 8, 6)
	Severe abdominal pain, elevated amylase lipase, fever and elevated white blood cell count (9)	Severe abdominal pain, elevated amylase lipase, no fever or evidence of fluid loss at admission; clinical score pending (US abdomen, 8, 7)
	Severe abdominal pain, elevated amylase lipase, hemoconcentration, oliguria, tachycardia (9)	
Blunt abdominal trauma	Stable patient (8)	Unstable patient (US screen for hemoperitoneum, 7, 4)
	Hematuria >35 RBC/HPF (stable) (8)	
Crohn's disease	Adult; initial presentation (abdominal pain, fever, or diarrhea); Crohn's disease suspected (8)	Child (less than 14 years of age) with known Crohn's disease; stable, mild symptoms (US abdomen and pelvis, 6, 5)
	Initial presentation of a child (less than 14 years of age); Crohn's disease suspected (8)	
	Adult with known Crohn's disease and fever, increasing pain, leukocytosis, etc. (8)	
	Child (less than 14 years of age) with known Crohn's disease, increasing pain, leukocytosis, etc. (8)	
	Adult with known Crohn's disease; stable, mild symptoms (7)	
Dysphagia		Oropharyngeal dysphagia with an attributable cause (X ray barium swallow modified, 8, CT not mentioned)
		Unexplained oropharyngeal dysphagia (X ray pharynx dynamic and static imaging, 8, CT not mentioned)

General clinical scenario	Scenario variants to which CT is the most appropriate exam (appropriateness rank, 1-9)	Scenario variants to which CT is not the most appropriate exam (Most appropriate modality, appropriateness rank, CT appropriateness rank)*
Jaundice	Painless; one or more of the following: weight loss, fatigue, anorexia, duration of symptoms greater than 3 months. Patient otherwise healthy (9)	Acute abdominal pain; at least one of the following: fever, history of biliary surgery, known cholelithiasis (US abdomen, 9, 7)
		Clinical condition and laboratory examination make mechanical obstruction unlikely (US abdomen, 8, 5)
		Confusing clinical picture; patient not described in previous scenarios (US abdomen, 8, 7)
	Painless; one or more of the following: weight loss, fatigue, anorexia, duration of symptoms greater than 3 months. Patient will not tolerate radical surgical procedure (9)	
Left lower quadrant pain	Older patient with typical clinical presentation for diverticulitis (8)	Woman of childbearing age (US abdomen transabdominal with graded compression, 8, 7)
	Acute, severe, with or without fever (9)	
	Chronic, intermittent, or low grade (8)	
	Obese patient (8)	
Liver lesion characterization	Indeterminate on initial imaging, >1 cm, no suspicion or evidence of extrahepatic malignancy or liver disease (CT or MR depending on availability, 8)	Typical benign on initial imaging, no history of malignancy (No imaging at this time, 8, 4)
	Indeterminate mass on initial imaging, >1 cm, known or suspected liver disease associated with a high risk of hepatocellular carcinoma (chronic hepatitis, cirrhosis, hemochromatosis, etc.), (CT or MR depending on availability, 8)	Typical benign on initial imaging, known history of extrahepatic malignancy. (No imaging at this time, 8, 5)
		Typical malignant mass on initial imaging. (No imaging at this time, 7, 6)
		Indeterminate solitary mass on initial imaging, >1 cm, known history of extrahepatic malignancy. (Percutaneous biopsy liver, 8, 7)
		Small lesion on initial imaging, <1 cm. (No imaging at this time, 8, 5)
Palpable abdominal mass	Palpable abdominal mass (8)	
Pretreatment staging of colorectal cancer	Rectal cancer, large lesion (8)	Rectal cancer, small or superficial (US rectum transrectal, 8, 6)
	Colon cancer, other than rectum (8)	
Right lower quadrant pain	Fever, leukocytosis, and classic presentation clinically for appendicits in adults (8)	Fever, leukocytosis, pregnant woman (US abdomen RLQ, 8, 6)
	Fever, leukocytosis; possible appendicitis, atypical presentation, adults and adolescents (8),	Fever, leukocytosis, possible appendicitis, atypical presentation in children, less than 14 years of age (US abdomen RLQ, 8, 7)

General clinical scenario	Scenario variants to which CT is the most appropriate exam (appropriateness rank, 1-9)	Scenario variants to which CT is not the most appropriate exam (Most appropriate modality, appropriateness rank, CT appropriateness rank)*
Right upper quadrant pain		Fever, elevated WBC, positive Murphy sign (US abdomen, 9, 5)
		Suspected acalculous cholecystitis (NUC cholescintigraphy, 8, 6)
		No fever, normal WBC (US abdomen, 8. 7)
		No fever, normal WBC, ultrasound shows only gallstones (NUC cholescintigraphy, 8, 6)
		Hospitalized patient with fever, elevated WBC, and positive Murphy sign (US abdomen, 9. 7)
Suspected liver metastases	Initial imaging test following detection of primary tumour (8)	
	Surveillance following treatment of primary tumour (8)	
	Abnormal surveillance US, CT, or MRI in PVP; high suspicion of malignancy (8, MR and percutaneous biopsy have the same score)	
	Abnormal surveillance US, CT or MRI in PVP; high suspicion of benignancy (8, MR has the same score)	
Suspected small bowel obstruction	Suspected complete or high grade partial SBO (8)	
	Suspected intermittent or low grade SBO (7, small bowel follow through and enteroclysis have the same score)	

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US = ultrasound, SBO = small bowel obstruction, NUC = radionuclide.
* Appropriateness rank ranges from 1 to 9, with 9 being most appropriate and 1, least appropriate

APPROPRIATENESS IN CARDIOLOGY: THE HOMER SYNDROME OF THE IMAGING SPECIALIST

E. PICANO
Institute of Clinical Physiology,
Consiglio Nazionale delle Ricerche (CNR),
Pisa, Italy
Email: picano@ifc.cnr.it

Abstract

The medical imaging market comprises several billion tests per year worldwide, and at least one-third of these are cardiovascular procedures. Keeping in mind that each test represents a cost, often a risk, and a diagnostic hypothesis, we must agree that every unnecessary and unjustifiable test is one test too many. Small individual costs, risks, and waste multiplied by billions of examinations per year become an important population, societal and environmental burden.

1. INTRODUCTION

The appropriateness of cardiac imaging is extraordinarily low, and patients and physicians are largely unaware of the differential costs, radiological doses, and long term risks of different imaging modalities. For a resting cardiac imaging test, if we take the average cost (not charges) of an echocardiogram as equal to 1 (as a cost comparator), the cost of a CT is 3.1x, of a SPECT 3.27x, of a cardiovascular magnetic resonance imaging 5.51x, of a PET 14.03x, and of a right and left heart catheterization 19.96x. Biohazards and downstream long term costs linked to radiation induced oncogenesis should also be considered. Radiation exposure is absent in echo and magnetic resonance, and corresponds to 500 chest X rays for a sestamibi cardiac stress scan and to 750 chest X rays for a cardiac CT scan. The corresponding extra risk of fatal cancer in a lifetime is 1 in 1000 exposed patients for a sestamibi stress, and 1 in 750 for a CT scan. Increased awareness of economic, biological, and environmental costs of cardiac imaging will hopefully lead to greater appropriateness, prudence and wisdom from both the prescriber and the practitioner. In this way, the sustainability of cardiac imaging will eventually improve [1].

Every year 5 billion imaging tests are performed worldwide, and about half of these are cardiovascular examinations [1]. According to recent estimates, 30–50% of all examinations are partially or totally inappropriate, in other words, risks and costs outweigh benefits [2]. Following the definition of the American College of Cardiology Foundation, “an appropriate imaging study is one in which the expected incremental information, combined with clinical judgement, exceeds any expected negative consequences by a sufficiently wide margin for a specific indication that the procedure is generally considered acceptable care and a reasonable approach for the indication.” [3] (Fig. 1). Negative consequences include the risks of the procedure itself (including radiation or contrast exposure) and the downstream impact of poor performance such as delayed diagnosis (false negatives) or inappropriate diagnosis (false positives). This implies potential harm for patients undergoing imaging (who suffer the risks of an imaging study without a commensurate benefit), excessive delay in waiting lists for other patients needing such examinations, and an exorbitant cost for society, with no improvement and possibly with a reduction in care quality [3]. Health care costs in the United States now exceed a stunning 2 trillion dollars, representing 16% of the country’s gross domestic product by 2016, and, in the words of Alan Greenspan, are on “an unsustainable trajectory”. Cardiac imaging greatly contributes to this escalation of costs, and stress imaging tests in particular have increased at an annual rate of 6.1% since 1993 in individuals covered by Medicare. Diagnostic imaging has increased more rapidly than any other component of medical care, and echocardiography is the single most frequently used test in the Medicare population, except for lab tests [4]. The volume of cardiovascular services increased 5.5% per capita between 2004 and 2005 in the United States, driven largely by the growth of cardiac imaging services [4]. Although the diagnostic and prognostic information provided by these tests is not without cost, some studies have shown that the use of non-invasive imaging in appropriately selected patients translates into savings because of more proper selection of even more expensive procedures [5, 6]. However, these studies involved patients who were appropriately selected for testing, and the trade-off between costs and benefits will not

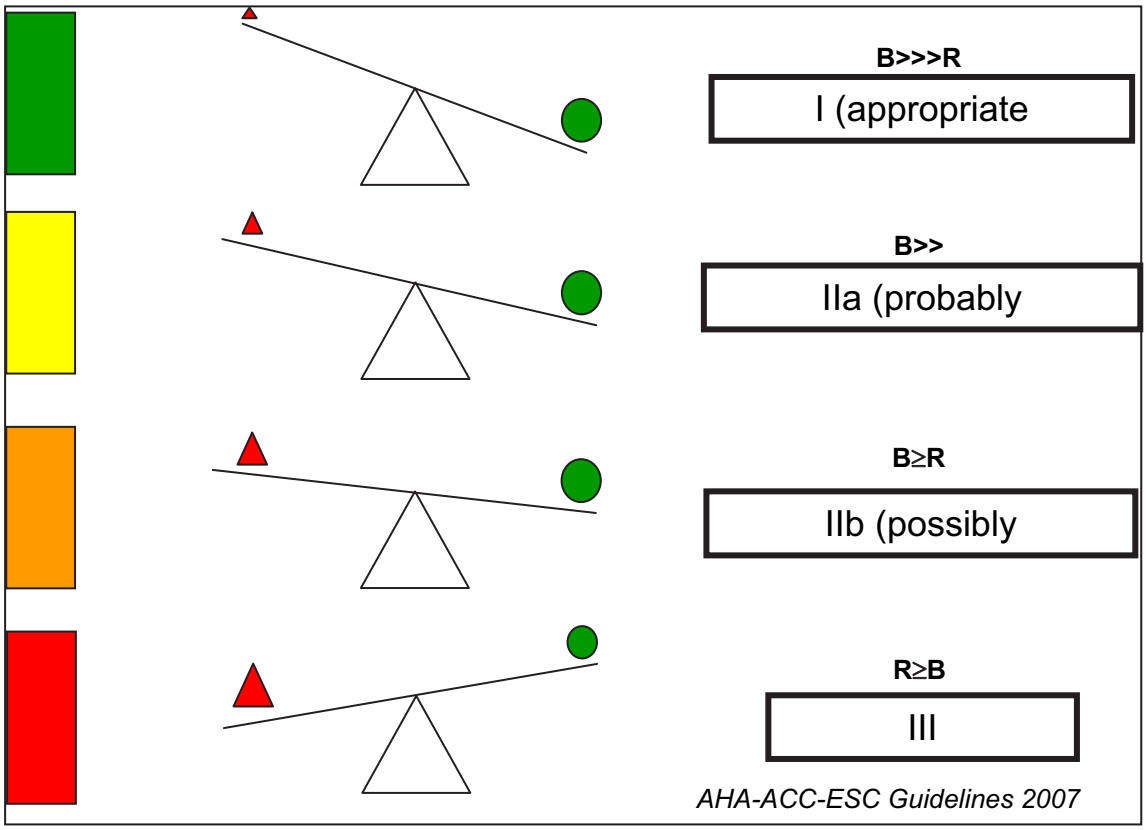

FIG. 1. The balance between risks (red triangle) and benefits determining the appropriateness score of testing. The three angles of the red triangle represent acute, sub-acute, and long term (radiation) risks. Acute risks occur within seconds and minutes (for instance, death or myocardial infarction during stress or cardiac catheterization), sub-acute risks within days or weeks (for instance, contrast-induced nephropathy); and long term risks (due to cumulative exposure to ionizing radiation) after years or decades.

be the same when studies are performed less appropriately [7]. In order to limit the detrimental consequences of the pandemic of inappropriateness and diagnostic bloat, the UK college of radiology in 1999 [8], the European Commission in 2001 [9], and more recently the American College of Cardiology [3] have prepared guidelines on appropriateness in general or specialized imaging testing [10, 11]. The ultimate goal of these documents is to define the appropriate test for the appropriate indication in the appropriate patient: a difficult, elusive and moving target which is, however, one of the new features — and not the least important — of good quality medical care [3, 9].

2. THE ULYSSES SYNDROME IN THE PATIENT WITH ISCHEMIC HEART DISEASE

The Ulysses syndrome was first described in 1972 by Canadian physician Dr. Mercer Rang, who applied it to the ill effects of extensive diagnostic investigations conducted because of a false positive or indeterminate result in the course of routine laboratory screening [12]. Ulysses left Troy in full physical and psychological health. Equipped with a safe ship and a competent crew, he was sure he would return home quickly; instead it turned out that he lost all his crew and his ship and he was able to make it home only after a journey full of hardship. Today, the most frequent diagnostic investigation is a cardiac imaging test. Mr. Ulysses, a typical middle aged 'worried-well' asymptomatic subject with an A-type coronary personality, a heavy (opium) smoker, leading a stressful life, would be advised to have a cardiological check-up after 10 years of war (Fig. 2). The family physician directly refers the patient to the cardiologist (step 2) who suggests a trans-thoracic echocardiogram (step 3), which is perfectly normal, but with poor visualization of segment 17, the true apex. The patient is again sent to the echo lab to repeat the trans-thoracic echo with echo-contrast injection (step 4): the apex is perfectly visualized and looks normal. However, just to be on the safe side, the cardiologist suggests a multi-slice computed tomography (step 5).

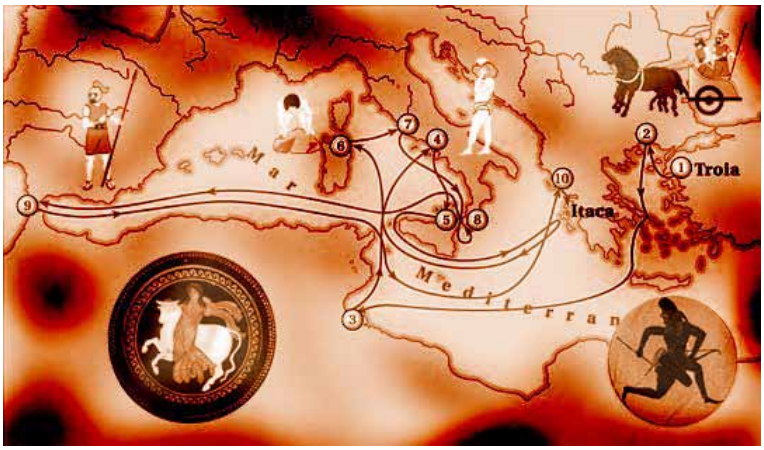

FIG. 2. Ulysses' voyage as a metaphor for the diagnostic pathway of the patient with suspected coronary artery disease. At the end of the first round of this odyssey, the cumulative cost is more than 100 times a simple exercise electrocardiography. The cumulative radiation dose is that of more than 4000 chest X rays. The cumulative damage (including acute, sub-acute, and long term risks) will cause a serious health detriment (including infarction, renal insufficiency, or cancer) in about 5–10% of patients.

- *Total cost: > €20 000;*
- *Total radio load: 4000 CXR;*
- *Total serious complication load: 5% (contrast + gadolinium+stress+cath+radiation-induced cancer).*

Ulysses accepts enthusiastically since he recently read the front page and cover story of Time magazine (September 5, 2005) explaining that in this way you can detect asymptomatic life-threatening coronary artery stenosis. The scan shows only minor luminal irregularities of very uncertain pathological meaning. At this point, Thallium stress perfusion scintigraphy (step 6) is performed. A very mild, questionable hypo-perfusion of the infero-basal wall is documented. The stress echo (step 7) is performed and a very mild apical hypokinesis is observed at peak exercise in presence of marked systolic blood pressure rise. At this point the cardiologist asks for further examinations and Mr. Ulysses is becoming increasingly anxious.

One after another, Ulysses undergoes a PET adenosine stress (step 8: marginally positive at basal lateral wall) and MRI adenosine with gadolinium contrast (step 9: marginally positive on the basal inferior septum). The patient is eventually referred to coronary angiography (step 10); the island of Ithaca is crowded with non-significant coronary stenoses, unrelated to perfusion defects or wall motion abnormalities, which may however trigger the oculo-stenotic reflex [4] leading to the vicious circle of angioplasty (obviously with drug-eluting stent), imaging test for the diagnosis of silent re-stenosis, presence of perfusion or wall motion defects, re-angiography, and so on and so forth.

None of these examinations are free, and they imply a financial and a safety cost. For a resting cardiac imaging test, taking the average cost (not charges) of an echocardiogram as equal to 1 (as a cost comparator, the cost of a CT is 3.1x, of a SPECT 3.2x, of a cardiovascular magnetic resonance imaging 5.51x, of a PET scan 14.03x and of a right and left heart catheterization 19.95x [13]. For stress cardiac imaging, compared with the treadmill exercise test considered as equal to 1 (as a cost comparator), the cost of a stress scintigraphy is 2.1x, and of a stress SPECT scintigraphy 5.7x [14].

There are not-negligible acute risks in several non-invasive imaging techniques.

Risks are acute (linked to stress), sub-acute (linked to contrast use), and long term (linked to radiation): Table 1 [15–19].

Besides the clearly recognized acute and sub-acute risks, long term risks linked to imaging radiation should also be considered. Medical X rays and γ-rays are a proven human carcinogen [8, 9]. In radiology and nuclear medicine, higher acute doses correspond to higher long term risks; there are no safe doses, and all doses add up in determining the cumulative risks over a lifetime [8, 9]. Doses of common imaging are reported in yellow in Fig. 2, and range from the equivalent of 300 chest X rays of a coronary angiography to that of 1250 chest X rays of a Thallium scan [19–21]. With cumulative imaging doses (radiation expenditure), the patient 'buys' increasing risks of developing cancer during his lifetime.

TABLE 1. ACUTE, SUB-ACUTE, AND LONG TERM RISKS IN CARDIAC IMAGING

	Acute	Sub-acute	Chronic
Most frequent cause	Stress	Iodinated contrast	Radiation
Timing	Seconds	Days	Years
Examples	Myocardial infarction	Renal failure	Cancer
Cellular target	Endothelium of coronary arteries	Kidney tubular cell	Somatic cells (lung, breast, bone narrow)
Risk per exam	1 in 500–1 in 1000	1 in 50–1 in 100	1 in 50–1 in 1000
Cumulative nature	No	No	yes

In other words, at the end of the first round of examinations shown in Fig. 2, Ulysses has paid about 100 times the cost of a simple exercise electrocardiography test — probably all that he needed. He received a 5% cumulative risk of major short term adverse events (from renal insufficiency to myocardial infarction). He received a cumulative dose exposure of about 4000 chest X rays, corresponding to an extra risk of cancer of 1 in 150. The invasive and interventional procedures that he received did not improve his quality of life since he was asymptomatic at the beginning of his cardiological history and the anatomy driven revascularization will not increase his life expectancy [22, 23]. Periodic follow-up examinations with imaging testing will be scheduled — mostly inappropriately [9] — and the odyssey will probably go on forever.

3. APPROPRIATENESS IN STRESS ECHOCARDIOGRAPHY

The proliferation of cardiac stress imaging may represent an added value when appropriate, and an added cost when inappropriate. Unfortunately, the definition of appropriateness is obvious in theory, but not so straightforward on practical grounds. Unlike prevention and treatment strategies supported by evidence based practice guidelines, the evidence base for imaging is anecdotal, fragmented, and lacking in prospective clinical trials [3]. As a consequence, the process for developing appropriateness criteria is only partially evidence based and is heavily weighted by expert consensus [3]. On an arbitrary scale of 1 (most inappropriate) to 9 (most appropriate), indications are classified as ‘appropriate’ (a score of > 7 means a test is generally acceptable and is a reasonable approach for the indication), ‘uncertain’ (a score of between 4 and 6 means a test may be generally acceptable and may be a reasonable approach for the indication), and ‘inappropriate’ (a score of < 3 means a test is not generally acceptable and is not a reasonable approach for the indication). Following these criteria, only 2 out of 3 stress echo or nuclear stress imaging tests are appropriate, with similar numbers observed in disparate geographic, cultural and economic situations — from Italy to Australia [24] to the USA [25]. Of interest, the vast majority of inappropriate studies were restricted to only a few patient indications, with the four most frequent inappropriate indications accounting for 88% of all inappropriate examinations [24, 25]. This repetitive pattern of inappropriateness points to a need for quality improvement and educational programmes to achieve measurable improvement in results [26]. This is especially important today and in view of the projected spectacular rise of cardiac imaging in the next 15 years [27] (Fig. 4).

It is certainly good to have multiple imaging tools, which allow us to avoid the contra-indications and limitations of each technique and to tailor the best (most effective) test in individual patients. The best test choice should also consider the test with the lowest cost — for any given accuracy — and, importantly, the test with the lowest acute, chronic and long term risks. This concept was clearly spelled out in the guidelines of the UK College of Radiology in 1999 [8], the Medical Imaging guidelines in 2001 [9], and the American College of Cardiology guidelines in 2006 [10, 11].

With special regard to the radiation issue, European Union guidelines state that “for instance, because MRI does not use ionizing radiation, MRI should be preferred when both CT and MRI would provide similar information and when both are available”. The American College of Cardiology definition of appropriateness defines an imaging study as “one in which the expected incremental information exceeds the negative

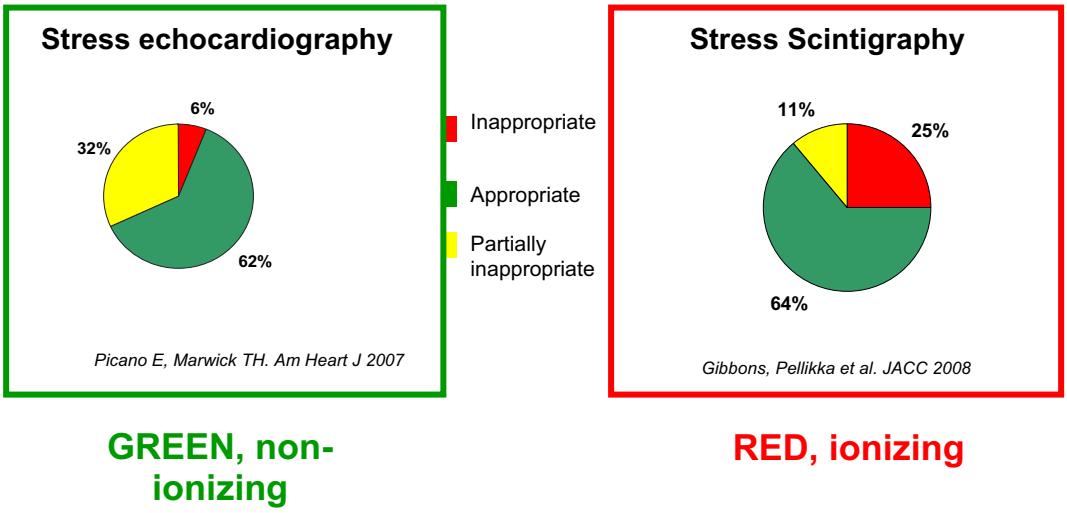

FIG. 3. Inappropriateness in stress echocardiography (left) and cardiac stress imaging (right). Data are derived from [24] Pisa and Brisbane echo labs in Italy and Australia and the Mayo Clinic nuclear cardiology lab in the USA.

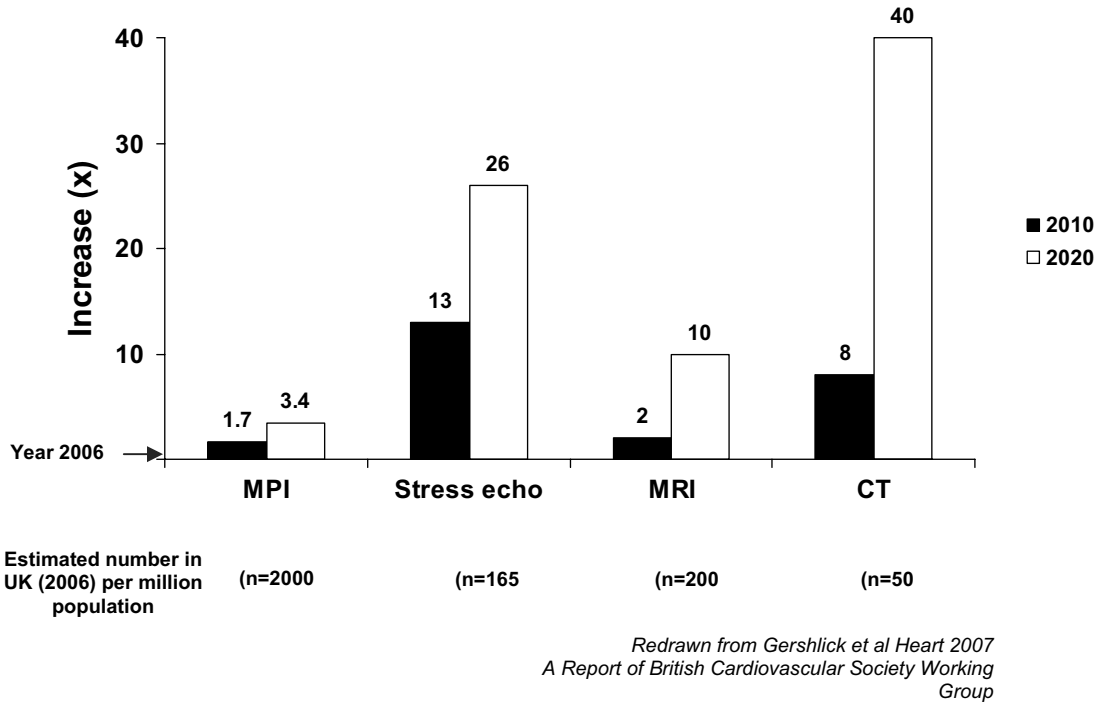

FIG. 4. Future trends in the use of cardiac imaging up to the year 2020. Redrawn from the original data of [27].

consequences, which include the risks of the procedure (such as radiation or contrast exposure) and the downstream impact of poor test performance".

This important concept can be expressed with an image. Imaging technology evolution in the last 30 years was characterized by a shift from 1-dimensional (1970s) to 2-dimensional (1980s–1990s) and today to 3-dimensional representation of the heart provided by all major imaging modalities. Probably the evolution of technology has not always been fully matched by our maturity in using it. We should probably move from a 1-dimensional approach to imaging (typical of the 1980s) to the 2-dimensional approach (considering cost effectiveness, not only effectiveness) up to a 3-dimensional approach including long term radiation risk as an essential depth dimension.

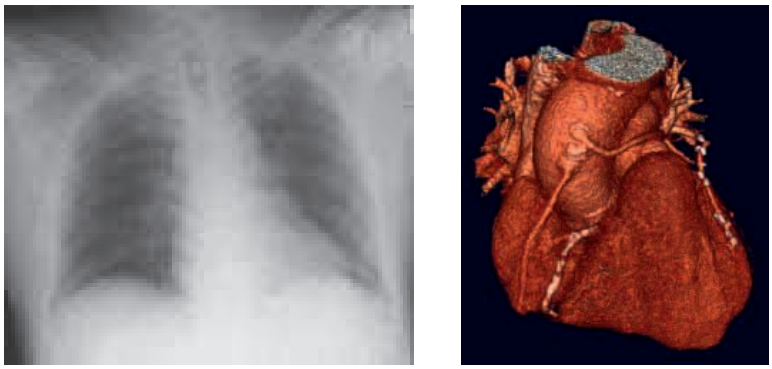

FIG. 5. The Homer Simpson syndrome of the modern cardiologist. The evolution of technology in the last 30 years is best represented with the transition from chest X ray (left panel) to 64-slice CT (right panel). However, technology evolution was not matched by evolution in awareness and — like Homer — the contemporary cardiologist knows very little about doses, ignores risks, and neglects appropriateness of imaging testing.

Appropriateness in health care, like quality, can be a moving target and not easy to define. However, it is also true that, as with many quality measures, the very act of having appropriateness criteria and measuring your own appropriateness performance is likely to improve the quality of what is being measured [26]. This needs to be done to improve the quality of our profession, to address the existing concerns of those who pay for these services, and to optimize the immense benefits our patients can derive from the appropriate practice of cardiac imaging and stress echocardiography. Cardiac imaging must not become another chapter of the medical nemesis [27]. Ivan Illich wrote in 1976 (at the beginning of the imaging era): "Act so that the effect of your action is compatible with the permanence of genuine human life. Very concretely applied, this could mean do not raise radiation levels unless you know that this action will not be visited upon your grandchild". The contemporary practice of imaging seems to ignore this sound advice [28].

4. THE HOMER SYNDROME OF THE CARDIOLOGIST

The Ulysses syndrome of patients with heart disease is a serious disease with far-reaching detrimental effects for society and the individual patient, but the Homer (Simpson) syndrome is an even more dangerous disease affecting the doctor, not the patient. The Homer we are referring to is not the great Greek poet, but our more modest Homer Simpson, the contemporary cartoon character created by Matt Groening. Homer is the security inspector of Springfield Nuclear power plant, and in theory, should serve as the guardian of the culture of safety in a potentially dangerous working environment. Unfortunately, he neither knows nor cares about the risks he is taking every day at work. As a contemporary cardiologist, Homer Simpson would not be surprised that, for instance, 35% of myocardial perfusion scintigraphies in the United States used Thallium, 86% of them being dual isotope studies, perhaps because of the relatively fast patient throughput [29]. The dose of a Thallium scan is about 1500 to 2000 chest X rays, three- to four-fold higher than the dose of a sestamibi scan (same myocardial perfusion stress test, very similar information). The practicing/prescribing cardiologist does not know doses, ignores risk, and intones the "Yes, we scan!" mantra [30, 31]. If the patient is happy, and the budget increases, why should we care? This is also why we like Homer so much: he is like us. A radical change is now possible, and necessary —"Yes, we can!" know doses, recognize risks, share decisions with informed patients, improve appropriateness, and become better doctors.

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SOME ASPECTS OF DIAGNOSTIC RADIOLOGY IN BRAZIL

J.P. MATUSHITA
Universidade de Minais Gerais (FMG)
Belo Horizonte, Minais Gerais
Email: jpauloejulieta@gmail.com

H.J. KHOURY
Universidade Federal de Pernambuco (UFP),
Pernambuco, Recife

Brazil

Abstract

The paper provides — for a very large country — an overview of the availability of facilities and radiology services, citing data that demonstrates the unequal distribution thereof, and underscoring the results of a study that indicates that procedures are not optimized. There is a large variation in exposure parameters that indicates that much can be done to reduce patient doses and improve image quality.

Brazil is a country with an area of 8 514 877 km^2 and a population of 188 098 126 inhabitants. There is an unequal distribution of facilities and radiology services in the country and a great contrast in the technology of available equipment. Table 1 presents the distribution of radiology equipment in Brazilian facilities [1]. This data shows a high concentration of medical units in the south and south-east regions.

In addition to this unequal distribution of facilities and radiology services in the country, there are great contrasts in the technology of available equipment. Some services have equipment with the newest technology, while others have equipment with older technology. The regulatory authority in the diagnostic field is The National Sanitary Vigilance Agency (ANVISA) of the Health Ministry. ANVISA has the authority to carry out inspections and to issue operation licences to the State Sanitary Vigilances of State Health Secretaries. Requirements for medical use of radiation are in agreement with the Basic Safety Standards (BSS) with respect to infrastructure, staff and quality assurance and they are established in Resolution 453/1998 (MS) of the National Health Ministry [2]. The Programme of Quality Assurance and the radiometric survey have been obligatory since 1989.

Surveys of patient dose and image quality have been undertaken in some states of the country [3, 4]. These studies have demonstrated that for pediatric radiology there is no dedicated X ray equipment and the use of anti-scattering grids is common. In general, patient protectors and immobilizers are not used. Figures 1 and 2 show the

TABLE 1. DISTRIBUTION OF RADIOLOGY EQUIPMENT IN BRAZILIAN FACILITIES LOCATED IN DIFFERENT REGIONS OF THE COUNTRY [1]

Type of equipment	Region of the country					
	North	Northeast	Southeast	South	Midwestern	Total
Mammography	105	573	1738	523	586	3245
X ray units	858	1072	7551	3586	1366	16 433
Fluoroscopy equipment	30	110	794	221	98	1253
Hemodynamic equipment	14	73	312	93	45	637
Computed tomography	71	294	1088	342	166	1961

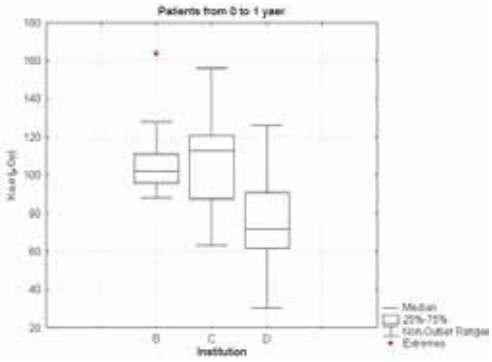

FIG. 1. Distribution of the Entrance Surface Air Kerma (K_e) for chest examinations for each institution for chest examinations in AP projections with age group from 0 to 1 year old.

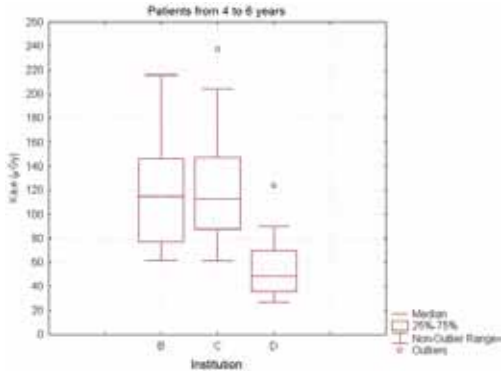

FIG. 2. Distribution of the Entrance Surface Air Kerma (K_e) for chest examinations for each institution for chest examinations in AP projections with age group from 4 to 6 years old.

results of the Entrance Surface Air Kerma (K_e) obtained in a study of chest AP/PA radiographic examinations of patients in the age groups 0–1 year and 4–6 years performed in four Brazilian hospitals (two in Rio de Janeiro, one in Curitiba and one in Recife) [3]. This study demonstrated a large variation in exposure parameters used in different clinics, many of which were found to be outside the values recommended by the European Commission [5]. The results indicate that the procedures are not optimized.

Regarding computed tomography, it has been observed in Brazil that there has been an exponential increase in CT scanners installed in the last five years. Many facilities have acquired multi-slice CT scanners (MDCT), creating the possibility for new clinical applications, such as CT angiography and virtual endoscopy. Evaluation of CT procedures has demonstrated that in many cases the volume irradiated is greater than necessary. Protocols are not optimized in clinics and protocols for adults are used for children. In general, no special devices are used for shielding of superficial organs such as thyroid, breast, eye lens and gonads, particularly in children and young adults.

Another important aspect is related to the physical infrastructure of services and personnel training. Investment in new technologies is not accompanied by investment in staff training.

CONCLUSION

It is possible to conclude that, in Brazil, territorial dimension and expressive differences in income distribution in the country leads to a contrast in technology installed, in the qualifications of radiology service staff and, consequently, in the quality of the service offered to the population. There is a large variation in the exposure parameters used in different clinics, many of which are outside the values recommended by the European

Commission. This large variation in exposure parameters and in the Entrance Surface Air Kerma indicates that much can be done to reduce patient doses and improve image quality. Important actions in Brazil can be started to optimize patient radiation protection with the goal of obtaining high quality images, such as the implementation of quality control programmes.

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COMMUNICATION AND RISK

(Session 3)

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Rapporteur

W.R. HENDEE
United States of America

MEDIA PERSPECTIVE: A GOOD STORY

P. RICKWOOD
Vienna, Austria
Email: rickwoodp@gmail.com

Abstract

Media coverage about the risk associated with medical radiation exposures is increasing, and if not appropriately addressed could result in a drastic loss of public faith in the health benefits from the use of ionizing radiation in medicine. This paper explains from a journalistic perspective why the issue of radiological justification meets the criteria of a newsworthy topic, and outlines how to engage the news media in an outreach programme to achieve a new and better informed relationship between patients and those who deliver radiation in medicine.

1. INTRODUCTION

Medicine in all its guises draws broad public attention, whether as the tool of science that defeats disease, or a theme of entertainment, and when it fails, given the dependence of patients on the expertise of its practitioners, it constitutes a major breach of faith. Therefore it will be surprising if the current culture of radiology with its attendant problems does not become a focus of news media attention and public concern. Perhaps it's only surprising that the issue has not yet gained significant attention.

Either by the efforts of the radiological community or the curiosity of reporters the story will emerge and given the manner in which news is gathered and presented to the public, could become as significant a story as other recent previously submerged medical issues, such as the tainted blood scandal.

There is every indication of a gathering storm that has yet to break. From the perspective of news reporting there are a number of features to the issue that predispose it to becoming the focus of journalistic attention and concomitant public alarm: the two will feed upon each other.

To illustrate the proposition that there is growing news media interest in the subject, the following headlines in the English language news media from August 2009 are cited.

— 5 August, "CT scans raise risk of cancer in young", *The Australian*
— 8 August, "Alarm grows over high CT radiation", *The Australian*
— 18 August, "Rise in thyroid cancer may be tied to radiation", *USA Today*
— 26 August, "Radiation risk: Younger Americans overexposed", *Reuters News*
— 27 August, "Imaging dose again comes under fire in New England Journal of Medicine", *Diagnostic Imaging*
— 28 August, "Study: Patients may Face Radioactive Risk (sic) From Imaging Tests", *Medical News Today*
— 28 August, "How Safe Or Unsafe Are Medical Imaging Procedures?", *Science Daily*

2. CRAFTING THE NEWS

To begin to better understand how a significant story will be broached, the nature of news gathering is described. In a typical newsroom the relationship between senior editors and reporters defines the topography: an editor may be provided with anecdotal evidence; his neighbour, his children, his spouse become the locus for his awareness. A reporter, on the other hand, particularly one who specializes (has the medical beat for example) may become informed by her, or his sources: physicians, radiologists, or a consumer group, about the issue.

The editor can assign a reporter to investigate the story; the reporter who's received the tip-off will seek to persuade her, or his, editor to authorize a follow-up, to allocate time for research, or more likely, space for a story.

The important point is that the issue of radiological justification, from a journalistic perspective, meets all the criteria of a newsworthy topic.

Sooner or later a reporter *will* connect all the dots and a story that is now at the foot of page A11, or in the lifestyle sections of daily newspapers, will command above the fold front page attention, the stentorian prose of editorial page writers, TV interviews with anxious mothers and sick children, and radio documentaries.

The collection of information for a damning indictment may well be underway at present.

When the Journal of the American College of Radiology reports that rapid growth of CT and certain nuclear medicine studies over the past quarter century may result in an increased incidence of radiation related cancer in the not-too-distant-future, we hear alarm bells ringing.

In the currency of journalism, the issue of radiological justification offers the most essential values:

- **Aggrieved patients:** For a journalist to 'stand up' her or his story requires the direct evidence, or claim, of a person, or persons who can attest to the impact of, in this case, a medical practice: given the ubiquity of imaging it seems unlikely a reporter will have far to look;
- **Universality:** It's about health, the alleviation of suffering that has somehow gone wrong: "There but for the grace of God go I." In other words, if the individual reader/viewer has not been touched by the issue, it's likely she or he will know someone who has been exposed; the story has the potential to have huge resonance. Also, there's no longer blind faith in the delivery of health care, plus, authority in general has suffered an erosion of trust, and exposure of the justification issue will have the added value of feeding innate fears;
- **A vulnerable group:** Reuters in a 26 August FACTBOX accompanying its report on the New England Journal of Medicine, for example, cites 'younger Americans' may be getting too many imaging tests;
- **A whiff of unscrupulousness:** Not articulated clearly but supported anecdotally is the suggestion that shop front CT operations, for example, may waive caution to meet the payments for their extremely expensive equipment. The referring physician may often be the owner of the facility;
- **Inaction and complacency:** Fits the commonly held perception that bureaucracy is merely self-serving. If not, why is the problem still an unresolved issue eight years after the 2001 International Conference on the Radiological Protection of Patients in Diagnostic and Interventional Radiology, in Malaga?;
- **Radiation:** It continues to be the Beelzebub of technology. You can't see it, smell it, feel it … but it can kill you, and post 9/11 fears of dirty bombs have replenished fears that may have been declining since the Chernobyl accident rekindled fears from the period of atmospheric nuclear weapons testing.

3. BANAL JOURNALISM

There is, often, a tendency to perceive journalism as an exercise in triviality, an excess offering on the altar of banality.

But don't underestimate the power of journalism. Shortly after World War I in Munich Max Weber told a group of students:

> "Not everyone realizes that to write a really good piece of journalism is at least as demanding intellectually as the achievement of any scholar. This is particularly true when we recollect that it has to be written on the spot, to order, and that it must create an immediate effect, even though it is produced under completely different conditions from that of scholarly research. It is generally overlooked that a journalist's actual responsibility is far greater than the scholar's."

An additional incentive for pro-active action, for public outreach, is that it's hard to restore public trust once it's been lost.

"Once factually inaccurate ideas take hold in people's minds there are no reliable strategies to dislodge them — especially from the minds of those for whom the misinformation is most ideologically convenient," from the work of Brendan Nyhan, a political scientist and blogger, as reported in the Columbia Journalism Review.

This can also be attested to in the most recent debate in the United States about proposed health reform, where recipients of federally (central government) funded Medicare complained about the threat of the 'socialization' of medicine, or government running it.

4. ENGAGING THE NEWS MEDIA

Engagement with the news media remains an expedient means of stimulating debate about the radiological exposure issue.

From the perspective of an outsider it also appears there is a very clear obligation for a community of practitioners, insiders privy to knowledge, to better inform consumers about risks attendant with current practices of which they are well aware.

Any steps towards amelioration will require engagement with external stakeholders and consideration of their response. Although there is lively debate, it is currently being conducted behind opaque walls. Such practice is abhorrent to the tenets of journalism: It can be anticipated that without declaration/outreach, the news media will eventually find fertile ground.

Of course, there remains the necessity to establish a balance between the utility of a medical procedure with a high potential value for accurate diagnosis and its over-prescription.

There is no quick fix, but the debate over tobacco consumption — while not clearly analogous — demonstrates that media driven outreach can have a positive effect, can change a culture.

5. STAKEHOLDER ENGAGEMENT

The following elements of an outreach programme might engage stakeholders:

- A cross-cutting outreach strategy aimed at internal and external stakeholders;
- Targeted communications — delivered to key audiences;
- A commitment to ongoing frank debate;
- Respect for transparency and accountability;
- Recognition that trust has to be earned.

These are some of the steps that will be required to be taken to establish and maintain a satisfactory partnership in an endeavour to change a practice of medicine for the improvement of safety.

Such engagement will also yield its own chemistry and may cut the Gordian knot that appears to leave the issue currently unresolved.

Without outreach there is the risk of a complete loss of confidence and demonization of medical imaging.

Parenthetically it should be noted, and this may have some bearing on the justification issue, that the mantra for nuclear safety in general, since Three Mile Island and Chernobyl, is that the main threat to safety is complacency, and stakeholder engagement is considered a necessary antidote.

The International Nuclear Safety Group (INSAG) in its IAEA published report ‘INSAG 20’ states: “stakeholder involvement makes regulatory organizations and other authorities acutely aware that their actions are under public scrutiny. Transparency increases the motivation of individuals and institutions to meet their responsibilities in: (a) drafting rules and regulations; (b) strictly verifying compliance and (c) enforcing necessary corrective actions.”

6. AN OUTREACH PROGRAMME

To embark on an outreach programme, and because of the speaker’s background as both a journalist and a press officer for international organizations, in addition to launching a broad education programme, targeting key journalists should also be among the initial steps.

In order to equip, to empower patients and patient advocate organizations, whose role will be vital in changing the current culture, targeted outreach to journalists will be an important part of stimulating debate.

Cherry-picking journalists, identifying informed and influential writers will be an effective means of putting into context some of the key elements in a broad debate.

Despite massive recent layoffs of journalists from news organizations and the trend towards smaller newsrooms, there remain well organized groups of specialist journalists who can be targeted in any outreach activity.

In particular, the power of television should not be discounted. For example, “the leading type of media use among teens is still television, with the average teenager watching three hours and 20 minutes per day, debunking the myth of YouTube as the lead medium. Actually, Nielsen says, teens watch more TV than ever, with usage up six per cent over the past five years in the U.S,” from Nielsen Business Media, 25.06.09.

7. AN INFORMATION COMMONS

A caveat should be added: this is an era, where, despite claims to authority, there is, in the current information commons, no longer significant claim to sovereignty over communications outreach.

“Fundamental change is occurring across message creation, channels and audiences simultaneously. This change is taking many forms, but there is one inescapable reality across all of them: we are no longer in control,” the Arthur C. Page Society, The Authentic Enterprise, 2007. (Page was a doyen of corporate communications in the USA).

If, and it appears inevitable, there will have to be an outreach/public information campaign targeting external stakeholders in concert with efforts to establish guidelines and improve referral patterns among internal stakeholders, the process will require considerable commitment and support.

But the challenge of informing patients, of informing the consumers without whose engagement a sweeping cultural change is unlikely to occur, is not an unknown quantity, it is not without precedent and formulas for successful fulfillment have clearly been established.

The National Research Council of the National Academies in the US in 2008 published ‘Public Participation in Environmental Assessment and Decision Making,’ sets a path: Public participation works but depends strongly on the way the process is organized.

Process design should be guided by four principles:

- Inclusiveness of participation;
- Collaborative problem formulation and process design;
- Transparency of the process;
- Good faith communication.

8. IN CONCLUSION

At this point in the history of concern about the justification of medical exposure in diagnostic imaging, it seems that a ‘good story’ would in fact best be a negative story about the issue. Such a ‘good story’ will clearly have negative ramifications for the radiological community — a mea culpa would be in order — not the least because the public until now has been ill informed about the issue by it and offered scant protection.

A ‘good story’ will need to be a story that holds the culture and inappropriate practice to account, without which a new and better informed relationship between patients and deliverers will not be able to flourish.

In this sense a ‘good story’ is a bad story and a bad story is a ‘good story.’

COMMUNICATION, CONSENT AND THE PATIENT: UNLOCKING THE RADIOLOGICAL CHAMBER OF SECRETS

E. PICANO
Institute of Clinical Physiology,
Consiglio Nazionale delle Ricerche,
Pisa, Italy
Email: picano@ifc.cnr.it

Abstract

In theory, good medical practice implies knowledge of the doses and long term risks of radiological and nuclear medicine testing, since awareness of risk is essential for tailoring the risk–benefit balance regarding test appropriateness. In practice, extensive recent data show substantial unawareness of radiological doses and risks — not only on the part of patients, but on behalf of prescribing and practicing doctors as well.

1. BACKGROUND

Non-specialists (and sometimes specialists) often do not understand the difficult jargon of radiation protection in which doses are expressed in various, often esoteric, units (megabecquerel, millicuries, kilovolts, dose-area product, etc.), and simple information on doses and risks is difficult to find and hard to interpret. The pressures of an old-fashioned paternalistic view of medicine combined with modern efficiency work against the existence of truly informed consent. Ineffective communication currently poses significant ethical problems, with high litigation potential. Informed consent is necessary to establish a respectful and ethical relationship between doctors and patients. A transparent, informative, honest consent form should spell out the type of examination, the exposure in effective dose (mSv), derived from reference values in guidelines or — better — from actual values from the irradiating department. The dose equivalent should be also expressed in the equivalent number of chest radiographs and the risk of cancer as the number of extra cases in the exposed population, derived from the most recent and authoritative guidelines (such as the BEIR VII Committee, released in 2006). Complete radiological informed consent is an important step in the direction indicated by the American College of Radiology recent White Paper, recommending that physicians “should work with patient advocacy organizations to more effectively communicate the potential radiation risks and health benefits of imaging procedures”. Forced to explain to the patient what they currently disregard, doctors will gently and painlessly learn what they should already know.

Every radiological and nuclear medicine examination confers a definite (albeit low) long term risk of cancer, but patients undergoing such examinations often receive inaccurate or no information about these risks, which are directly related to the radiological dose received [1–5]. Excessively detailed information on radiological dose and risk may result in undue anxiety, but information ‘economical with the truth’ may violate basic patients’ rights well embedded in ethics (Oviedo convention 1997) [6] and law (97/43 EURATOM Directive 1997) [7]. In fact, one of the three fundamental principles of the ‘charter of medical professionalism’ in the new millennium is the principle of patient autonomy: “Physicians must empower their patients to make informed decisions about their treatment” [8].

2. PATIENT’S AWARENESS OF RADIOLOGICAL RISK

Informed consent for radiological examinations is often not sought, and when it is, patients are often not fully informed, even when facing considerable levels of radiation exposure and long term risk [2]. This risk of a 64-slice computed tomography coronary angiography can be as high as 1 in 100 in a young woman or in a child [9]. In theory, the majority of pediatricians from the Greater Toronto Area in Canada, practicing in a wide variety of hospital and clinical settings believe that a risk of 1 in 10 000 or more should be discussed with the parents [10]. In reality, patients are not given information about the risks, benefits, and radiation dose for a CT scan, even when a

considerably higher risk is involved. In another study performed in the emergency department of a US academic medical centre, adult patients who underwent diagnostic CT scans were surveyed. Only 7% of patients reported that they were told about risks of their CT scan, and all patients were unable to estimate the dose for one CT scan compared with that for one chest radiograph [10]. Only 3% of patients believed that their lifetime risk for cancer was increased as a result of the CT scan [10]. In another study performed in the Nuclear Medicine Department of a leading academic centre in Italy, 79% of surveyed patients thought that the cardiac stress scintigraphy they had performed gave a radiation dose of <1 chest X ray (instead the true dose was the equivalent of 500 chest X rays), and 40% thought that no cancer risk at all was present. Ironically, 71% of patients thought they received good-to-excellent information on the risks and benefits of the procedure from their physician [11].

3. PHYSICIAN AWARENESS OF RADIOLOGICAL RISK

Extensive recent data show a substantial lack of awareness of radiological doses and risks, not only among patients but of prescribing and practicing doctors as well. In theory, good medical practice warrants knowledge of the doses and long term risks of these tests — which can be judiciously employed when they are most appropriate. The results of recent surveys of British physicians [12], Israeli orthopedists [13], Italian cardiologists [14], Canadian pediatricians [15] and US academic radiologists [15] show that the majority of doctors grossly underestimate radiation doses (usually by up to 500 times) and corresponding cancer risks for most commonly requested tests. Emergency room physicians and radiologists alike are unable to provide accurate estimates of CT doses regardless of their experience level. In particular, among radiologists, 5% of respondents thought that a computed tomography scan dose was less than one chest radiograph, and 56% estimated a computed tomography scan dose to be between 1 and 10 chest radiographs, with dramatic underestimation of the true dose (about 500 chest radiographs) [15]. Forty per cent of pediatricians underestimate by up to 100 times the dose of a pre- and post-contrast head CT [10]. A minority of doctors also suffer from what we might call ‘imaging Daltonism’, or the inability to separate ‘green’ (non-ionizing) from ‘red’ (ionizing) techniques. Five per cent of British doctors do not realize that ultrasound does not use ionizing radiation, and 10% do not realize that magnetic resonance imaging does not use ionizing radiation [12]. Among Canadian pediatricians, 4% believed that ultrasound involves ionizing radiation and 12% were not aware of what scintigraphy scans do [10]. In the presence of this diffuse background level of radiological awareness, inappropriate examinations may proliferate, to the profound detriment of society and patients [16–19].

4. INFORMED CONSENT: HOW IT IS

There are three possible ways to look at radiological risk communication in medicine — no mention of risk, understatement of risk, and specific detailing of risk [2].

Strategy 1: ‘Don’t say a word’

One philosophy is not to mention radiological risk. Even for procedures involving high radiation dose, such as interventions under fluoroscopic control, there is no explicit or implicit mention of long term risk. The risk exists and may be substantial, but it remains unheard (by the patient) and unspoken (by the doctor). The basic argument is that radiologists are too busy to spend time obtaining informed consent and anyway are too wise to undertake inappropriate examinations [20]. A patients’ legal right to information is eclipsed by the two forces of efficiency and a paternalistic, ‘expert knows best’ vision of individual autonomy. Neither the long term nature of a risk, nor its absolute amount, seems to be the excuse for disregarding informed consent.

Strategy 2: Understatement

In other aspects of radiological practice, obtaining written informed consent is part of standard practice. In this case, the issue of efficiency bias is not raised: a patient must give informed consent before contrast is injected. But what is the quality of the information provided to patients? On the websites of scientific societies, in the

information section for patients and in the informed consent forms to be signed by patients, we read statements such as “A nuclear medicine examination is safe, with an irradiation corresponding to a simple radiograph” or “almost always less than a common radiological examination” [20]. Both patients and clinicians might believe that a ‘common radiological examination’ or ‘a simple radiograph’ would be a chest X ray, which is by far the simplest and most common radiological examination [21]. In reality, however, the dose exposure in cardiology ranges from 500 chest X rays for a sestamibi to 1500 chest X rays for a dual isotope cardiac stress scintigraphy [22]. Such imprecise statements are probably intended to reassure patients, to avoid useless concern about an unavoidable risk. However, this attitude of ‘one consent fits all’ for radiological examinations may mislead clinicians to underestimate the associated risks.

Strategy 3: Full disclosure

Some organizations, such as the US National Institute of Health, describe radiological risk in more straightforward terms, at least when a test is performed within a research project and with a radiation dose greater than 15 millisieverts (corresponding to the average dose of 64-slice computed tomography coronary angiography): “Your scan involves exposure to radiation. Although it can vary from person to person, your whole body radiation exposure during each scan will be about 15 millisieverts. This is about five times the average annual radiation exposure a person in the United States receives from natural background radiation. Although no harmful effects are expected, your long term risks of harm from this degree of radiation exposure might be as high as 1 in 1000. Harmful effects could include the development of cancer and genetic changes” [23].

5. INFORMED CONSENT: HOW IT SHOULD BE

Non-specialists (and sometimes specialists) often do not understand the difficult jargon of radiation protection, in which doses are expressed in many varied units (megabequerel, millicuries, kilovolts, dose area product, etc.), and simple information on doses and risks is difficult to find and hard to interpret [2]. The pressures of an old fashioned paternalistic view of medicine as well as more modern efficiency act against the creation of a truly informed consent [2]. The well known permeability of medical opinion leaders and media to industry and corporate interests can further modulate communication towards underestimating and obscuring risks. As the late best selling author Michael Crichton wrote when he was a young Harvard medical school graduate, “medical writing is a highly skilled, calculated attempt to confuse the reader” [24] — and a successful one in case of radiological risk.

Nevertheless, in an ‘ideal’ consent process, the standard of risk communication already adopted for irradiation in research might be fruitfully followed for irradiation in clinical practice. The form should spell out at least the type of examination, the exposure in effective dose (mSv), the dose equivalent in number of chest radiographs, and the risk of cancer clarified as the number of extra cases in the exposed population [1, 2, 5]. The associated graph (Fig. 1) underlines the linear relation between dose and risk and might be useful for passing information from doctors to patients and between doctors because the figure format complements the traditional table format (Table 1) and the colour coding helps readers to understand risk levels [2]. This simple evidence based communication strategy, if used when obtaining informed consent, will raise the currently suboptimal level of radiological awareness among doctors and patients. Better knowledge of risks will help us to avoid the small individual risks that translate into substantial population risks [16–19]. Consent forms would also help reduce pressure from patients for redundant and often useless examinations [2].

Common sense, deontological code, patients’ rights, medical imaging guidelines, EURATOM law — all coherently and concordantly suggest, encourage and order a responsible and informed use of ionizing testing. Current practice clashes with these guidelines and laws [25, 26]. It will become more and more difficult to defend physicians ignoring doses and risks of exams with a high radiation load, especially in the case of inappropriate examinations, which plague the current practice of medicine in every field [27–29]. By law, there are strict limits for the general population (1 mSv per year) and for professionally exposed workers (20 mSv per year). Paradoxically, a citizen upon becoming a patient loses his/her radiological rights and can receive literarily hundreds of mSv of exposure without receiving any information and, in the case of inappropriate examinations, without any

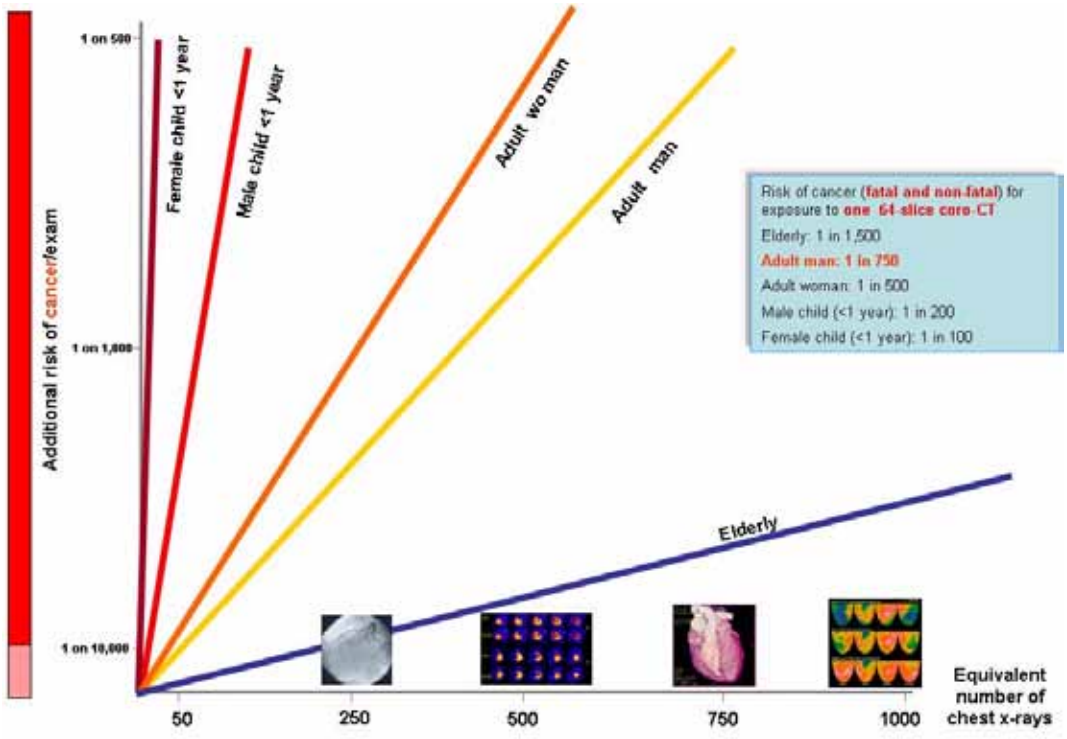

FIG. 1. Dose (in x-axis, in equivalent dose in chest X rays) and risks (in y-axis, calculated from BEIR VII) of commonly performed examinations.

Investigation	Effective dose (mSv)	Equivalent no. of plain chest radiographs	Approximate equivalent period of natural background radiation	Additional lifetime risk of fatal and non-fatal cancer*	RCR Symbolic representation**
Plain PA chest radiograph	0.02	1	3 days	1:1 000 000	
Lung perfusion scintigraphy (Tc-99m)	1	50	6 months	1:10 000	
CT chest (non contrast)	8	400	3.6 years	1: 1200	
Perfusion cardiac rest-stress Technetium 99m sestamibi scan	10	500	4 years	1:1000	
MDCT Cardiac (64-slice)	15	750	7 years	1:750	
Coronary stenting	20	1050	8 years	1:500	
Thallium-201 scan	41	2000	16 years	1:250	

*These examples relate to a 50 year old male. Multiply by 1.38 for women, by 4 for children under 1 year, and by 0.5 in an 80 year old male.

**: <1 mSv, : 1–5 mSv, : 5–10 mSv, : > 10 mSv.

On the right side column; symbology proposed by Royal College of Radiology, 2007.

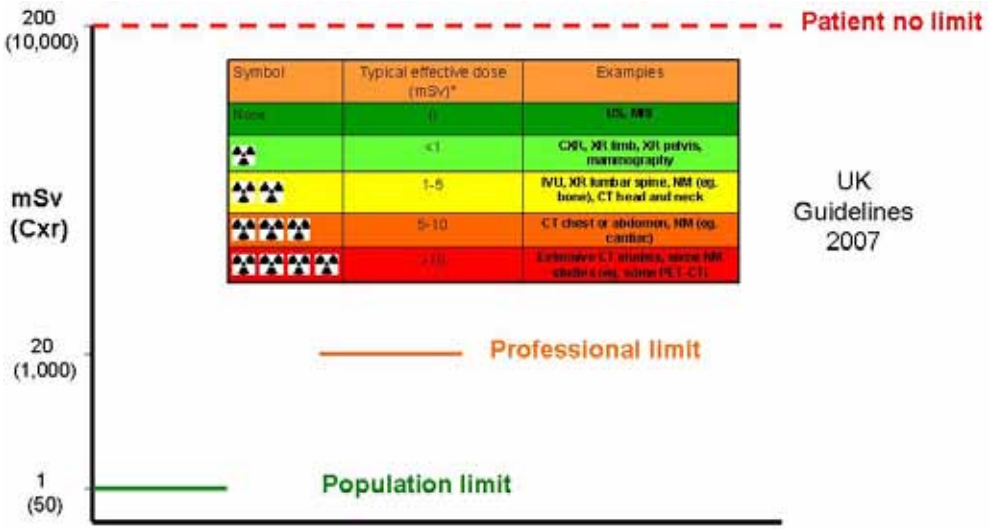

FIG 2. Dose limits for the population (1 mSv per year, corresponding to the radiological dose of 50 chest X rays) and for exposed workers (20 mSv per year, corresponding to 1000 chest X rays). Paradoxically, limits are nonexistent for exposed patients, who can receive cumulative dosages for a single pathology (for instance, coronary artery disease or renal colic) up to hundreds of mSv without any warning, awareness or information.

commensurate benefit. Perhaps it is time to change, and informed consent can help in this long overdue turnaround from a culture of paternalism, efficiency and waste to a new culture of safety, prudence and appropriateness.

6. CONCLUSION

Correct informed consent plays an essential role in the physician–patient relationship. A proper, complete, updated and comprehensive informed consent form is essential for an effective patient–physician partnership, to determine the best risk–benefit ratio for each individual case. The ideal informed consent form should spell out the dose equivalent in number of chest X rays and the estimated risk of cancer. This simple informed consent form policy will gently force doctors to be more aware of what they are doing and the patient more aware of what he/she undergoes, thus enabling both to make more responsible choices.

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DOSE AND RISK: THE HARD FACTS

P.W. HORTON
Department of Medical Physics,
Royal Surrey County Hospital,
Guildford, United Kingdom
Email: patrick.horton10@btinternet.com

Abstract

The paper examines the relationship between radiation dose and carcinogenic risk at doses of less than 100 mSv, and considers the presentation of risk in an understandable format for radiologists, physicians and patients. To make justification of the radiological procedure a more clear and balanced process, it is important to identify the relevant patient or organ doses for the calculation of cancer risk and see if the discussion of such complex matters as effective dose can be avoided in the outcome.

1. BACKGROUND

A number of publications have shown a lack of knowledge of the radiation risks from different diagnostic procedures by radiologists and physicians, as well as members of the public. This comes about from a lack of knowledge of the radiation doses involved and the complex quantities used to express them and from a lack of understanding of the relationship between radiation dose and the risk of carcinogenesis with relatively low radiation doses. There is also difficulty in expressing risk in the every day terms that both radiologists and members of the public understand and the danger that risks are amplified or diminished by the knowledge and attitude of individual patients. All these factors point to a lack of familiarity with radiation doses and risk that does not provide radiologists and physicians with the needed confidence to talk about these matters to patients, whereas other aspects of an investigation which appear more commonplace and understandable are discussed prior to an investigation. For example, Lee et al. [1] in a survey of informed consent for radiological procedures at 91 US academic medical centres found that 84% explained possible allergic reactions to the contrast medium but only 15% explained radiation risk.

The purpose of this communication is to look at the relationship between radiation dose and carcinogenic risk at doses of less than 100 mSv and consider the presentation of risk in a format understandable to radiologists, physicians and patients. In doing so, it is important to identify the relevant patient or organ doses for the calculation of cancer risk and to see if the outcome can avoid discussion of such complex matters as effective dose in order to simplify and improve the clarity of balancing the radiation risk with the benefit arising from a proposed procedure for improved patient management, in other words, to make justification of the radiological procedure a more clear and balanced process.

2. RADIATION DOSE AND CANCER RISK

Data from the Japanese atomic bomb survivors represent the ‘gold standard’ for the quantitative assessment of carcinogenic risk at low radiation doses [2]. These data show that the risk of all solid cancers except lung cancer increases linearly with radiation dose from low doses up to approximately 2.5 Sv. They also show that children are much more radiosensitive than adults and there is a continuous decline in radiosensitivity with age for most cancers. Two analyses [3, 4] have addressed the issue of what the lowest radiation dose is at which a statistically significant increase in cancer risk is apparent. Brenner et al. [4] analysed the A-bomb survivor data into successively lower radiation bands and have come to the conclusion that excess cancer relative risk is statistically significant down to 35 mSv.

The data from the Japanese atomic bomb survivors (termed the Life Span Study) is thought to be the most reliable data for the following reasons:

- The study involves a large population, approximately 100 000 people;
- The population is not selective on an age and sex basis;
- The follow-up covers more than 60 years;
- Both cancer mortality and incidence data are now available;
- The population received a wide range of doses with 30 000 in the range of 5–100 mSv;
- Calculation of the radiation doses received is accurate, as the DS02 system was used.

However there are some concerns about the data. These are:

- The population suffered a single acute radiation exposure;
- The radiation dose rate was relatively high (hence the need for the Dose and Dose Rate Effectiveness Factor (DDREF) in calculating cancer risks — see later);
- The population was malnourished and the outcome is biased towards healthy survivors;
- The underlying cancer incidences in a Japanese population are different from those in other parts of the world, and this needs to be taken into account when extrapolating risks to a wider population. This is especially pertinent to the incidence of breast and thyroid cancer.

Further information on the relationship between cancer incidence and dose can be obtained from medically exposed, occupationally exposed and environmentally exposed populations. Medically exposed groups tend to be small (with low statistical power) with exposure arising from past use of now outdated practices. Occupationally exposed groups, such as nuclear industry workers, can represent large populations, especially in meta-analyses, but lack statistical power due to the low occupational doses. They also have the disadvantage of variable standards of radiation dosimetry and a lack of mortality data to date. Environmentally exposed groups generally have low statistical power due to the small populations involved. Where results are statistically significant, the excess cancer risk in groups exposed at low or moderate doses are statistically compatible with those of the Japanese A-bomb survivors [5].

The radiation risk from ionizing radiation is reviewed at intervals by a number of international and national organizations. At an international level, these are the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and the International Committee on Radiation Protection (ICRP). At national levels, there are the US National Academy of Sciences Biological Effects of Ionizing Radiation (BEIR) committee, the US National Council on Radiological Protection and Measurements (NCRP), the UK Health Protection Agency and the French Academy of Sciences.

3. LINEAR NO THRESHOLD (LNT) MODEL

Cellular responses to ionizing radiation are now thought to result from targeted effects, where the effects occur in cells that are directly irradiated and non-targeted effects in neighbouring cells which are not directly irradiated. The traditional paradigm for the consequences of radiation exposure has been the nuclear target paradigm, in which DNA is the critical target macromolecule in the cell and energy deposition by radiation leads to DNA damage of various forms with the eventualities of cell death, mutations and chromosome aberrations. Double strand breaks in DNA molecules are thought to be the most carcinogenic. This results in a microdosimetric response in which the number of cells hit and hence the damage inflicted is linearly related to dose. In the last twenty years, evidence of a new paradigm has emerged with the discovery of extranuclear and extracellular effects (non-targeted effects).

These new effects are thought to be the result of cell signalling processes and give rise to the following responses [6]:

- Inducible/adaptive responses — where the response to radiation is modified by a small dose of radiation given shortly before or there is gene activation following low doses of radiation;
- Genomic instability — in which cells that survive radiation exposure have a permanently raised level of chromosomal aberrations that lead to long-lasting sub-lethal effects;
- Bystander effects — in which radiation effects can be seen in adjacent unirradiated cells.

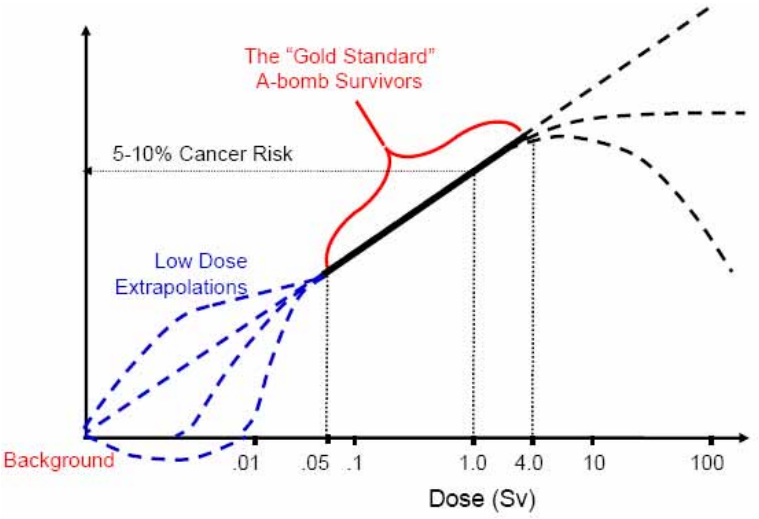

FIG. 1. The relationship between radiation related cancer risk and radiation dose (After Morgan WP, LH Gray Conference, Edinburgh, UK, 2008).

The linear relationship between radiation related cancer risk (as excess relative risk) derived from the epidemiological study of A-bomb survivors is shown in Fig. 1. Brenner et al. [4] suggest that there is good evidence that the linear relationship extends down to 35 mSv for acute doses and 100 mSv for protracted doses and reasonable evidence for increased cancer risk down to 5 mSv for acute doses and 50 mSv for protracted doses.

It can be seen from Fig. 1 that below a radiation dose of about 100 mSv, a number of models have been suggested for the extrapolation of risk to lower doses. The linear extrapolation to zero dose is the 'linear no-threshold model'. The presence of non-targeted effects could give rise to an increased or decreased cancer incidence at low doses. In the supra-linear models, there is an increased cancer risk at low doses. This could arise from low dose hypersensitivity, genomic instability and/or detrimental bystander effects. In the sub-linear models, there is a lower risk of cancer at low doses. This could result from beneficial bystander effects or an adaptive response to background radiation. These models also include the possibility of a threshold dose below which all pre-malignant cells are eliminated. There is also the case of the hormesis model, which says that complex biological systems have cellular physiological barriers against damage, which block damage propagation to clinical disease. Epidemiological evidence for a particular model is unlikely to be forthcoming because of the large populations needed at low doses to provide the precision required and the increasing presence of other causes of carcinogenesis, such as smoking. Evidence at low doses is more likely to be forthcoming from radiobiological studies, but the relevance of the results of experimental irradiations of cell cultures or animal models to complex human systems will possibly be uncertain. For example, Lobrich et al. [7] found that the number of DNA double strand breaks induced by CT examinations was linearly related to the radiation dose length product and remained constant with time using an *in vitro* lymphocyte analysis. However *in vivo*, they found that the number of breaks reduced with time after exposure and returned to background levels in normal patients.

Evidence in favour of the LNT model at low doses [8] includes the Japanese A-bomb survivors who show a statistically significant increase in cancer mortality in the dose range of 5–125 mSv; the data of Mole et al. [9] shows a statistically significant increase in childhood cancer risk following 6 mGy exposures with 80 kV X rays during pregnancy and the data of Doll and Wakeford [10] shows an increased risk of childhood cancer following a 10 mGy foetal dose during pregnancy. These last two studies achieve significance with a small number of cases because of the greater sensitivity of children to ionizing radiation. Principal opposition to the LNT model has come from the French Academy of Sciences (2005) and through the publications of Tubiana and his co-workers [3, 11]. The Academy report states that "the use of the LNT model for assessing the risks of doses less than 20 mSv is unjustified and should be discouraged." The Academy favours a threshold or significantly reduced risks at low doses. It states that there is no significant epidemiological evidence for cancer risk below 100 mSv and notes that mankind has been subject to natural radiation for millions of years at low doses without increased cancer risk. It also uses some non-targeted effects to support this position.

Clearly a complex and developing relationship between cancer risk and low doses has to be codified at the present time to provide a practical basis for the protection of radiation workers and patients undergoing radiological examinations. This needs review as further evidence becomes available. ICRP Report 99 [12] states (para. 264) that "emerging results with regard to a radiation related adaptive response, genomic instability and bystander effects suggest that the risk of low level exposure is uncertain and a simple extrapolation from high-dose effects may not be wholly justified in all instances. However, a better understanding of the mechanisms for these phenomena, the extent to which they are active *in vivo*, and how they are interrelated is needed before they can be evaluated as factors to be included in the estimation of potential risk to the human population of exposure to low levels of ionizing radiation." ICRP Report 103 [13] states (para A187) that, "The Commission judges that there are at present no good scientific reasons to include the possibilities of supra-linear dose responses or of a low dose threshold in cancer risk calculations for the purposes of radiation protection." It also states (para 65), "From an analysis conducted by the Commission [12], the Commission considers that the LNT model combined with a judged value of a dose and dose rate effectiveness factor (DDREF) provides a prudent basis for the practical purposes of radiation protection, i.e. the management of risks from low dose radiation exposure." ICRP 103 [13] suggests keeping the DDREF as a factor of two.

The United States National Research Council of the Academy of Sciences in its BEIR VII Phase 2 Report [14] has also reviewed the biophysical data for evidence of supra-linear, sub-linear and threshold relations for cancer risk at low doses and also concluded that "the current scientific evidence is consistent with the hypothesis that there is a linear, no-threshold dose–response relationship between exposure to ionizing radiation and the development of cancer in humans". However the BEIR VII committee prefers a DDREF of 1.5.

Adoption of the LNT model is therefore the recommended way of calculating risks at low doses at the present time.

4. EFFECTIVE DOSE, EQUIVALENT DOSE AND EFFECTIVE RISK

Medical radiation exposure has been increasing steadily in recent years. The principal causes are CT scans, barium enemas, and nuclear cardiology investigations. Increased exposure has also occurred due to interventional radiology, but this can be considered to be part of patient treatment, though it may result in increased cancer incidence in the population in the future. NCRP Report 160 [15] states the collective effective dose in the United States of America arising from diagnostic medical procedures has risen 7.3 fold between the early 1980s and 2006. At the same time, organ doses from certain examinations, particularly CT, have risen to levels comparable with the doses received by the Japanese A-bomb survivors, where there is direct epidemiological evidence of excess cancer risk and no need to extrapolate to low doses with the uncertainties described above. A number of publications have drawn attention to this increased cancer risk in a large population, notably Brenner and Hall [16]. They estimate that an abdominal CT scan in a neonate with an equivalent organ dose of 30 mSv results in an additional lifetime risk of death by cancer of 0.14%. An abdominal CT scan in an adult aged 65 with an organ dose of 15 mSv leads to an additional lifetime risk of death by cancer of 0.01%.

ICRP 103 (2007) recommends (para 87) that "the approximated overall fatal cancer risk coefficient of 5% per sievert on which current international radiation safety standards are based continues to be appropriate for the purposes of radiation protection". While the coefficient of cancer risk has been used by some investigators to calculate cancer risks in high dose examinations (see, for example, Efstathopoulos et al. [17] for 256-slice CT coronary angiography), this coefficient and effective dose are not intended for this purpose but for general radiation protection. Since a particular organ or group of organs is usually being irradiated, there is no need to use effective dose with its uncertainties; organ equivalent doses are a better basis for the calculation of risk. As stated earlier, the Japanese A-bomb data shows that cancer induction is both age and sex related. Hall and Brenner (2008) state that "the risk to an individual from a high dose radiological procedure is optimally estimated by measuring or calculating organ doses and then applying organ specific, age specific, gender specific and country specific cancer risk estimates. The risks for all organs should be summed." ICRP 103 [13] states (para 64) that "it is scientifically plausible in the low dose range below 100 mSv that the incidence of cancer or heritable effects will rise in direct proportion to an increase in the equivalent dose in the relevant organs and tissues".

The BEIR VII report [14] provided for the first time the incidence of cancer, both fatal and non-fatal, for 11 cancer sites against age and sex, based largely upon data from the Japanese A-bomb survivors. These data enable

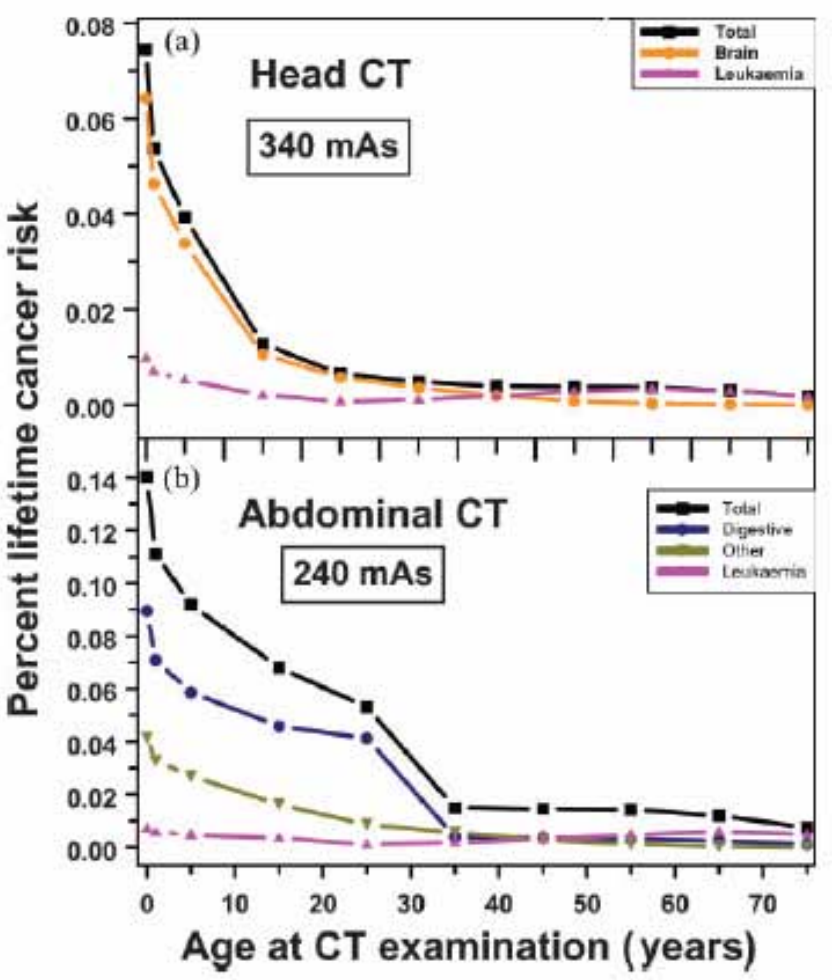

FIG. 2. Relationships between lifetime cancer risk and age for CT examinations using gender averaged data from BEIR VII (Reproduced from Hall and Brenner [2008]).

us to calculate the risk of cancer induction at specific sites from radiation doses of radiological and nuclear medicine investigations assuming the LNT model for low doses. These data use a DDREF of 1.5. However the uncertainties in risk estimates of site specific cancers are large and a factor of two or three larger or smaller cannot be excluded. Figure 2, taken from Hall and Brenner [2], shows how cancer risk can be calculated against age in CT examinations for particular sites, assuming typical radiation doses for the sites concerned, in this example head and abdomen. It is important to note that the radiation dose is also age dependent due to the smaller body cross-sections at younger ages.

Picano [18] has introduced the concept of explaining radiation risk to patients as part of informed consent using a linear graphical presentation of increasing risk from 1 in 20 000 at 1 mSv (lung scintigraphy) to 1 in 1000 at 20 mSv (interventional fluoroscopic procedures) based upon the generalized risk factor of 5% per sievert [13]. The risk is colour coded going from white to red as the risk increases and Picano suggests that informed consent should be mandatory for all ‘red code’ examinations which have an associated risk factor of 1 in 10 000 or higher. This approach showing risk as a continuum has been updated by Picano [19] using the data in the BEIR VII report to produce linear relations between dose and risk for five different groups of patients, *viz* females below one year, males below one year, adult women, adult men and the elderly. The first of these groups shows the greatest risk, closely followed by the second, with the elderly having the least risk as one might expect from the lower life expectancy. This approach also has the benefit of avoiding the complexity of units of radiation dose for different examinations by expressing the dose received as multiples of that received in a simple chest radiograph.

Brenner [20] also notes that effective dose is ‘often confused and misused’. It is often used wrongly in radiology as the basis of risk calculations (more than two-thirds of PubMed citations in 2008) [21], when it is in fact

a weighted average radiation protection quantity designed to enable the radiobiological detriment to be compared in different partial body radiation exposures. It is not age dependent and relies on a reference person as a model. As the BEIR VII report has shown, cancer risk is very much related to sex and age at exposure. Brenner [20] also used the site specific risk data in the BEIR VII report to calculate the lifetime cancer incidence radiation risk for a unit equivalent dose at the 11 sites of 100 mSv in children and adults in a Western population. Most important, because of its unscientific use in this context and its complexity, Brenner [20] suggests that effective dose should no longer be used and should be replaced by a quantity termed ‘effective risk’.

Effective risk is calculated from the sum of the weighted equivalent doses to the tissues irradiated by the examination, where the weighting factors are derived from the tissue specific lifetime cancer risks per unit equivalent dose.

$$\text{i.e. } R = \sum r_T \cdot H_T$$

where r_T is the lifetime radiation attributable, tissue specific cancer risk per unit equivalent dose to tissue T, and H_T is the tissue specific dose in tissue T.

Using the data from the BEIR VII report would result in weighting factors that are age and sex related. The benefit of this approach is that effective risk is an intuitive and more directly interpretable quantity compared with effective dose and has a much greater chance of being understood by radiologists and physicians. Consequently, it is more likely to be used in properly explaining the risks and benefits of a radiological procedure to a patient or the parents of a small child. This approach is similar to that of Picano [19], but takes into account the possibility of irradiation of more than one tissue.

5. CONCLUSIONS

The cancer incidence and survival data from the Japanese A-bomb survivors (the Life Span Study) continues to be the best source of epidemiological data for the relationship between lifetime attributable cancer risk and radiation dose and is still being elaborated. The relationship between cancer risk and radiation dose is linear down to acute doses of about 35 mSv and is age and gender related. The new radiobiology of targeted and non-targeted cellular effects has introduced a number of possibilities for the relationship between cancer incidence and dose at very low doses, including the possibilities of a supra-linear relationship with greater sensitivity to ionizing radiation, a sub-linear relationship with lower sensitivity and a threshold below which carcinogenic events are eliminated. However, ICRP Report 103 [13] and the BEIR VII report state that there is insufficient evidence to support any of these models at the present time and that the linear no threshold (LNT) model remains the conservative model for calculating risk at low radiation doses.

Radiation doses from medical examinations have continued to increase [15] and the radiation exposure of large populations has become significant with an expected increase in long term cancer incidence [22]. At the same time, radiation doses from some individual radiological examinations, particularly CT examinations, are at levels comparable to the doses received by the A-bomb survivors with a known risk of cancer incidence. There is, therefore, the need to include the risk of cancer incidence in the risk/benefit analysis or justification of the procedure and in obtaining the informed consent of the patient, especially with regard to high dose procedures. A number of studies have shown that this is not happening due to unfamiliarity with radiation doses and associated risks and the complexities in defining radiation doses. Publication of the BEIR VII report on the latest analysis of the data from the Japanese A-bomb survivors with the cancer incidence for 11 sites for increasing ages and gender, introduced the possibility of calculating the lifetime attributable risk of cancer incidence (fatal and non-fatal) based on age at exposure and gender for different tissues. The risk of cancer incidence can then be calculated more rigorously from equivalent doses of the tissues irradiated than from the whole body averaged effective dose, which is not intended for clinical examinations with partial body irradiation. This methodology has been followed by Picano [19] who has used a graphical representation of increasing risk with dose in five patient groups and Brenner [20, 21] who has introduced the concept of effective risk. This approach has the merit that it directly estimates risk, avoids poorly understood quantities such as radiation dose, and is therefore more likely to be understood by both the radiologist and the patient during justification and informed consent.

Consideration now needs to be given to how best to present the risk of cancer incidence for particular examinations. This includes:

- The equivalent radiation dose to relevant tissues irradiated in each examination need to be agreed upon;
- The risk of cancer incidence needs to be calculated in relation to the 11 sites in the BEIR VII report;
- The presentation of cancer risk in different groups needs to be considered to ensure they are readily understood. Picano [19] has used the five categories of males less than one year old, females less than one year old, adult males, adult females and the elderly. Brenner [20] has used the three categories of children (under 15 years old), adults (over 15 years) and all ages. The risks should be presented in a standard format that is clear.

This approach, initiated by Picano [19] and Brenner [20], has much to recommend it because it will make justification and informed consent a more transparent and balanced processes. Accuracy regarding radiation doses is not paramount in view of the three fold uncertainties in site specific cancer incidence rates. Data need to be reviewed regularly as better information becomes available on equivalent doses, or dose changes as a result of radiological equipment development and as site specific cancer incidence is updated from future analyses of the A-bomb survivor data.

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TRAINING AND DOSE AWARENESS: CRITICAL FACTORS IN PHYSICIANS' MOTIVATION

P. SMEESTERS*, T. KIFFEL**
Working Party on Medical Exposures of the Group of Experts
Referred to in Article 31 of the Euratom Treaty
Email:
* patrick.smeesters@fanc.fgov.be
** thierry.kiffel@asn.fr

Abstract

In the European Union, medical exposures are regulated through the adoption into national legislations of the Euratom BSS directive and the Medical Exposure directive, which is mandatory for Member States. The Medical Exposure directive addresses the justification issue through direct requirements, including the mandatory availability of referral criteria and the need for education and training. This paper describes the implementation of those requirements in France and Belgium, and draws three major conclusions from the experience gained in these two countries.

1. THE EU APPROACH

Regulation in radiation protection of the population is mainly elaborated at the international level. In the EU, according to the EURATOM treaty, mandatory safety objectives for Member States are set by means of directives. These directives are adopted by the European Council (with a qualified majority), on a proposal from the European Commission (EC). To elaborate upon these proposals, the EC is assisted by a group of independent scientific experts referred to in Article 31 of the EURATOM Treaty. The directives have then to be adapted to national legislations within the prescribed time. Regarding medical exposures, essentially two directives have to be enforced: The BSS directive (Council Directive 96/29/ EURATOM of 13 May 1996, laying down basic safety standards for the health protection of the general public and workers against the dangers of ionizing radiation), giving the general framework, and the Medical Exposure directive (Council Directive 97/43/Euratom of 30 June 1997).

Guidelines for the application of the Medical Exposure directive have also been elaborated by the EU Article 31 Group of Experts, more particularly by the Working Party on Medical Exposures*.

The first directive dealing with medical exposure was the Council Directive of 3 September 1984 laying down basic measures for the radiation protection of persons undergoing medical examination or treatment. It was a relatively 'soft' directive but, nevertheless, it contained clear requirements regarding competence in radiation protection and training of practitioners, including those who were already in practice. This gave rise to the organization of mandatory complementary training efforts which were not always well accepted by physicians, particularly the more aged among them.

In the following years, a lot of research took place dealing with optimization of image quality and patient exposure, quality criteria for diagnostic radiographic images and methodology and instrumentation for assessing doses. The associated workshops and resulting Technical Guidelines and relevant literature were well known and followed by qualified experts in radiophysics, but the participation and awareness of practitioners were generally very low. A real need for dissemination and simplification of knowledge was already underlined at this time, all the more since serious overexposures of patients were increasingly noted.

* These guidelines are freely available on the EC website in the Radiation Protection collection: http://ec.europa.eu/energy/nuclear/radiation_protection/publications_en.htm. For example: Guidance on medical exposures in medical and biomedical research; guidance for protection of unborn children and infants irradiated due to parental medical exposures; guidance on diagnostic reference levels for medical exposures; guidelines on education and training in radiation protection for medical exposure; referral guidelines for imaging.

All these evolutions gave rise to the far reaching Council Directive 97/43/ EURATOM of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure. This directive addressed the justification issue through direct requirements, such as the mandatory availability for prescribers of recommendations concerning referral criteria or shared responsibilities in the justification process between prescribers and practitioners. The necessity to justify medical exposures was also addressed indirectly through various measures promoting dose awareness, such as the promotion of diagnostic reference levels, the explicit inclusion of patient dose evaluation in optimization procedures, or the obligation to supply new radio-diagnostic equipment, where practicable, with a device informing practitioners of the quantity of radiation produced during procedures.

The need for education and training was also reinforced. Appropriate curricula and recognized qualifications had to be established for all interveners. Member States must ensure that continuing education is provided, that training for new techniques is organized and that appropriate training is given regarding medical exposure in interventional radiology, computed tomography, radiotherapy, and health screening, particularly regarding the exposure of children. Unfortunately, the directive did not impose a course in radiation protection in the basic medical curriculum and, as a result, there remains a persisting unawareness of radiation doses and risks by many physicians and prescribers.

2. FRENCH EXPERIENCE

Training is a major necessity to increase physician knowledge of dose awareness and thus increase the level of radioprotection knowledge.

France decided to develop three different levels of training:

— Basic training for medical school students. A lesson of three hours is provided to all students, and questions about radioprotection can be asked during ENC, which is the last classifying examination students must take in order to access training courses in various medical specialties.. At the time, all MDs heard about radioprotection and dose. But is a three hour lesson enough?;
— Initial and continuous training for radiologists, radiotherapists and nuclear medicine doctors. This training very much supports the importance behind justification and dose awareness. However, these topics do not seem to be so important for junior MDs or even senior MDs. For most of them, all medical examination is justified no matter what the dose level is;
— Special training in patient radioprotection. Such training is now mandatory for all persons using ionizing radiation on patients (since June 2009). A common core syllabus for all professionals includes dose in all kinds of medical examinations using ionizing radiation, patient information and practical aspects for children, pregnant or breastfeeding women. Specific training is undertaken for radiologists, nuclear medicine doctors, radiotherapists, and other MDs using ionizing radiation (such as surgeons or cardiologists), as well as physicists and radiographers. For doctors, this training includes individual justification for patient exposures based on general justification using guidelines. These guidelines break dosimetric levels into classes, allowing a physician to know the dose level delivered by an examination. These guidelines are accessible to all MDs, but essentially used by radiologists and nuclear medicine doctors. Finally, this special training allows the trainee to better understand the diagnostic reference levels (DRLs), and increases participation in the national survey of dose. If this training is undertaken for all radiologists, nuclear medicine doctors and radiotherapists, a lack of training is still apparent for surgeons and cardiologists.

In France, training seems to have better motivated physicians in using the justification process, dose awareness and DRL. But some problems remain: Better knowledge for all physicians (prescribers), a clinical audit to check case by case justification, more participation in a national survey of dose and dosimetric indicators in all reports. But probably the most important topic will be how to justify new techniques and new practices using ‘old’ techniques.

3. BELGIAN EXPERIENCE

Although EU directives, and even EU guidance, has been transposed in due time into national legislation, the result has been rather disappointing. The road is long from change of regulation to change of culture! So, many prescribers are still completely unaware of the problem and — although the education and training of practitioners is mandatory — there is still a lack of radiation protection and ALARA culture in many radiological services. Outside radiological services, the situation is worse: training and lectures for users of Rx (mainly interventions guided with radioscopy) are often not organized or not followed, this being partly due to a counterproductive local culture.

This gave rise to a change in approach and several resulting initiatives at the level of the Belgian Federal Agency for Nuclear Control (FANC), all aiming to increase physicians' awareness and participation.

First, the FANC launched a large scale campaign on patient dosimetry in radiology. A major point has been that this campaign has been negotiated and cosponsored by professional organizations, which favoured acceptability in the field. The patient dosimetry programme consisted, on one hand, of triennial dose studies, with the participation of qualified experts in radiophysics and, on the other hand, of mandatory online evaluations in interventional and dynamic procedures, using dose area product (DAP) meters or similar devices. Currently studies have been realized in more than 30% of radiological services.

Financing of multi-centre research was the second initiative. Several studies have been performed or are currently ongoing, mainly in interventional radiology. They addressed patient doses (for example, determination of alarm or 'trigger' DAP levels to avoid deterministic effects in specific procedures) but also doses to practitioners (particularly to lenses and fingertips). The important thing is that all main universities and hospitals were invited to participate in these studies. This allowed for the creation of a kind of appropriation of results by the stakeholders.

Last but not least, a third initiative has been to launch and organize round table conferences with medical stakeholders. All stakeholders have been invited to give opinions on what is going well and what is still wrong (including within regulations) and to make suggestions for improvement. This initiative proved to be very successful. A major lesson from these consultations is the request for a 'no blame no shame approach', allowing the application of notification systems and discussion of events and dysfunctions without fear of sanctions. Regarding ways to improve application of the justification principle, it is worth mentioning some of the suggestions made by the physicians themselves, such as mandatory radiation protection courses in the basic medical curriculum or good practice labels based on audits.

This being said, there remain some fundamental difficulties to really changing the culture. There is a kind of tradition of accepted concurrent harm in therapy and in medicine in general. It is all the more accepted if some doubt is cast on the reality of this harm because of conflicting, misleading or incomplete messages regarding risks from ionizing radiation, which of course jeopardizes the motivation. Besides, there is some kind of conflict of interest for those whose work implies 'irradiating' people: minimizing risks may be a temptation, certainly when considering possible juridical implications. There is also the classical psychological "resistance to cognitive dissonances", when information coming from authorities or from non-medical experts conflicts with beliefs, with the education received many years ago, with the flavour of their favourite publications or with the local culture.

Finally, the current predominance of 'evidence based' approaches in choosing appropriate treatments or drugs may create inappropriate behaviours in the field of radiation protection and in the application of the principles of optimization and justification.

In the 'evidence based' kind of 'cautiousness', the main concern is to avoid adopting a potentially harmful treatment or drug before their beneficial effect is firmly proven: primum non nocere!

Radiation protection is founded on another ethical basis. In the 'cautiousness' expected in radiation protection, the main concern is to avoid unnecessary doses/risks: doing this certainly causes no harm! As there is scientific plausibility to the existence of a risk of serious and irreversible harm (e.g. cancer induction), the precaution principle must be applied even if there is still some uncertainty regarding the risks at low dose.

4. CONCLUSIONS AND SUGGESTIONS FOR BETTER DOSE/RISK AWARENESS

Three major conclusions can be drawn from these national experiences. We need to:

(1) Increase the efforts in education (basic and continuous, including ethical reflection) and try to broaden the audience;
(2) Work with the practitioners, particularly in deepening scientific aspects (research);
(3) Avoid misleading and demotivating messages on radiation risks.

KNOWLEDGE OF REFERRING PHYSICIANS WITH RESPECT TO DOSE, RISK AND RELATED COMMUNICATIONS

R. GULERIA
Department of Medicine,
All India Institute of Medical Sciences,
New Delhi, India
Email: guleria59@gmail.com

Abstract

Studies undertaken in various countries show that the knowledge among referring physicians about dose and the risk from ionizing radiation is inadequate. This paper discusses these studies, and the direct bearing that this lack of knowledge has on patient information and consent for diagnostic tests that use ionizing radiation.

Since the discovery of X rays in the 1890s, major advances have been made in the use of ionizing radiation in medicine. It would not be wrong to say that these advances in technology and creative pioneering have led to a tremendous increase in the use of ionizing radiation both in diagnostic and intervention radiology. It is estimated that about 5 billion imaging examinations are performed throughout the world every year, and two out of three of these employ ionizing radiation either in radiology or nuclear medicine [1]. Computerized tomography (CT) was introduced into radiology in the 1970s and since then there has been an explosion in the use of CT scans for screening, diagnosis and intervention in medicine. It has been estimated that more than 70 million CT scans are currently obtained in the United States per year and this figure continues to grow each year [2, 3]. In the 1990s, there were less than 3 million nuclear cardiology studies performed. This figure had tripled to more than 9.9 million in 2002 [4]. Similarly, the number of procedures performed in cardiac catheterization laboratories where ionizing radiation is used increased from 2.45 million in 1993 to 3.85 million in 2002 [5]. These numbers continue to grow each year.

There is no doubt that all these procedures using ionizing radiation have brought great medical benefits. Over the last 20 years, diagnostic radiology has completely changed the way medicine is practiced and these tests have significantly enhanced physicians' ability to achieve an early and accurate diagnosis. Similarly, procedures using ionizing radiation play a key role in clinical cardiology and help in diagnosis and risk stratification. These procedures have helped to significantly decrease the morbidity and mortality associated with coronary artery disease.

However, as with many other procedures, ionizing radiation also has a dark side. The harmful effects of ionizing radiation were recognized more than 100 years ago with the discovery and use of X rays. It is well established that radiation has an adverse biological effect on living organisms. These adverse effects vary according to the dose and the duration of exposure. The radiation exposure dose with conventional radiology has usually been small. With the increasing use of CT scans over the last two decades, the dose of radiation delivered to an individual has become much higher than with conventional diagnostic X rays. Also, the radiation dose from CT scans has increased as the speed and complexity of procedures has increased, for example in vascular, cardiac and multiphase examinations [6]. There has also been an increase in CT scans in pediatrics, a more vulnerable group, mainly due to the decrease in time needed to perform a scan and thereby eliminating the need to use anesthesia to prevent a child from moving during image acquisition [7].

Although the level of radiation exposure is low, evidence has emerged linking radiation use in medical imaging to the development of cancer. The doses of radiation in diagnostic CT scans have been shown to be similar to those received by Japanese survivors of the atomic bomb; they have a small but statistically significant risk of developing cancer due to radiation [8]. Also, many patients may have multiple CT scans over time and this may further increase the risk of cancer. Berrington et al. [9] in 2004 estimated that in the United Kingdom an approximately 0.6% cumulative risk of cancer up to the age of 75 years could be attributable to diagnostic X rays (equivalent to 700 extra cases of cancer per year). The attributable risk for cancer from diagnostic X rays in this study was estimated to be about 0.9% for USA, 1.5% for Germany and 3.2% for Japan.

Although the risk to an individual may be small, the increasing number of persons being exposed to radiation due to scans could translate into many cases of cancer occurring due to radiation exposure. One study estimated that the approximate number of deaths attributable to CT scans during one year in the United States of America was about 700 for head scans and 1800 for abdominal examinations [10]. Also, CT scans are increasingly being used in healthy individuals, where the potential of cancer may outweigh diagnostic utility.

The performance of any diagnostic test requires a careful assessment of the risk and benefit of the test. Optimization of the protocol is also needed to minimize patient risk. All procedures that use ionizing radiation should be undertaken in accordance with the as low as reasonably achievable (ALARA) philosophy. Alternative tests which are safer and may provide similar information need to be kept in mind. It therefore becomes important for physicians ordering or performing tests using ionizing radiation to be familiar with the dose of radiation being used and the means by which it can be minimized. Physicians also need to be aware of alternative tests that may be available where ionizing radiation is not used. In almost all parts of the world, treating clinicians order radiological tests, or as in the case of cardiology, perform diagnostic or therapeutic procedures using ionizing radiation. Thorough knowledge of radiation exposure, dose and the potential harm ionizing radiation can cause is essential amongst clinicians who are actively involved in ordering or performing such tests.

Considering the number of tests undertaken daily using ionizing radiation, one would expect physicians to be well versed with the knowledge, risks, costs and legal restrictions associated with the use of these tests. An awareness of alternate tests is also important so that these tests can be used where they can provide adequate information and tests using ionizing radiation can be employed judiciously and only if they are necessary. Studies suggest most doctors grossly underestimate or are not aware of the dose of radiation involved in common investigations performed in day-to-day practice. Also, the potential hazards of a test or the risk of cancer are almost never discussed with a patient.

An initial study done by Shiralkar et al in 2003 amongst doctors in two hospitals in the United Kingdom highlighted this lack of awareness [11]. One hundred and thirty doctors including senior house officers, specialist registrars, consultants and consultant radiologists completed a questionnaire. In this questionnaire, doctors were asked to identify the average dose of radiation received when a person underwent a chest X ray. Also, taking a chest X ray to represent one unit, they were asked to estimate the equivalent doses of radiation for various radiological investigations. A 20% derivation above or below the correct value was acceptable. The authors found that none of the doctors knew the approximate dose of radiation received by a patient during a chest X ray or its measurements in units of radiation. Overall, 97% of the answers underestimated the dose of ionizing radiation, 5% did not know that ultrasound does not use ionizing radiation and 8% thought that ionizing radiation is used in magnetic resonance imaging (MRI).

We conducted a similar study among junior doctors at our hospital. One hundred junior doctors, including senior residents, junior residents' research officers and interns from the departments of medicine, pediatrics and surgery, filled out a questionnaire. About 27% were correctly able to state the radiation exposure that occurs with a chest X ray. Correct answers ranged from 2% to 43%, for various tests using ionizing radiation. Twenty percent of the respondents did not know that an ultrasound is not associated with ionizing radiation and 30% felt that an MRI is associated with ionizing radiation. Overall, 32% expressed a desire to know about the degree of exposure with each test and the risk associated with it. Interestingly, none of the doctors felt the need to provide patients with any information or the need to get patient consent.

In another study by Jacob et al. from the United Kingdom, the knowledge of radiation exposure doses and risks among both the referrers and practitioners was assessed [12]. They also tried to correlate this with attendance at a radiation protection course. A simple multiple choice questionnaire with a total of 11 questions was distributed amongst doctors of various grades and specialties. This included house officers, senior house officers, registrars and consultants in various specialties. The pass mark was set at 45% and there was no negative marking. Only 27.5% doctors attained pass marks and the medium mark was 3 out of 11. Only 15% to 25% of doctors knew the doses related to a chest radiograph of various procedures involving ionizing radiation. Here again, 28% of doctors thought that magnetic resonance angiography and 10% thought that ultrasound posed a radiation risk. The study also showed that attending a radiation protection course in the past correlated with better performance in the test. Thirty two percent of the respondents who had attended a radiation protection course passed, compared to a 16% pass amongst those respondents who had not attended such a course. The study concluded that practitioners are not knowledgeable about relative and absolute dose, or about risks as might be expected from them. As well, referrers

(those prescribing the tests) are even less aware of these issues. Further, the retention of information after attending a radiation protection course was not good.

Two studies from Turkey have looked at radiation exposure knowledge among doctors [13, 14]. The first study [13] evaluated knowledge among doctors and interns on the dose of ionizing radiation patients are exposed to during common radiological tests. Doctors were selected from university hospitals, education and research hospitals, dispensaries and outpatient clinics. A questionnaire was administered to all and a 20% deviation from normal was considered correct. About 93% of doctors and interns underestimated the actual ionizing radiation dose received by patients during radiological imaging procedures. Also 4% and 27% of the participants, respectively, thought that abdominal ultra sonography and abdominal MRI exposed patients to ionizing radiation. The other study from Turkey [14] investigated the awareness of radiation exposure among pediatric surgeons. A simple multiple choice questionnaire was distributed to doctors at the XXV annual meeting of pediatric surgeons. One hundred and two out of the 240 participants completed the questionnaire. Participants were from training, state and private hospitals. Seventy three percent of the participants underestimated the radiation exposure from an abdominal pelvic CT examination. About 21% and 10% of pediatric surgeons, respectively, were not aware that MRI and ultrasounds are radiation free. Also, 42% of the participants did not consider discussing with their patient's families the lifetime increased risk of cancer due to radiation exposure that would occur with an investigation using ionizing radiation. The difference in awareness between junior and senior pediatric surgeons, academic and non-academic staff and between those working in training and non-training hospitals was not significant.

In the field of cardiology, the number of diagnostic procedures using ionizing radiation has increased tremendously. It is estimated that cardiologists directly or indirectly account for more than 50% of all imaging examinations using ionizing radiation. Commonly performed cardiac diagnostic imaging tests include nuclear scintigraphy, CT for calcium scoring and coronary angiography, and conventional and interventional arteriography and coronary angiography. Most of these investigations are performed by clinical cardiologists with no formal training in radiology or radiation protection. Correia et al. [15] assessed the level of radiological awareness amongst physicians working in a tertiary care cardiology centre. One hundred physicians were asked to answer a multiple choice questionnaire. The questionnaire consisted of four basic parts which evaluated knowledge on: 1) environmental impact, 2) individual biorisks, 3) dose exposure of common radiological examinations, and 4) medico-legal regulations of ionizing diagnostic examinations. The environmental impact of medical ionizing radiation was correctly identified by 11% of the physicians; bio risk by 5% and 29% correctly identified dose exposure. The legal regulation of presumption was correctly perceived by 42%. No physician correctly answered all four questions. The study concluded that physicians working in an adult or pediatric cardiology environment are largely unaware of environmental impact, bio risks and dose exposure of the ionizing examinations they prescribe and/or perform daily.

Coronary angiography is probably the most common test performed by cardiologists using ionizing radiation. Often this test is unwarranted and unnecessarily exposes patients to ionizing radiation. A study from Brazil looked at the appropriateness of coronary angiography in patients with ischemic heart disease [16]. This study was carried out by a health care organization in Brazil. They found that 65.5% of elective coronary angiographies being undertaken within the organization for evaluation of stable angina had uncertain or inappropriate indications. It is therefore obvious that amongst cardiologists both a lack of awareness regarding the harmful effects of ionizing radiation and the performance of a number of unnecessary tests using ionizing radiation may inadvertently expose a number of patients to the harmful effects of ionizing radiation.

A study from the United States of America [17] evaluated awareness of radiation dose and possible risks associated with CT scans among patients, emergency department physicians and radiologists in the emergency department (ED). Three similarly designed surveys were administered to patients, ED physicians and radiologists at a tertiary care hospital. Patients who were seen in the ED with mild to moderate pain in the abdomen, pelvis or flanks that necessitated a diagnostic CT scan were included. Physicians in the ED and all radiologists who were involved in the reading of body CT scans were included. Analysis of the data revealed that 47% of radiologists, 9% of ED physicians and only 3% of patients believed that there was an increased cancer risk from an abdominal pelvic CT scan. Also, 28% of patients believed that the dose of their CT scan was less than or equal to that for a chest radiography. Surprisingly, 7% of ED physicians and 5% of radiologists also believed that a CT scan conferred less or equal radiation exposure than a chest X ray. Seventy one per cent of patients underestimated the dose of their CT scan in comparison to 66% of ED physicians and 71% of radiologists. Results of this study showed that patients

were poorly informed about radiation dose and possible risks attributable to their CT scan, although they were told about other risks, including possible adverse effects to the intravenous contrast material. This study highlighted the fact that patients, ED physicians and radiologists are largely unable to provide accurate estimates of CT doses and cancer risk. Also, patients are not provided with information about the risks, benefits and radiation doses of a CT scan. Similar results have been indicated by studies from different areas of the world and among physicians of different specialties [18, 19].

A recent study [20] evaluated the patient's perspective regarding medical decision making processes with respect to obtaining a CT scan. They also assessed patient knowledge concerning radiation dose and risk resulting from a CT scan. A questionnaire was given to consecutive adult patients awaiting an outpatient CT examination between March and April 2007. A total of 768 questionnaires were distributed and 296 were returned with a response rate of 38%. The authors found that only 6% of respondents knew that the radiation associated with a CT scan increased the lifetime risk of cancer. This study again shows that patients are not receiving adequate information regarding the risks of ionizing radiation and that this is mainly due to a lack of awareness amongst physicians. The authors also found that patients rely heavily on the referring physicians for this information. Unfortunately most referring clinical physicians have very little knowledge in this regard.

It is quite obvious that awareness about the risk of radiation exposure that occurs with different tests is poor among physicians. This lack of knowledge is present in all parts of the world. Also, irrespective of the medical specialty, awareness about the risk of ionizing radiation is poor. Physicians such as cardiologists, internists or pediatricians who order a lot of tests utilizing ionizing radiation have no training and are not educated enough in this regard. Moreover, the need to inform patients undergoing these tests about the accompanying radiation risk is not perceived by most physicians. In recent years there has been some attempt to increase awareness amongst physicians and medical students. Singh et al. [21] tried to develop a consensus opinion on competency based topics in radiation protection that a UK medical student should possess at the time of graduation. They used the Delphi technique in this decision making process. A group of 69 varied but qualified experts (including radiologists and clinicians) took part in a three stage e-mail based study to establish competencies in radiology, including knowledge of and practice of radiation protection expected of a medical student at the time of graduation. The data collected from the first two questionnaires was refined into 57 individual clinical competencies directly relevant to radiation protection. In the third and final questionnaire, the experts rated these clinical competencies on a seven point Likert scale from 'definitely not core' to 'definitely core' with an 82% response rate. The core competencies that a newly qualified doctor should possess regarding dose and risk included:

— To be able to explain that all radiographic, fluoroscopic, CT and nuclear medicine procedures involve ionizing radiation whereas ultrasound and MRI do not;
— To describe the hazards of ionizing radiation;
— To be able to describe which common ionizing procedures involve low, moderate or high doses of radiation;
— To be able to recall the typical doses for commonly performed tests as listed in the Royal College of Radiologists guidelines.

In 2007, the American College of Radiology released a "White Paper on Radiation Dose in Medicines" [22]. This document was written by a 'blue ribbon committee' which included private practitioners, academic diagnostic radiologists, medical physicists, representatives of industry and regulatory groups and a patient advocate. The panel was of the opinion that the expanding use of imaging modalities using ionizing radiation may result in an increased incidence of radiation related cancer in the exposed population in the not too distant future. They also felt that these problems can be minimized by preventing the inappropriate use of such imaging and by optimizing studies that are performed to obtain the best image quality with the lowest radiation dose. The paper stated that although some referring physicians are very knowledgeable regarding safety issues and incorporate such information into their imaging decisions, others had little or no training in radiation exposure and do not routinely consider this factor when ordering imaging examinations. Regarding patient information, the white paper states that radiologists understand the potential dangers of ionizing radiation far better than patients do, yet not every radiologist provides a balanced assessment of the risks and benefits of imaging when patients undergo tests. The document adds that it is incumbent on radiologists to assume responsibility for patient safety with regard to radiation exposure. They should also educate patients on these issues so that they may make an informed decision about their health care.

In conclusion, it is quite evident that knowledge among referring physicians regarding dose and risk from ionizing radiation is grossly inadequate. This also has a direct bearing on patient information and consent when tests using ionizing radiation are undertaken. Every physician has a responsibility to minimize the radiation hazard to patients. This, however, does not happen due to a number of factors, the most important being lack of awareness. A lot needs to be done in this regard. There is an urgent need to increase knowledge among referring physicians about the risk and importance of patient safety with regards to ionizing radiation, especially the long term risk of cancer. Also, awareness among patients needs to be increased so that patients can make more objective decisions in this regard. A proper consent and patient information sheet detailing the benefits and risks of a test using ionizing radiation in a balanced manner is needed. Since patients may have multiple scans, all radiological reports using ionizing radiation should mention the degree of exposure that has occurred during that investigation. Finally, hospitals need to develop a system of audit so that inappropriate tests can be minimized.

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AUDIT AND JUSTIFICATION

(Session 4)

Chairperson

A. JANSSENS
European Commission

Rapporteur

E. PICANO
Italy

EC CLINICAL AUDIT GUIDELINES: JUSTIFICATION IS AMONG THE PRIORITIES OF AN AUDIT PROGRAMME

H. JÄRVINEN
Radiation and Nuclear Safety Authority (STUK),
Helsinki, Finland
Email: hannu.jarvinen@stuk.fi

Abstract

European Commission Directive 97/43/EURATOM (MED) introduced the concept of clinical audit for the assessment of medical radiological practices for European Union Member States. Some Member States have since developed a systematic approach to clinical audit, while other countries have only occasionally or not at all implemented clinical audits in practice. Thus a special project was conducted in 2007–2008 to prepare further guidance for an improved implementation of the directive, and the result is the publication of a guideline that provides a general framework to establish sustainable national systems of clinical auditing of radiological practices. This paper discusses the objectives, scope and elements of the guideline.

1. CLINICAL AUDIT AND THE EUROPEAN GUIDELINE

For a variety of reasons — professional, public, financial and political — most countries seek to establish visible systems for managing quality in heath care. One of the key elements in this is the establishment of the clinical audit. The concept of clinical audit is not a new one; it has long been applied in some health care practices. In European Commission (EC) directive 97/43/EURATOM (MED) [1], this concept has been introduced for the assessment of medical radiological practices. Simultaneous to European work in this area, the International Atomic Energy Agency (IAEA) has developed comprehensive audit programmes under the term ‘clinical audit’ [2, 3].

In Europe, EU Member States are required to implement clinical audits “in accordance with national procedures” (Article 6.4 of the MED). Despite the very precise definition of clinical audit in the MED, a questionnaire to Member States revealed that there is wide diversity in approaches to clinical auditing, and a lack of practical implementation in several Member States. While in some countries a systematic approach to clinical audit has been established (for example, in Finland, France, Germany and the UK), in most countries clinical audits have only been occasional, or have not been implemented in practice. Several problems have also been identified, such as poor understanding of the purpose of clinical audits, lack of criteria for the standards of good practices and practical problems such as financing of audit work. In some countries, clinical audit seemed to be confused with internal quality assurance programmes or external assessments such as accreditations and regulatory inspections.

For these reasons, the EC conducted a special project in 2007–2008 to prepare further guidance on the principles of clinical audit for the improved implementation of Article 6.4 of the MED. Before submission to the EC, the draft guideline was subjected to critical reviews by major scientific professional organizations and further introduced and discussed at an international workshop. The published EC guideline [4] provides a general framework for Member States in order to establish sustainable national systems of clinical auditing of all radiological practices (diagnostic radiology, nuclear medicine and radiotherapy). It is sufficiently flexible, and will enable Member States to adopt a clinical audit model with respect for national legislation and administrative provisions.

The EC Guideline introduces the basic principles of clinical audit (objectives, coverage, standards of good practice, etc.), aiming at clarifying its profound meaning and recommended application. It defines the topics which should be covered while the criteria of good practice are discussed only at the generic level. It discusses the interrelation of clinical audit with other audit systems, such as certification of quality systems, accreditation, peer review and quality award, as well as its interrelation with regulatory control. Finally, it provides general advice for the practical implementation of audits, including organization of audits, recommendations for auditors, models of financing, national coordination and the role of scientific and/or professional societies and regulatory authorities.

It is important to recognize that the EC guideline is not a legal requirement. It only provides recommendations and highlights some possible ‘national procedures’ as expected by the MED.

2. CLINICAL AUDIT IN DIAGNOSTIC RADIOLOGY

2.1. General purpose

The MED directive defined 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".

In the EC Guideline, the general purpose of any clinical audit is further meant to:

- Improve the quality of patient care;
- Improve the effective use of resources;
- Enhance the provision and organization of clinical services;
- Further professional education and training.

Clinical audit will thus be an important tool of quality improvement and should yield multiple benefits to the health care system such as:

- Improvement of practice;
- Recognition of quality and awareness of good practices;
- Recognition of outdated practices;
- Motivation of staff to increase quality;
- Improvement of local standards and adherence to national standards;
- Prevention against litigation;
- Improvement of communication within institutions;
- Revelation of weak points;
- Promotion of the development of quality systems.

In particular, clinical audit can have a major impact on developing practices in compliance with the most recent data on good examination practices, as well as improving the safety of practices.

2.2. Coverage and priorities

It is evident from the definition that clinical audit should be a multi-disciplinary and multi-professional activity [4]. It should be a continuous activity for quality improvement (Fig 1), and should be carried out by competent experts with strong experience in clinical practice. Both internal audits (auditors coming from inside a given health care unit) and external audits (auditors coming from outside a unit) should be implemented. These are of equal importance and should supplement each other.

External audits are needed to remove possible 'blindness' of internal experts in recognizing weaknesses in their own unit and to provide more universal and broader perspectives. External audits also better detect substantial variations in practices and result in more consistent approaches, and therefore can be used as a benchmarking tool.

Clinical audit should address the structure, process and outcome of practices, for example:

- Structure: Physical attributes such as buildings, facilities and staff;
- Process: Care provided by staff (what the staff actually does);
- Outcome: The end result of examination or treatment on the health of a patient.

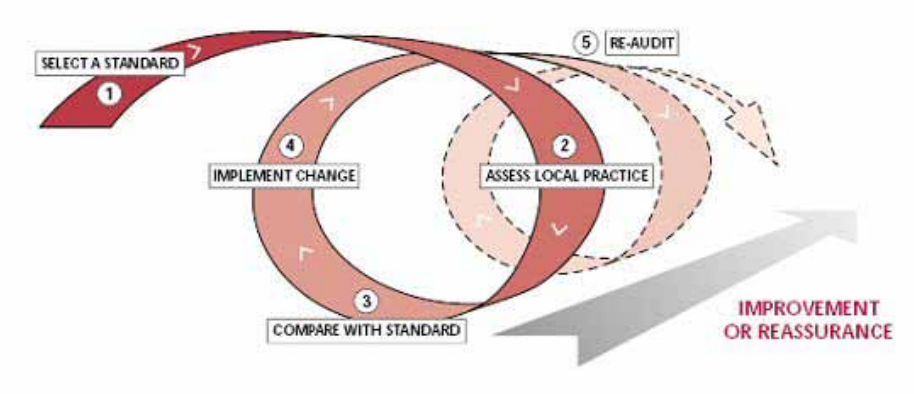

FIG. 1. The audit cycle. Reprinted from Clinical Audit in Radiology: 100+ Recipes, 1996 (GOODWIN, R., de LACEY, G., MANHIRE, A. [eds]) by permission of The Royal College of Radiologists [5].

The main focus should be an assessment of the overall performance of the radiological department being examined and how staff, equipment, procedures, outcomes, patient safety and comfort correspond to the aims and objectives of the department. Responsibilities and reporting structures within the department must be clearly defined. Clinical audit should also evaluate how the department interacts with external service providers, including relationships with referring clinics and clinicians, equipment providers, etc.

It is appreciated that auditing the clinical *outcome* may be very difficult, in particular for external audits. Therefore, audits of outcome are often limited to auditing only the methods of follow-up and not actual results. For assessing output, or the impact of a radiological procedure on patient management, an audit should include a review of examination reports.

For diagnostic radiology, the priorities of clinical audit should be as shown in Table 1 [4]. The concepts of justification and optimization should be among the top priorities of the audit programme, as irradiation protection in medicine is underpinned by these two principles.

Clinical audits can be of various types and levels, either reviewing specific parts of the radiology process (*partial audit*; including justification of examinations) or assessing the whole process (*comprehensive audit*). Audits can address various ‘depths’ of procedure, from generic features to details of a given examination. A comprehensive clinical audit must include the full patient pathway from referral to follow-up. Patient dosimetry is an important topic for partial audits and should be within the scope of a comprehensive clinical audit.

Auditing the detailed practice for a given examination can usually mean only a few selected processes per audit run. Full details of procedures should be assessed when a reasonable consensus on good practice can be achieved for application as the criteria of assessment. Such items for a given examination could be, for example:

TABLE 1. THE PRIORITIES OF CLINICAL AUDIT OF DIAGNOSTIC RADIOLOGY PRACTICES

Structure	— The mission of the unit for diagnostic radiology practices
	— Lines of authority and radiation safety responsibilities
	— Staffing levels, competence and continuous professional development of staff, in particular for radiation protection
	— Adequacy and quality of premises and equipment
Process	— Justification of referral practices, including referral criteria
	— Quality of examination guidelines (protocols, procedures)
	— Optimization procedures
	— Patient dose and image quality and comparison of patient dose with nationally accepted reference levels
	— Quality assurance and quality control programmes
	— Emergency procedures for incidents which can arise during the use of radiation
	— Reliability of information transfer systems
Outcome	Methods for the follow-up of examination outcomes

- Indications (based on studying a sample of referrals);
- Image criteria, reproduction of anatomical structures;
- Patient position, radiographic technique, use of grid/tube voltage;
- Protective shielding.

2.3. Standards of good practice

It is imperative for clinical audit that standards of good practice be defined. These should be derived from evidence based data, long term experience and knowledge gained. In practice, these can be adopted from legal requirements, results of research, consensus statements, recommendations by learned societies or local agreements (if there is no other more universal reference). Examples of documented good practices are the European Guidelines on Quality Criteria [6, 7, 8] and the EC referral guidelines [9]. Further examples are provided in the EC Guideline [4].

It should be understood that good practice is not a fixed concept, but should evolve with the general development of evidence based medicine, equipment and techniques.

2.4. Aspects of practical organization

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, unrecognized areas for improvement. Thus both internal audits, self-assessments and external audits have a role to play, should be part of the life of a department, and are recommended [4].

The practical organizing of *external* clinical audits can take place through site visits by an audit team or, for a limited part of practices with relevant documented or measurable data, by mailed review and central analysis of data. A site visit enables a comprehensive review due to direct access to all relevant documents and the possibility of holding interviews with responsible practitioners. A mailed review could be, for example, a collection of samples of referrals and other information, with a central assessment by designated auditors (referral quality, appropriate selection of examinations) [see Ref. 10]. National or regional audits enable benchmarking and will identify departments in the lowest quartile of performance and those with a special need for variation [11] for which improvement strategies may be suggested.

Comprehensive guidance for audit visits has been published in the EC Guideline [4] and by the IAEA [3].

2.5. Clinical audit should not be confused with other quality assessments

In the jungle of quality management concepts, with diversity in approaches and procedures for trying to improve and maintain high quality, the meaning of concepts can easily be confused with each other. This has been particularly true for clinical audits. While it is obvious that clinical audits have some similarities with other quality assessments and controls, it is important not to confuse it with such activities as:

- Research;
- Quality control programmes for equipment;
- Quality (system) audits to verify that the quality systems conform to a quality standard;
- Accreditation;
- Regulatory inspection nor any other regulatory activity.

The purpose of these other activities should be properly understood, and rather than duplicating any efforts, clinical audits should be developed to supplement other activities. The relationship between clinical audit and several other quality assessments and with regulatory inspections has been discussed in detail in the EC Guideline [4].

3. AUDIT OF JUSTIFICATION

Justification is a cornerstone of radiation protection and should be among the top priorities in an audit programme. An indicator for the adequacy of justification should be a high level marker for the quality of a radiological service.

The clinical audit of justification mainly addresses the selection and decision making processes, but should also cover necessary structure (such as clinical responsibilities, training) and outcome (feedback processes, and how radiological or nuclear medicine procedures affect the management of clinical problems and patient care). An audit of compliance with guidelines can be a simple and effective tool for improving referral patterns. Its value includes reassurance for patients, the public, regulators and legislators, while giving to those being audited the confidence that their work is appropriate, and often excellent. It provides an incentive and information that facilitates improvement.

An audit of the justification process includes the correct application of referral guidelines in order to avoid unnecessary, inappropriate and unjustified medical exposure. The net impact should be the reduction of significant and systematic practices of inappropriate examinations, particularly those arising from systems failures.

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 and risk/benefit considerations including adverse effects and contraindications;
- Use of referral guidelines or appropriateness criteria;
- Communication with patients and communication between radiological and referring medical practitioners;
- Due consideration for patient and information/consent issues;
- Adequacy and timeliness of referral requests;
- Identified responsibility for justification (for example, with radiological and referring medical practitioners);
- Level of availability of each modality;
- Availability of a resulting report and how it is used.

Subsequently, an audit programme for justification should include:

- Referral guidelines and other guidance documentation;
- Adequacy of requests/referrals;
- Repeat examinations (are these purposeful and dose efficient?);
- The process to ensure justification is transparent, accountable and well adapted to current social values;
- Confirmation that referrals and procedures are properly authorized;
- Actions of referring and performing medical practitioners, as appropriate, for:
  — Review of referrals;
  — Application of referral guidelines, including consideration of alternative examinations;
  — Review of patient records, including earlier exams;
  — Checking for contraindications and limitations (pacemaker, allergy, etc);
  — Checking information on typical radiation doses to patient;
  — Having appropriate awareness and knowledge of benefits, dose and risk;
  — Evaluating timeliness of examinations;
  — Checking or providing information and advice to patients;
  — Obtaining consent in appropriate form.

4. CONCLUSIONS

A clinical audit is a multi-disciplinary, multi-professional assessment of radiological practices for the improvement of safety and quality of practices. It should be a continuous activity whereby both internal and external audits are implemented and these should supplement each other.

Clinical audits should not be confused with other quality assessment or control activities such as regulatory inspections, accreditations or certifications of the quality system. Clinical audits should be developed to supplement and not duplicate other efforts of quality assessments.

The priorities of clinical audit should include essential parts of the structure, process and outcome. Justification is a cornerstone of radiation protection and must be among the top priorities. An audit of compliance with guidelines can be a simple and effective tool for improving referral patterns.

The recent guideline for clinical audits, published by the European Commission [4], provides guidance for clinical audit principles and practical implementation, as well as a general framework to establish a sustainable national system of clinical audits. More detailed guidance for the practical implementation of comprehensive external clinical audits has been published by the IAEA [3]. Other existing guides provide practical guidance for internal audits/partial external audits (on selected topics, for example, Audit Live in the UK) [12].

ACKNOWLEDGEMENT

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CLINICAL AUDIT FOR REFERRAL GUIDELINES: A PROBLEM SOLVING TOOL

D. REMEDIOS
Northwick Park Hospital,
RCR Clinical Radiology Audit Sub-Committee,
Harrow, United Kingdom
Email: denis.remedios@imperial.ac.uk or denis.remedios@nwlh.nhs.uk

Abstract

In the United Kingdom, the Health Act of 1999 places the responsibility of monitoring and improving the quality of health care with hospital and primary care trusts. All National Health Service employees must perform audits, and in some cases pay progression is limited if there is no evidence that a clinical audit has been carried out. An audit cycle or spiral facilitates a continuing system for quality improvement. About 40 local internal clinical audits are contained in the Royal College of Radiologists' AuditLive, which encourages participation in clinical audits.

Clinical audit is defined as "The systematic, critical analysis of the quality of medical or clinical care, including the procedures used for diagnosis and treatment, the use of resources, and the resulting outcome and quality of life for the patient." [1].

Guidelines are concepts of good practice against which the needs of the individual must also be considered [1]. They are statements of principles which have been developed in order to assist practitioners and patients in making decisions about appropriate health care in specific clinical circumstances. Guidelines are not rigid constraints upon clinical practice. They are usually produced and agreed upon by a national body.

Clinical audit and guidelines both fit into the larger framework of clinical governance or corporate responsibility for quality in health care [2]. The unifying principle of good medical practice flows through this concept. The greatest value of clinical audit is achieved by improvement as a result of examination and comparison of one's own practice with best practice, often informed by evidence based guidelines.

In the UK, the clinical responsibility of monitoring and improving the quality of health was placed clearly with hospital and primary care trusts through legislation (the Health Act of 1999). By so doing, the resource to perform and present audits became clear. It is the duty of all National Health Service employees to perform audit and this is reflected in job plans in the UK. Some hospital trusts have gone so far as to limit pay progression if there is no evidence that clinical audit has been carried out.

The Royal College of Radiologists (RCR) published a collection of audit recipes in 1996, giving simple examples of internal clinical audit used locally in different hospitals, many of which could be performed in two clinical sessions (8 hours). Ten percent of the recipes were based on guidelines, their availability and their compliance. The RCR recommended that 5% of a radiologist's time should be devoted to clinical audit and that regular audit meetings should be held within departments for the presentation of audit projects. Records should be kept of such meetings and the results of such audits used to guide improvement measures, to support the need for further training or allocation of resources and, where appropriate, to provide reassurance and evidence that practice was optimal.

The methodology for internal clinical audit is best summarized by five steps:

(1) Select a standard. This standard is preferably evidence based and accepted nationally or globally but may be a local standard where no national standard exits;
(2) Assess local practice;
(3) Compare local practice with standard;
(4) Implement change where needed;
(5) Re-audit.

FIG. 1. The audit spiral. From Clinical Governance and revalidation: a practical guide for Radiologists (GOODWIN, R., de LACEY, G., MANHIRE, A. [eds] RCR (2000)).

A continuing system for quality improvement is facilitated by such an audit cycle or spiral. This system can be used for any structure or process in a department of radiology and in some cases can be based on patient outcome measures. Although most audits will be based on process and structure, outcome audits carry the greatest impact but are also the most difficult to carry out, often requiring the cooperation of other departments or patients themselves.

Audits for referral guidelines and justification are process and structure audits. It is essential that reliable and trusted guidelines are made available to those for whom they were produced, including general practitioners and doctors-in-training. An example of such an audit of structure is the RCR Guideline Distribution [see recipe 88 in Ref. 1] which assesses the percentage of medical referring practitioners who have access to referral guidelines. The majority of audits for justification will be along the lines of compliance. Unlike protocols, guidelines inform a clinical decision, and there will inevitably be some variation between patients and in the provision of resources and expertise. Hence some leeway in full compliance must be expected and a target of 90% to 95% compliance would be reasonable. Published audits of compliance with guidelines for justification have largely focused on higher dose radiographic examinations, for example for the lumbar spine (see recipe 81 in Ref. 1) or, more recently, Computed Tomography (CT).

AuditLive, [3] the RCR web based repositories of local internal clinical audits, contains some 40 audits based on guidelines (a searchable keyword), many of which cover an aspect of radiation protection, often justification. Encouragement of participation in clinical audit, for example via poster presentations and competitions at the RCR Annual Scientific Meeting, is undertaken, in addition to the mandatory contractual requirements in the UK National Health Service (NHS). Approximately a third of accepted poster abstracts used a standard based on a guideline and 20 audits were directly based on RCR referral guidelines. The winning entry in 2008 showed a 71% reduction in GP lumbar spine radiograph requests using guidelines, enhanced justification, audit and feedback as intervention modes. Some hospital trusts have gone further to restrict pay progression in the absence of demonstrable audit participation.

The value of local internal audit is based on the ‘bottom-up’ nature of this process and can be summarized as follows:

- Increases potential to reach aspirational targets for improvement rather than a minimum governance level;
- Improves ability to target problem areas which have low levels of compliance;
- Motivates local referring and radiological practitioners to improve;
- Inexpensive to perform.

National audits run by the RCR have helped to benchmark departments, enabling individual departments to identify needs and to seek additional resources where appropriate. More recently the use of statistical process control has enabled the identification of outliers who will have special cause for variation, some of which may benefit from remediation [4]. Furthermore, such simple statistical analysis can readily identify which processes

should be improved nationally via remediation of outliers and which basic processes require improvement by all departments.

CONCLUSIONS

- Local internal audit has the potential to target problem areas, motivates those involved and can produce dramatic change;
- Identification of time and responsibility are essential;
- Statistical process control may help to identify where and when to intervene.

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A STUDY ON JUSTIFICATION OF CT EXAMINATIONS IN SWEDEN

W. LEITZ, A. ALMÉN, S. RICHTER
Swedish Radiation Safety Authority,
Stockholm, Sweden
Email: wolfram.leitz@sse.se

Abstract

The paper presents the results of a study conducted in Sweden in 2005 to assess how justification is achieved in daily clinical practice, and especially to seek evidence in relation to the common opinion that many examinations are not justified. The study focused on CT examinations because they contribute to a high fraction of the radiation burden from medical examinations. Findings of the study are discussed, and future areas of improvement are outlined.

1. INTRODUCTION

Justification and optimization are two of the basic principles in radiation protection. Much work has been done and published with respect to optimization but there is a lack of studies assessing how justification is achieved in daily clinical practice. A common opinion is that many examinations performed are ‘not justified’, but this is mostly stated without proof of evidence. Thus, the Swedish Radiation Protection Authority (SSI) launched a project with the aim of assessing justification for X ray examinations.

Statistical data about Sweden (2005):

Population: 9.1 million inhabitants
Number of X ray departments: 140
Amount of X ray equipment: 2000
Amount of computed tomography (CT) equipment: 161
Number of medical X ray examinations: 5.4 million per year
Number of CT examinations: 650 000 per year

2. STUDY DESIGN

For this study, CT examinations were chosen because they are contributing to a high fraction of the radiation burden from medical examinations. Retrospectively, the degree of justification for all CT examinations performed in Sweden during one particular day was assessed. Somewhat arbitrarily, Wednesday, 22 March 2006 was chosen, and it was proven that this day was representative of a normal day’s distribution of CT examinations. Copies of the referrals and the evaluation reports for all these examinations were collected, representing 2435 examinations from all but one of the 95 X ray departments performing CT examinations in Sweden.

Eighteen physicians, both clinicians and radiologists, were engaged to evaluate the quality of the referrals and to assess the level of justification. The evaluations were based on the EC guidelines for referrals [1], on national and local health programmes and on the experience of the evaluators. In general, every referral was evaluated by one clinician and one radiologist and the total number of evaluations was 4714. The referrals contained data on the age and gender of the patients, and on the anatomical region to be examined. Information was provided on whether the CT examination was the first radiological examination in the current investigation of the patient, or whether it was undertaken to check the progress of a disease or effect of treatment, or whether it was a further step in an ongoing investigation. Information on geographical location and on the health care level, both concerning the prescriber’s affiliation and the performing X ray department, was available. Four levels were identified: primary care centres and small, county and university hospitals.

A prerequisite for the study to be conclusive is that a major part of the referrals allows for an evaluation of justification. The quality of the referrals was assessed by answering the question “can the appropriateness and the

justification of the examination be assessed?" The adequacy of information in the referrals was assessed by evaluators on a four grade scale, from adequate to inadequate. For simplification, this four-grade scale was reduced to a two grade scale, where 'adequate' 'and relatively adequate' was regarded as 'sufficient' and 'not really' and 'inadequate' as 'insufficient'.

Justification was assessed as the answer to the question "is the CT examination appropriate?" a positive answer indicating that the CT scan was the correct initial radiological procedure or was indicated as an examination for control or for further investigation. CT examinations for which a different method (such as MR) should have been used or which were not indicated were regarded as unjustified.

The main aims of the study:

- To assess the quality of referrals;
- To assess the degree of justification of CT examinations in Sweden;
- To investigate how justification is affected by geographical region, the organs examined, the age of the patient, the quality of the referral and the affiliation of the prescriber;
- To get information about the causes behind non-justified examinations.

3. RESULTS

3.1. Quality of the referral

Ninety-three per cent of the referrals were adequate and provided sufficient information for the working radiologist to decide upon the most appropriate investigation of the patient, and 7% were not. Prescribers from each of the three categories of hospitals (university hospitals, county hospitals and small hospitals) had approximately the same level of quality regarding referrals; 94–95% were judged to be 'satisfactory' whereas for prescribers from primary care centres only 87% were 'satisfactory'.

This quality of the referrals was sufficiently high for the study to be conclusive, in other words, it showed that justification can be assessed based on the referrals for most examinations.

The overall result was that about 20% of the CT examinations were judged to be not justified.

3.2. Anatomical region examined

Examinations were grouped into 12 categories, mainly according to anatomical region. The assessment of justification in relative numbers for these 12 categories is provided in Table 1.

3.3. Category of prescribers

The prescribers of primary care centers requested a higher percentage of examinations that were not justified: 36% of the examinations requested were not justified, more than twice that of the other prescribers (14–17%).

For further analysis, justification was derived for different examination categories, for prescribers from hospitals and those from primary care centers; see Table 2. Only the five most frequent categories were analysed — the remainder are of such low frequency that no reliable results could be achieved.

3.4. Age of patients

The age distribution for males and females is shown in Fig. 1. As expected, the distribution is skewed, with the least amount of examinations being performed on children and young adults and the most on patients between 70 and 80 years old. The number of males and females is approximately the same.

Figure 2 shows the degree of justification in age intervals for both males and females for all examinations, and Fig. 3 shows data for the three most frequent examination categories. The figure indicates that justification increases with increasing age, at least to the age of 70.

TABLE 1. LEVEL OF JUSTIFICATION FOR THE TWELVE CATEGORIES OF EXAMINATIONS

Examination	Justified	Not justified	No answer
Abdomen/Pelvis	70	29	1
Angiography	90	9	1
Brain	81	17	2
Colon	51	49	0
Extremities	77	23	0
Multi-region	90	8	2
Neck	76	18	5
Skull	83	16	1
Spine	57	42	2
Thorax	87	11	3
Trauma	98	2	0
Urinary tract	66	31	3
Total	79	19	2

TABLE 2. LEVEL OF JUSTIFICATION (%) FOR FIVE CATEGORIES OF EXAMINATIONS, REFERRED TO BY PRESCRIBERS FROM HOSPITALS (A) AND FROM PRIMARY CARE CENTRES (B)

Examination	Prescriber	Justified	Not justified	No answer
Abdomen/ Pelvis	A	73	27	1
	B	58	41	1
Brain	A	83	15	2
	B	72	27	1
Spine	A	77	23	1
	B	29	68	2
Skull	A	86	12	2
	B	73	27	0
Thorax	A	88	10	2
	B	78	16	6

3.5. Evaluators' specialty

This study showed a relatively high inter-observational difference, which varied with the examined anatomical category. To a large extent, these differences in judgement were found between the different evaluator specialties. Two categories of evaluators were involved in this study: Physicians working in clinics experienced in referring patients ('clinicians') and radiologists. The goal was that each examination should be evaluated by one radiologist and one clinician. This was achieved for all examinations except those for extremities, spine and trauma, which were evaluated in 95% of cases by radiologists only.

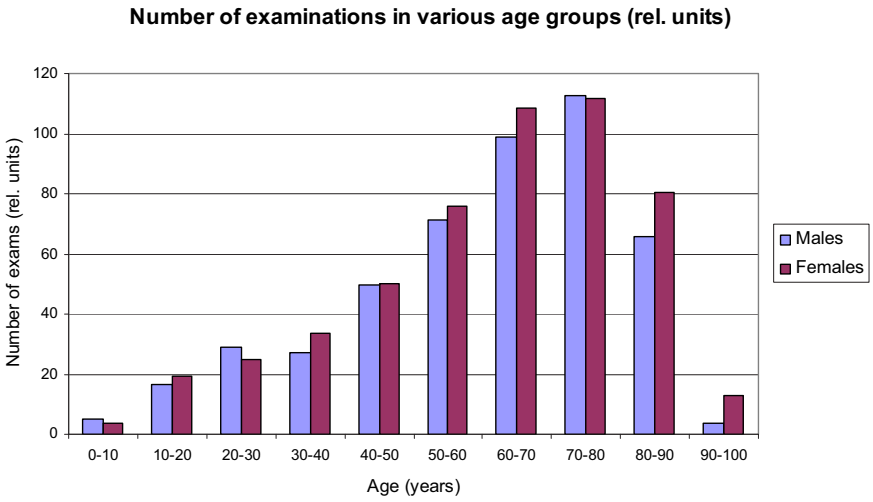

FIG. 1. Age distribution of CT examinations in this study.

FIG. 2. Level of justification for different age groups (all examinations).

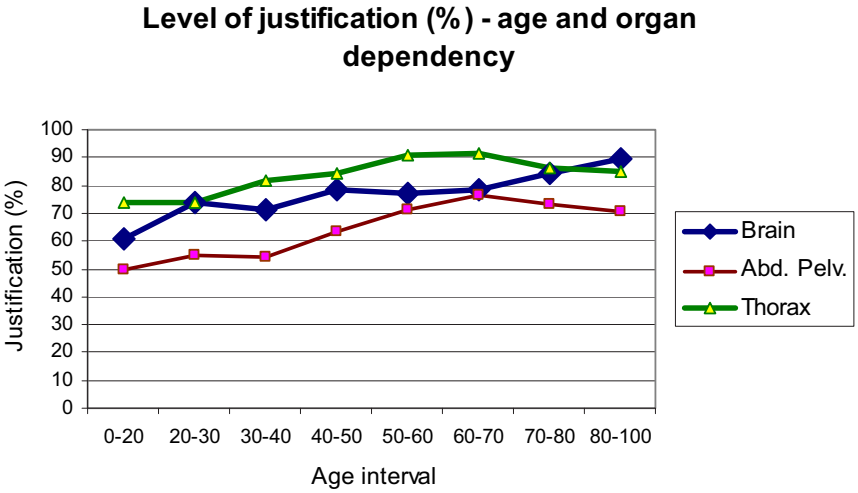

FIG. 3. Level of justification for different age groups and examination categories.

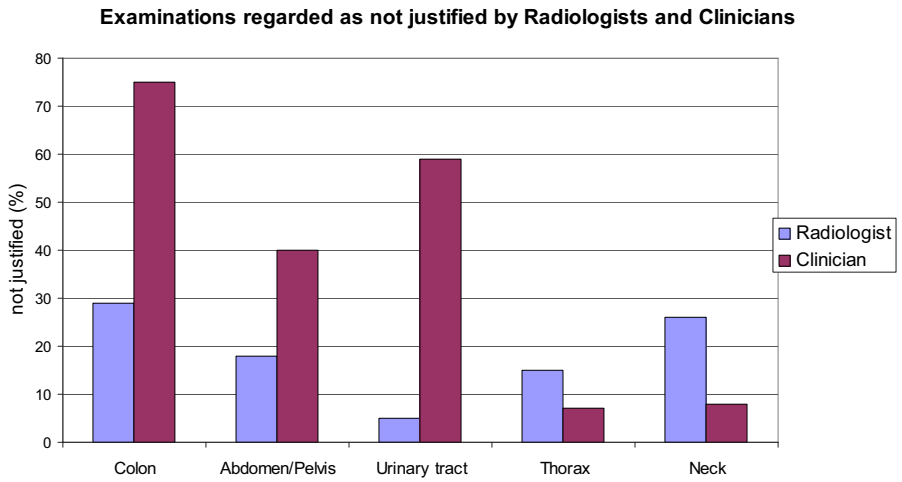

FIG. 4. Unjustified examinations as assessed by radiologists and clinicians for five categories.

Figure 4 shows justification as evaluated by clinicians and radiologists for those examinations in which clinicians and radiologists carried out approximately the same number of evaluations each. For some examinations, the differences between clinicians and radiologists are remarkably high. The percentage of justified examinations of the abdomen/pelvis, colon, and urinary tract is lower when assessed by clinicians and the opposite holds true for neck, skull and thorax exams. It cannot be determined whether these findings are generally valid in Sweden, because only a small number of evaluators were engaged. However, some tentative conclusions can be drawn which could be checked in a follow-up study.

4. SUMMARY OF IMPORTANT FINDINGS

- The study setup was adequate, although inter-observational variance was rather high (regarding differences between clinicians and radiologists);
- The quality of referrals was generally high, though somewhat poorer for prescribers from primary care centers (95% and 87% respectively were satisfactory);
- Approximately 80% of all CT examinations were justified;
- The number of justified examinations when prescribed within hospitals was larger than those prescribed by primary care centres. The largest difference was for spine examinations (77% and 29%, respectively);
- Justification differed depending on the examined organ (with a range of between 51% and 98%);
- The degree of justification was lower for younger patients.

5. DISCUSSION

5.1. Anatomical region examined

The degree of justification varied with the type of examination, from between 50% to 98%. Colon, spine and urinary tract exams are at the low end of justification. These three examinations were until recently mostly performed as conventional X ray examinations. Most likely — depending on local practices — there are different opinions about which modality is preferred. An investigation on how local practices vary throughout the country should be performed in order to see whether this can explain differences in the level of justification.

5.2. Category of prescribers

Prescribers from primary care centres referred twice as many non-justified CT examinations as those from hospitals. One of the reasons is that their contact with radiologists is more sporadic, whereas prescribers from hospitals more frequently participate in discussions of examination outcomes with radiologists and hence are more familiar with which examinations are suitable for which clinical indications.

5.3. Age of patients

The degree of justification is lower for younger patients. The reason for this is not quite clear. It could be that the evaluators placed special emphasis on the increased radiation risk to young patients in their judgement, which might have resulted in more strict evaluations.

5.4. The study design

It cannot be determined whether these findings — showing large differences in the judgement of justification between radiologists and clinicians — are generally valid in Sweden. However, some possible explanations can be provided, which could be checked in a follow-up study.

Radiologists and clinicians play different roles in the management of patients, which might lead to different views on what the best radiological procedure is for a given patient. Clinicians might not be familiar with the newest examination methods and their possibilities, or radiologists might not be aware of all details in investigation schemes for certain diseases or suspects for disease. A closer cooperation between clinicians and radiologists would improve mutual understanding.

All evaluators, both clinicians and radiologists, are certainly influenced by their personal views, formed through local practices. It is one of the reasons the study cannot provide an unambiguous answer to justification questions. Nevertheless, the study is informative: when justification doubts about a certain radiological procedure are brought forward, it is reason enough to review a practice.

Only those referrals that lead to a CT examination were included in this study. Referrals for CT examinations that were not performed were excluded. It would be of value to also investigate these referrals, which could provide additional information on the quality of referrals and on how justification is assessed in clinical practice.

6. FUTURE WORK

The study has shown that there is a need for improvement concerning justification of CT examinations. This could be achieved by:

- Education and training, both for prescribers and for radiologists in matters concerning justification;
- Information for prescribers, especially those from primary care centres, about requirements and criteria for referrals;
- Promotion of the use of referral criteria such as RP 118 [1] for both prescribers and radiologists;
- Improved communication between radiologists and prescribers;
- QA documents on the content and format of good referrals;
- QA documents on the justification process.

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- Håkan Jorulf, Asst. Professor of Radiology, Uppsala
- Bengt Isberg, MD, Specialist in Radiology, Primary Care Centre, Odenplan, Stockholm.
- Ulla Svahn, Research Assistant, Primary Care Centre, Hötorget, Stockholm.

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WHETHER OR NOT TO IMAGE: WHO DECIDES?

W.R. HENDEE
Medical College of Wisconsin,
Milwaukee, Wisconsin, United States of America
Email: whendee@mcw.edu

Abstract

Of the four major steps in medical imaging — justification, optimization, implementation and consultation — the first, justification, is the step during which a decision is made about whether a particular imaging procedure will be useful for a particular patient under a specific set of conditions. This decision is often made by the referring physician. Three issues of growing concern, 'self-referral', 'defensive medicine' and 'self-presentation', are discussed in the paper.

The process of medical imaging consists of four major steps: justification, optimization, implementation and consultation (Fig. 1). These steps constitute the cycle of continuous quality improvement of medical imaging, because efforts to improve any of the steps leads to improvements in the entire imaging cycle. Continuous examination of the cycle to identify ways in which to improve each of the steps leads ultimately to a more useful and efficient medical imaging process.

The first step in the medical imaging process, justification, is the least examined but nevertheless one of the most important steps because it is here that decisions are made that determine whether a particular imaging process will be useful for a specific patient with a specific set of conditions. Justification involves two questions: Is an imaging procedure necessary and, if so, which imaging procedure should be chosen. Three levels of justification have been defined by the International Commission on Radiological Protection (ICRP). The three levels are: (1) justification of medical uses of radiation in general; (2) justification of generic medical procedures (such as the value of mammography as a practice); and (3) justification of a specific procedure with a specific patient. Justification at level 1 is a societal decision that has been positively affirmed since the introduction of X rays into

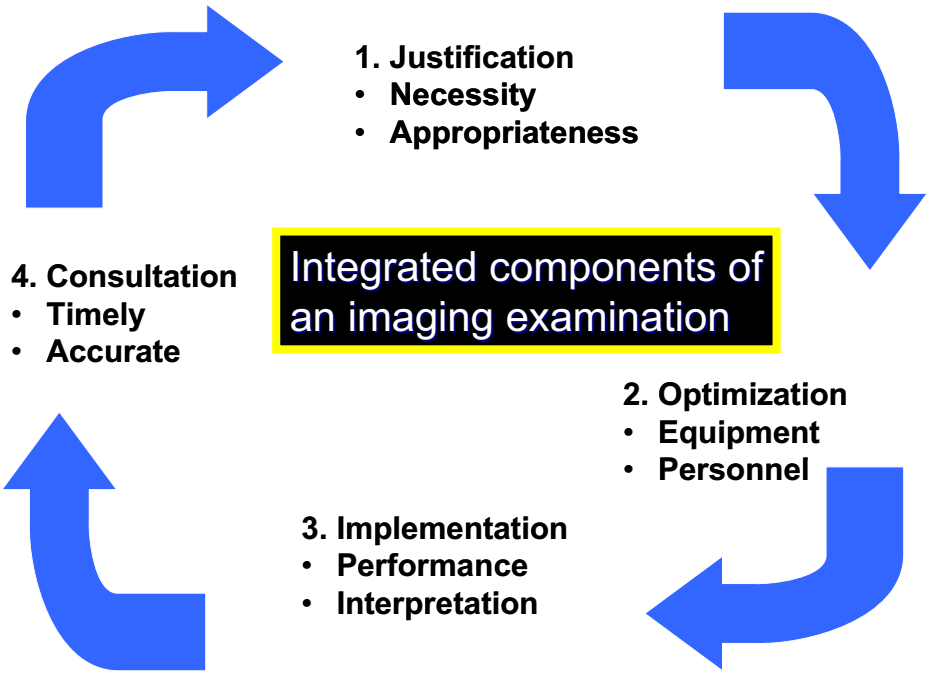

FIG. 1. Continuous quality improvement cycle of medical imaging.

medicine before the beginning of the previous century. Justification at level 2 is reflected in advisories such as the appropriateness criteria for medical imaging prepared by the American College of Radiology and referral guidelines for medical imaging developed by the Royal College of Radiologists and the Canadian Association of Radiologists. At level 3, justification is usually the province of the individual physician (or physician surrogate) responsible for the care of an individual patient with a particular set of conditions. In most cases, this physician is a non-radiologist who is termed the 'referring physician' because he or she is responsible for referring the patient for one or a set of imaging examinations.

In deciding whether an imaging procedure is necessary for a particular patient and, if so, which imaging procedure or procedures should be selected, a referring physician can acquire assistance in a number of ways. Appropriateness criteria and referral guidelines are available for decision making about patients with a variety of conditions. These guides to good decision making are generic, however, and a referring physician must still decide whether they are applicable to the individual patient under his or her care. Deviations from referral guidelines are permissible; however, deviations employed at a greater frequency than expected (for example, by comparison to the rate of deviation averaged over several similar physicians) should cause a referring physician to review his or her decision making procedure. In most cases, appropriateness criteria and referral guidelines are developed by imaging experts employing a consensus development process such as the Delphi method. They represent expert opinion, but are not directly based on data compiled through comparative effectiveness research in which health outcomes are determined for patients examined by competing imaging technologies. This type of research is difficult and expensive to conduct, and to date research funds have been inadequate to pursue it to anywhere near the degree to which it is needed.

Radiologists are another source of assistance for referring physicians making imaging decisions about individual patients. Radiologists are knowledgeable about the benefits, risks and costs of various imaging procedures, and can guide a referring physician by providing educational programmes about imaging methods and by consulting with physicians about preferred imaging techniques for an individual patient. Radiologists are pleased to help guide patients through the plethora of available imaging techniques, because this helps ensure that the time and effort spent in imaging will yield the maximum return to both patients and referring physicians. Medical specialty societies are encouraged to provide opportunities for radiologists to discuss imaging procedures of value to their members at meetings where members congregate, and to invite radiologists to author articles on imaging choices in their scientific and professional journals. Radiologists should make themselves available at every opportunity for consultation with referring physicians about imaging choices for individual patients. These educational and consultative practices will help ensure that imaging procedures are chosen wisely and efficiently, and that futile imaging procedures are not selected that yield little return on investment and expose patients to unnecessary risks and costs.

Electronic order entry of requested radiological procedures is gaining favor in larger health care institutions, and over the next decade will likely become an integral component of the electronic infrastructure of health care. Electronic order entry should include a decision support system to aid referring physicians in choosing a preferred imaging procedure or set of imaging procedures. For example, imaging procedures could be ranked in terms of the probability of yielding helpful information (a utility ranking) for patients with particular presenting conditions. This utility ranking is intended to help physicians select the procedure most likely to yield helpful information, taking into consideration cost and risk to a patient. A referring physician could override the decision support system and select a procedure with a lower utility ranking, but at least the physician would know that he or she is consciously making this choice on behalf of the patient and against the 'advice' of the decision support system.

An issue of growing concern is the presence of imaging facilities in physicians' offices or in stand alone imaging facilities in which physicians have a financial interest. The use of these facilities, a process known as 'self-referral', is a conflict of interest for the physician because of the tension between what is best for the patient and what is best for the physician in terms of the income that the physician derives from the use of the facilities. In addition, self-referral means that a radiologist is not available for consultation on the selection of imaging method(s) that would best suit a patient. A recent study of radiation dose to patients resulting from imaging studies revealed that more than 80 percent of the total effective dose to the patient population was delivered in outpatient settings, most often in physicians' offices.

A second issue of longstanding concern is the degree to which 'defensive medicine' causes images to be obtained for the purpose of protecting a physician against possible malpractice claims that may be filed in the future. Often these images are of little or no value to the patient, and do not impact the way that the patient's

condition is managed by the physician. They are obtained to aid the physician, not the patient. Probably the frequency of images obtained for defensive medicine purposes varies with the intensity of the legal environment in which the physician practices. In the United States where the medico-legal environment has been characterized as 'predatory', the frequency of images to help protect physicians against malpractice claims is probably substantially higher than in most other countries.

Self-referral and defensive medicine are issues that cannot be addressed by medicine. They are issues that require the passage of legislation to regulate the practice of self-referral in medicine and to revamp the legal environment to protect physicians from unmeritorious lawsuits. Without action at the legislative level, it is highly unlikely that self-referral and defensive medicine will ever be effectively resolved.

Increasingly, imaging services are being marketed directly to the public, and individuals are encouraged to present themselves to facilities for imaging procedures. For example, whole body CT scanning is being marketed heavily in some urban settings as a way to determine if individuals are at risk for cardiovascular disease. The benefits of this procedure are nebulous at best, because the technique yields both false positive and false negative results that severely compromise its predictive value. The procedures are costly and expose participants to a substantial radiation dose. For younger patients, the case can be made that the long term risk of the exposure to radiation outweighs the long term benefits of the diagnostic information obtained with the technique, which appears to be of little value. The solution to the problems associated with this type of direct marketing of imaging services to the public is education of the public about the risks and benefits of medical imaging procedures. Public education programmes should be developed by radiology and medical physics professional societies to offset the efforts of marketing entrepreneurs who hope to make a profit by exploiting the health concerns of the public. These programmes should be presented in a simple and straightforward manner by individuals knowledgeable about the subject and accustomed to answering questions in a forthright and understandable manner. There is a downside to engaging the public in this manner; it takes time and effort away from work, family and leisure activities. However, there is a greater downside to ignoring this need, because those who are experts in a discipline stand to lose credibility if they are seen retrospectively to have remained silent while a public injustice was being perpetrated.

In the medical imaging process, justification is the step in which a decision is made, usually by a patient's physician, to perform a particular imaging procedure with a particular patient. Procedures that are chosen unwisely or for the wrong reasons yield images that are not helpful in caring for a patient. These images contribute to the overutilization of medical imaging, a concern of growing intensity among providers and payers of health care services and groups concerned about unnecessary risks in medicine. Recently a summit entitled Medical Imaging: Addressing Overutilization in an Era of Healthcare Reform was conducted in the Washington DC area by the American Board of Radiology Foundation, with co-sponsorship by the National Institute of Biomedical Imaging and Bioengineering and the American Board of Radiology. The summit identified several causes of overutilization in medical imaging, and developed several potential solutions to these causes, some of which are described in this paper. A white paper describing the summit and its conclusions will be published in the near future, and will be made subsequently available by the American Board of Radiology (www.theabr.org).

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REGULATORY PROCESS AND IMPLEMENTING JUSTIFICATION: A VIEW FROM DEVELOPING COUNTRIES

J.L. DELGADO-GUARDADO
Comisión Nacional de Seguridad Nuclear y Salvaguardias,
Mexico City, Mexico
Email: jldelgado@cnsns.gob.mx

Abstract

The paper intends to present the current situation of regulation of the principle of justification in different Latin American countries. The survey does not intend to be exhaustive because, at least for the author, not all the required information is available. Of course the situation in the author's country is presented simply for comparison with other countries of similar economies and development. The author would like to thank the Ibero-American Forum of Radiological and Nuclear Regulators (FORO), as this presentation is in part based on current work performed under the auspices of this organization by a task force named Radiological Protection to Patient.

1. INTRODUCTION

1.1. The current situation of regulation development in Latin America

The development of regulations is related in general to radiological protection in the region. It is not uniform and in some way it does not depend on the economic status of the countries; of course there are clear signs that, at least for countries with nuclear installations, the development of regulations in matters related to nuclear energy and ionizing radiation is accompanied by a more intensive access to modern technologies which are of service to the community.

Regulations to protect patients (in countries that establish such regulations) are based on the International Basic Safety Standards [1], most often with adaptations to fit the national way of doing things.

For Latin American countries that are part of the FORO (Argentina, Brazil, Chile, Cuba, Mexico and Uruguay), national regulations are certainly based on the International BSS.

However, it is important to say that not all these countries have the same procedures to promulgate norms and standards; some of them can easily (as soon as they have some kind of agreement with the rest of the society, including professional societies) promulgate such standards, but others have more complicated procedures that produce a considerable delay in the promulgation of norms; in the latter case some regulations are not updated to match current technologies.

The implementation of regulation (without taking into consideration the decree date of promulgation of regulations) implies another important problem, because this task is not always straightforward. In many cases, this implementation depends on the existence of different authorities, including health ministries or nuclear regulators, and the roles assigned to each of them.

It is recognized that the establishment of sustainable radiation protection programmes requires not only the promulgation of laws and standards; it is equally important to consider the synergy between all the stakeholders: health authorities, nuclear regulators, professional societies, other governmental institutions, industry representatives and eventually the interested public. In Latin America, the role of the lead interested party more often falls on the nuclear regulatory authority.

2. THE FIELD OF ACTION IN SOME LATIN AMERICAN COUNTRIES

As many people say, the potential solution always starts with an understanding of the problem. In this context, it is good to know the number of installations that need to be controlled in order to implement radiological protection to patients and, consequently, justification principle requirements.

Table 1 shows the situation in five Latin American countries [2] with regard to controlled radioactive sources or installations (by health ministries or nuclear authorities).

TABLE 1. CONTROLLED SOURCES/INSTALLATIONS*

Country	Radiodiagnosis and intervention radiography				
	Conventional X ray	X ray dental	Fluoroscopy (including intervention)	Mammography	Computed tomography
Argentina*	7000	12 000	1200 Private: 70% Public 30%	400	800
Brasil	19 440	27 850	1450 Private: 60% Public: 40%	3530	2300
Cuba	1287	487	28 Private: 0% Public: 100%	23	36
Mexico	7425	2800	1500 Private: 72% Public: 28%	530	440
Uruguay	590	1006	98 Private: 89% Public 11 %	71	36

* Data for radiodiagnosis and intervention are estimated, year 1998.

Country	Radiotherapy				
	Teletherapy			Brachytherapy	
	Cobalt therapy units	Gamma knife units	Linear accelerators	Low rate	High rate
Argentina	48	1 Private: 71.5% Public: 28.5%	65	57	5
Brasil	92	1 Private: 10% Public: 90%	142	52	62
Cuba	9	0 Private: 0% Public: 100 %	2	0	5
Mexico	60	2 Private: 39% Public: 61%	55	41	17
Uruguay	8	0 Private: 67% Public: 33 %	8	6	0

Country	Nuclear medicine		
	Diagnostic		Therapy
	Conventional	PET	
Argentina	292	9 Private: 87% Public: 13%	166
Brasil	407	23 Private: 60% Public: 40%	86
Cuba	21	0 Private: 0% Public: 100%	7
Mexico	135	11 Private: 68% Public: 32%	128
Uruguay	7	0 Private: 86% Public: 14 %	7

To see the impact of the use of radioactive sources and ionizing instruments in diagnostics, including nuclear medicine, and taking into account the radiotherapy process, it is estimated [3] that the number of patients in Mexico in 2008 was more than 17.5 million. In the national institution that covers people working in the private sector alone (Instituto Mexicano del Seguro Social, IMSS), for half of the year 2009, the number of patients was 5 010 351 [4]; the IMSS only covers 46% of the total population.

As expected for developing countries, increases in population and continuous access to information requires governments and private services be prepared to fulfill the expectations of people in relation to health services. Currently in Mexico, 13% of the country's 104 000 000 inhabitants have no institutional or private access to medicine.

Taking into account the situation as described, it is important to recognize that not all the parameters for control of radiological protection in medical exposures adequately cover medical services in relation to diagnostic and treatment responsibilities.

Table 2 provides an overview of the regulatory interaction of different authorities in the control of medical exposures. As can be observed, all countries have full coverage of the radiological impact affecting not only workers, but also patients and the public. In the next section, the intention is to analyze whether such coverage is adequate or whether there is room for improvement.

TABLE 2. REGULATORY INTERACTION OF DIFFERENT AUTHORITIES IN CONTROL OF MEDICAL EXPOSURES

Country	Regulatory authority	Reporting to	Competence						Legal basis
			Scope	Responsible for					
				NR	RX	OE	PE	ME	
Argentina	Autoridad Regulatoria Nuclear	National Presidency	National	x		x	x	x	National Law for Nuclear Activity 24.804/97
	Dirección Nacional de Regulación y Fiscalización	Ministry of Health	Federal and provincial		x	x	x	x	National Law for X Rays 17.557/67
Brazil	Comisión Nacional de Energía Nuclear	Ministry of Science and Technology	National	x		x	x	x	National Law No. 7.781 June 27 1989
		Ministry of Health	National		x	x	x	x	Decree/ Law No. 3571 August 21 2000
Cuba	Centro Nacional de Seguridad Nuclear	Ministry for Science, Technology and Environment	National	x		x	x	x	Decree/Law 207 on Utilization of Nuclear Energy (February 14 2000)
	Grupo Central Regulatorio Ministerio de Salud	Ministry of Health	National		x	x	x	x	
Mexico	Comisión Nacional de Seguridad Nuclear	Ministry of Energy	National	x	x	x	x		Nuclear Law (January 26 1979) and addenda
	Comisión Federal de Protección contra Riesgos Sanitarios	Ministry of Health	National		x			x	Law of Health (2004)
Uruguay	Autoridad Reguladora Nacional en Radioprotección	Ministry of Energy and Mines	National	x	x	x	x	x	Law of Creation of the Regulatory Authority N° 17930 (2005) Based on Law 15809/86.

NR: Nuclear Radiation; RX: X rays; OE: Occupational Exposure; PE: Public Exposure; ME: Medical Exposure

3. LEGISLATION

To assure that every patient is properly protected from radiological risk, the government has the obligation and responsibility to establish a legal and governmental framework to regulate facilities and activities that "give radiation risk and for the clear assignment of responsibilities" [5] by establishing an independent regulatory authority.

The first problem that is faced by most Latin American countries is that current legislation establishes competency for radiological protection for medical exposures to more than one regulatory authority. In this context, there could be a gap in coverage for different aspects: dosimetry of workers, competence of physicians, training authorization, and in the end a heavy bureaucratic load for the organizations offering radiological services.

In many cases, advances in technology are faster than legislative changes. There are still several countries in the region with a regulatory body that does not have the infrastructure to cope with the responsibility of regulating medical exposures.

In many cases, when there is more than one regulatory authority with responsibility in the medical area, competences are defined by taking into consideration the origin of the ionizing radiation.

Laws and regulations are part of the history of nations. Generally, countries with a higher technological level have a more sophisticated and, in some cases, complicated interaction between authorities and competences. An example of this complexity can be found in hospitals with integrated services. In this case, it is almost impossible to separate responsibilities when it is necessary to establish effective regulatory programmes, for example in different studies using nuclear radiation (under the umbrella of the nuclear regulatory authority). In the use of linear accelerators, for example, to define the field of interest, it is necessary to at least once use a simulator which has X rays as the fundamental basis for diagnosis (in many countries under the health ministry). In this case it is very difficult for physicians to define the boundaries of diverse regulations.

There is no common strategy between countries to define responsibilities between ministries, because in some cases the competences are defined only in relation to the exposed group: public, workers or patients.

There is no 'better approach' because sometimes the way of doing things stems from the heritage of how different authorities grew, and also depends on the human resources available in a country and its associated ministries, the hierarchy between organizations and also the influence and activity of professional societies with regard to regulations.

3.1. Justification principle in the laws of some Latin American countries

Independent of the different roles of authorities, the justification principle taken from the BSS 115 [1] is widely adopted by the national regulations, and in some cases even duplicated in different standards and rules. Table 2 lists some of the standards and regulations of different countries; it can be seen that most of them reproduce the philosophy of the BSS.

However, written statements do not mean that prescribers or physicians always reach their conclusions on medical exposures based on this principle. There are many examples in which the medical procedure used to achieve diagnosis through radiation exposure of patients is driven by economic motivation (in Mexico, for example, a tomography could cost about one thousand dollars); in the private sector of medicine, physicians of different specialties abuse this technology without ever notifying patients of dose levels.

In the public sector, medicine is not driven by economics, but at the end the situation for the patient is almost the same from the perspective of received dose as in the private sector, but for different reasons, including bureaucracy or lack of quality assurance, sometimes resulting in the duplication of studies and, in many cases, unnecessary doses for patients.

In some countries, private physicians do not have confidence in the diagnostic results gained by the public sector and force patients to undergo similar studies but with alternative or modern instruments. The reverse of this statement is in some cases also true of the public sector, which may argue that the only valid images are those that come from their own system.

For most physicians not related with oncology activities (namely radiotherapy, clinical oncology or medical physics), matters like radiological protection to patients mean almost nothing, because they are not accustomed to measuring the detriment or risk of the application of medical exposure to patients.

3.2. Some strategies to improve and effectively use the justification principle in medical practice

Taking into account that in many countries the justification principle is not well understood or applied, regulatory organizations need to lead a kind of national effort to coordinate the contribution of all stakeholders interested in the radiological protection of patients. A very important player requiring integration is without any doubt the health authorities, in addition to professional societies and manufacturers or equipment dealers (technicians or physicists).

To produce useful results, efforts need to be oriented (not in order of importance) to the following activities:

- Alignment of national standards with well established criteria, like those in the International Basic Safety Standards;
- National efforts to coordinate areas of responsibility and to perform joint inspections;
- Development of national campaigns to inform physicians, radiological protection supervisors, physicists and patients about the radiological safety implications of any treatment;
- Strong campaigns with all stakeholders to review legislation, filling voids, if any, and redefining fields of activity of both health and nuclear authorities;
- Regulatory authorities (collectively) should maintain strong communication with international organizations dealing with health and radiation protection; with the participation of the latter, agreements are reached, difficulties overcome and synergy achieved for the benefit of patients and the general society of our countries.

It is clear that despite all efforts that could be made by nuclear and health authorities, there are medical practices which require a safety culture deeply rooted in society. In this sense, self-medication and ‘self-referral’ are subjects of great concern, not only from the medical, but also from the societal point of view.

Another important matter that must be solved parallel to efforts in connection with the justification principle is undoubtedly that of medical competence in radiological protection issues, particularly for oncologists, radiotherapists or those who prescribe diagnostic procedures, and all those involved in medical practice. To achieve this, training requirements need to be implemented and at the same time these types of medical specialties need to be correctly promoted, to ensure that in case of a shortage of physicians, more specialists could be engaged in these types of medical practices.

4. LATIN AMERICAN EFFORTS TOWARDS HARMONIZED PATIENT RADIATION PROTECTION

One of the most recent efforts to harmonize with the highest standards of radiation protection for patients in Ibero-America is being conducted by the member countries of FORO (a non-profit organization founded in 1995 in Veracruz, Mexico), now comprising seven countries (Argentina, Brazil, Chile, Cuba, Spain, Mexico and Uruguay) which, through specific working groups, develop proposals in various fields of nuclear and radiation activities of participating countries, the ultimate goal of which is the transfer of knowledge.

Within FORO, the need to establish common criteria for an area that required immediate attention was raised, not because they had not been developed in each country, but because their results in relation to the radiation protection of patients could not be corroborated. In this situation, a task group was organized to develop a guide: the Self Regulatory Programme Evaluation of Radiological Protection Medical Exposure, which aims to:

- Assist in the formulation of efficient regulatory programmes that contribute to the implementation of NBS requirements for the radiation protection of patients;
- Facilitate the work of self-assessment of regulator performance in the control of medical exposures, in order to contribute to the continuous improvement of the radiation protection of patients.

Work is currently ongoing, but the achievements of inter-institutional integration between members of different countries augurs success in achieving these objectives. When the guide is ready, it will be of a great help to all Latin American countries trying to develop a sound culture in radiological protection of patients.

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SPECIAL PROBLEMS

(Session 5)

Chairperson

P. SMEESTERS
Belgium

Rapporteur

P.W. HORTON
United Kingdom

JUSTIFICATION ISSUES IN NON-MEDICAL IMAGING (MEDICO-LEGAL) EXPOSURES

G. O'REILLY
Department of Medical Physics and Bioengineering,
St. James Hospital,
Dublin, Ireland
Email: goreilly@stjames.ie

Abstract

Medico-legal procedures are defined in the EC Medical Exposure Directive (MED) as "procedures performed for insurance or legal purposes without a medical indication". The European Commission started a process in 2005, the revision and recast of the Basic Safety Standards, in which the definition of non-medical imaging exposure is proposed to be, "Any deliberate exposure of humans for imaging purposes where the primary motivation for making the exposure is not related to the health and well being of the individual exposed." Issues around this type of exposure are explored in the paper.

1. INTRODUCTION

The Medical Exposure Directive (MED), 97/43/EURATOM [1], defines medico-legal procedures as 'procedures performed for insurance or legal purposes without a medical indication'. The MED requires Member States to ensure that procedures are put in place that should be observed in the case of medico-legal examinations. It also requires that special attention be given to the justification and optimization of such exposures. Radiation protection in medicine is underpinned by these key concepts of justification and optimization and much work has been done in the last 20 years in terms of developing and consolidating approaches to optimization [2]. With respect to justification, less effort has been applied and there is ample evidence to suggest that the efforts applied have had limited success [3, 4].

Recent work on justification issues in medicine [2] identified a number of fundamental issues critical to the justification process. These included the importance of referrers and practitioners to be well informed on radiation risk and to have the ability to communicate this risk to patients in a manner that is easily understood. It also noted the requirements to: (i) respect the autonomy and dignity of patients, (ii) involve them in decisions that might impact on their well-being and (iii) secure informed consent in relation to medical exposures.

It will be seen that although similar considerations apply to the justification of 'medico-legal' exposures, in attempting to apply the principle of justification to 'medico-legal' exposures, significant challenges arise. One of the reasons for this is that the favourable balance of benefit and risk assumed in medicine does not apply to medico-legal exposures. It is clear that in relation to justification, the competing demands relating to individual and societal benefit require an approach that is specifically constructed with these in mind. As such, current EU legislation [1, 5] does not provide an adequate framework within which the full range of issues and concerns can be addressed.

2. EXISTING LEGISLATION

Within existing European legislation, medical exposures are considered to include not only those exposures which are part of the normal diagnosis and treatment of patients but also exposures undertaken for occupational health surveillance, health screening programmes, research and medico-legal exposures. So, it is seen that medico-legal exposures are considered to be a sub-set of medical exposures and therefore relevant provisions of the MED will apply. One of the objectives of the MED and the reason for including medico-legal exposures within the scope of medical exposures was to ensure that persons presenting for medico-legal procedures would be afforded at least the same level of protection as patients. However, the framework of the MED was designed primarily to deal with the protection of patients and thus may not be suitable to deal with exposures where the primary focus is other than diagnosis and treatment.

While medico-legal exposures were originally envisaged to be X rays for insurance purposes and X rays arising as the result of a court case, the scope is much wider than this. Other exposures that might be considered to be medico-legal would include those taken for the purposes of age assessment, weapons or drugs search, suspicion of child abuse, sports medicine (predictive/preventive), vehicle inspection, immigration, emigration and pre-employment assessment [6]. It is clear from this list that the scope extends beyond those performed for insurance or purposes of legal proceedings and covers a wide range of possible scenarios and exposures of a very different nature. A common feature is that the main reason for performing the exposure does not directly relate to the health of the individual being exposed and there is not a strict medical indication. This poses an immediate challenge in relation to justification, as the consideration of relative benefits and detriments that is an integral part of that process is challenged by the fact that the benefits may not be primarily for the individual exposed.

3. EXAMPLES OF MEDICO-LEGAL EXPOSURES

There are numerous examples which can be cited to illustrate the problem of justification in medico-legal exposures. One of these is the requirement by some countries for a chest X ray prior to immigration. In relation to the practice of requiring immigrant or emigrant chest X rays, the question that arises is: is it a public health safeguard or a trigger for deportation? If the reason for requesting the X ray is that the immigrant comes from a country with a high incidence of TB and positive identification of this disease will result in medical treatment then this is probably a medically indicated exposure. However, if it simply results in detainment and subsequent deportation, then it would almost certainly be considered to be a medico-legal exposure. Clearly justification of the exposure in the two situations outlined would involve completely different risk/benefit ratios.

Whatever the motivation for exposure, it should be carried out within an appropriate legal framework. As such, procedural aspects that should be integral to the process would include the use of selection criteria and obtaining of informed consent prior to an exposure being made. It is an implicit assumption in medical exposures that consent is freely given. However, in situations such as those that pertain in the example above, the inequity between the parties is such that it could potentially compromise the process. If, on the other hand, consent is not obtained and the exposure is mandatory, then this could be viewed as an aggression against the right to individual autonomy. It also contrasts very starkly with the situation in medically indicated exposures, where consent is a prerequisite and the autonomy and dignity of the patient are always respected. However, in situations where vulnerable individuals are at risk, it may be reasonable to place limits on individual autonomy in connection with the protection of public health.

These issues do not normally arise in the context of medical exposures but they are not uncommon in medico-legal exposures and so it is clear that a modified approach is required. Similar considerations arise in the case of pre-employment health assessments in which a prospective employee might be required to undergo an X ray examination as part of a routine medical check. In this instance, again, the individual is asymptomatic and there is no clinical indication for an examination. A potential outcome of the assessment might be the identification of persons suffering from conditions that would render them unfit for work or that might lead them to seek compensation from the employer at a later stage. The screening of such individuals, prior to employment, is of obvious benefit to the employer. While there may be some benefit to the individual exposed as a consequence of diagnosis of previously undiagnosed disease, it is questionable whether this will outweigh the potential loss of prospective employment.

In these examples of the use of X ray techniques in immigration, emigration and pre-employment, the benefits and detriments to both individuals and society must be considered. Classification of exposures will differ depending on whether the motivation for an examination is primarily for the health and well-being of the individual exposed or for other reasons. Justification needs to be considered with reference to motivation and subsequent action.

Another practice, which almost certainly involves medico-legal exposures, is the use of X ray scanning techniques for security screening in airports and other places. This has been a topic of both comment and debate in the media. Scanners were introduced into a number of European airports on a trial basis to complement and enhance existing security measures post 9/11. They have been deployed at airports in the UK, the Netherlands and Finland [7]. Most of the devices in use are based on back scatter technology and are low dose devices with a typical dose per scan of less than 0.1μSv [8]. They have also been used in some public houses and in prisons in the USA [8]. Transmission scanners have a dose of 2–5μSv per scan [8]. Scan time is in the order of eight seconds; thus they can

offer advantages in terms of both reliability and throughput compared to more traditional search methods. However, a number of ethical issues arise in relation to their use. These include that of consent, privacy and their use on children. Other issues that arise include justification of both the practice and individual exposures, the appropriate regulatory framework within which the scanners can be used and safety and training of operators.

For all of the exposure situations cited above, issues remain about the referral criteria and competence of the individuals making these assessments.

There are many other examples. The examples listed are clearly not medically indicated exposures, and should probably be classified as medico-legal exposures. However, it is not always clear which exposures are true 'medico-legal' exposures and which are not. Often certain exposures could be interpreted as medico-legal, occupational or medically indicated depending on one's point of view. The motivation for carrying out an exposure can indicate whether the exposure should be regarded as a 'true medical' or a 'medico-legal' exposure. This lack of clarity has given rise to practical problems, both for regulators and for those trying to comply with national legislations.

4. PROBLEMS WITH THE CURRENT LEGAL FRAMEWORK

As currently framed, medico-legal exposures are a subset of medical exposures. Therefore, the provisions of the Medical Exposure Directive are directly applicable. However, as many of these exposures are carried out in a medical facility by medical personnel, they are carried out in a similar way to medically indicated exposures and dose limits are not applied. Given that there is no medical indication for the exposure, the benefit/detriment ratio is significantly different for the two categories of exposures and the absence of a dose limit presents a problem.

An example in which this is particularly problematic is in the detection of concealed drugs. A typical procedure might involve a superficial body examination first, which could be followed by a more comprehensive body examination. This could involve an internal examination followed by an X ray. While in some countries the modality of choice for this would be plain radiography, in a number of European countries, CT is used [10]. The resultant dose from a CT examination could be some tens of mSv. If this is considered to be a medical exposure or is carried out within that structure, then no dose limit is applied. However, if this was considered to be a public exposure then a dose limit of 1mSv would apply. There is no limit applied in practice and the scans are usually carried out using typical diagnostic exposure parameters resulting in significant individual doses. It is clear that current legislation does not provide an appropriate framework within which to conduct such exposures.

5. JUSTIFICATION ISSUES IN MEDICO-LEGAL EXPOSURES

Justification involves the potential benefits and detriments to both the exposed individual and society. However, very often the population being scanned may not be the population deriving the benefit. Examples of this include the use of X rays in crime prevention, immigration and age determination. In these examples, the individual exposed may be disadvantaged as a consequence of the exposure. Informed consent may not be sought or given prior to exposure.

Justification is a key issue in medico-legal exposures but when these exposures are carried out within the construct of a medical exposure, problems arise**.** Justification of practices and individual exposures within diagnostic radiology is predicated on a risk–benefit paradigm that assumes benefit accrues to the person subjected to the risk as it would be in a medically indicated exposure. This is not the case in medical legal exposures. However, in some cases it may be reasonable to expect individuals to accept negligible risks when there are moral grounds and rational justification and perhaps there needs to be an acceptance that there will be limits on personal autonomy in connection with protection of vulnerable individuals in society. There may be cases where a strong public health, legal, security or safety issue dictates that an exposure should proceed. However, if this is the case, protective measures need to be an integral part of the process. Included in this would be the development and use of appropriate selection criteria and the establishment of either dose limits or dose constraints.

For medico-legal exposures that are motivated by financial concerns (as part of employment or insurance), there is often a relative inequity in bargaining power between the individual exposed and the party requiring the exposure, and this may reflect a wider social inequity. In general, there is social concern about the compromise of

health for commercial gain, and health and bodily integrity are usually regarded as worthy of legal protection from commercial contractual arrangements. These matters must be reflected in a legislative system which takes account of the varying issues that arise. The development of such a system will require input from sources that extend beyond the established radiation protection community so that wider social concerns may be adequately accounted for.

6. REVISION OF THE BASIC SAFETY STANDARDS — MEDICO-LEGAL EXPOSURES

In 2005, the European Commission initiated a process which will result in a number of directives related to radiation safety being recast as a single directive [11]. The new directive will be known as the Basic Safety Standards and will incorporate revised versions of the BSS (96/29/EURATOM) [5] and the MED (97/43/EURATOM) [1]. This affords an opportunity to strengthen certain requirements and take into account experience gained since 1996.

This experience has already confirmed that the current legal provisions within the Medical Exposure Directive are not suitable for medico-legal exposures. With the revision and recast of the Basic Safety Standards, there is an opportunity to revise the framework within which medico-legal exposures are carried out. In the first instance, the term 'medico-legal exposures' will no longer be used but instead a new category known as 'non medical imaging exposures' will be introduced, along with a revised definition. These exposures will no longer be considered to be a sub-set of medical exposures. The proposed definition is:

> **Non Medical Imaging Exposure**: Any deliberate exposure of humans for imaging purposes where the primary motivation for making the exposure is not related to the health and well-being of the individual being exposed.

It is clear that the defining feature of these exposure types will in the future be the motivation for carrying them out. This recognizes the fact that the benefit of such exposures may not accrue to the individual exposed and that special attention must be given to their justification. The new draft directive states that those practices that are justified will require: (i) authorization, (ii) criteria for individual implementation, (iii) dose constraints established in advance, (iv) optimization, and (v) informed consent.

It is envisaged that in exceptional circumstances, one might proceed without informed consent. However, the circumstances under which this would be permitted must be determined in advance by Member States and will not be solely at the discretion of individuals. There is also a requirement that when screening for security purposes is routine, alternative non-ionizing techniques must also be available.

7. CONCLUSIONS

It is clear that existing medical techniques and technology are being applied for non-medical reasons; it is important that the justification of these practices responds to input from a wider social base. When the Basic Safety Standards are revised, medico-legal exposures will no longer be regarded as medical exposures and will be dealt with in a more appropriate legal and operational framework. In the decision regarding authorization of practices, justification is the key issue. It is interesting that there is significant overlap between the issues that have been identified as critical in designing a revised implementation framework for 'medico-legal' exposures and those that were identified as fundamental to the justification process during IAEA consultation exercises. These include: (i) referral criteria, (ii) informed consent, and (iii) communication issues.

The very significant challenges that will be posed by full implementation of a revised legislative framework will necessitate the development and provision of guidance for Member Sates. A comprehensive solution to all of the issues that will arise will require communication between a diverse range of professions and disciplines. It is essential to develop understanding and improve practice and this will require input from sources that extend beyond the established radiation protection community.

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DENTAL RADIOLOGY: THE FORGOTTEN PROBLEM?

K. HORNER
School of Dentistry,
University of Manchester,
Manchester, United Kingdom
Email: keith.horner@manchester.ac.uk

Abstract

Radiology is an essential part of dental practice. Traditionally, this has relied upon a small number of simple radiographic techniques with a low level of associated radiation risk. High numbers of dental X ray examinations, the frequently young age of patients and the relatively low health benefits of dentistry mean that justification of examinations remains an important consideration. Most dentists work in independent practice and self-referral for imaging is normal. Non-clinical pressures, such as financial factors and defensive practice, may influence the use of X ray examinations. Referral criteria are available at national and international levels, but their evidence basis is variable and there is a lack of data for their impact on behaviour. Particular challenges in justification include frequency of X ray examinations, the use of routine panoramic radiography and cone beam CT. Improving the practice of justification in dental radiology will rely on the availability of high quality referral criteria, improved education of dentists and greater attention to audit of practice.

1. INTRODUCTION

The use of X rays in dental practice is almost as old as radiology itself. Despite the rather difficult challenge of radiography in the oral cavity, the first dental radiographs were taken in the early months of 1896, using primitive materials and homemade equipment. After dedicated dental X ray equipment and film was manufactured in the 1920s, the use of radiography accelerated and became essential for the practice of dentistry by the middle of the 20th century.

Traditional dental radiology consists of just a few techniques: intra-oral radiography (bitewing, periapical and occlusal), panoramic radiography and cephalometric facial bone radiography (Fig. 1a–c). For many dentists, only intraoral radiography is available. More recently the landscape has started to shift, with dental cone beam CT (CBCT) equipment becoming readily available to dentists and increasingly used as a tool for a wide range of dental applications.

2. SCALE OF DENTAL RADIOLOGY

It has been estimated that approximately one fifth of all X ray examinations are performed by dentists (UNSCEAR, 2000), but in some countries this proportion is much greater. Accurate estimates are difficult to obtain, because in many countries dentistry is performed in a private practice situation, without involvement of any external agency. However, where there is a national health service or national insurance system involvement, the numbers of X ray examinations can be estimated and are remarkable in their scale. The UNSCEAR report estimated an average frequency of 309 dental X ray examinations per 1000 people for health care level 1 countries [1]. This average concealed wide national variations in the use of X rays in dentistry, ranging from the highest (839 per 1000 people) in Japan to below 100 per 1000 for many countries. In the UK, for example, it was estimated in 2002 that over 9 million intraoral and over 3 million panoramic radiographs were taken annually [2]. Variations in the prescription of X rays can also be seen within individual countries and does not appear to reflect disease prevalence.

3. RADIATION DOSE AND RISK

Radiation doses from conventional dental radiography are individually very small, lying at a level often described as ‘negligible’. Recent changes to the weighting factors used in dosimetry [3], with allocation of a

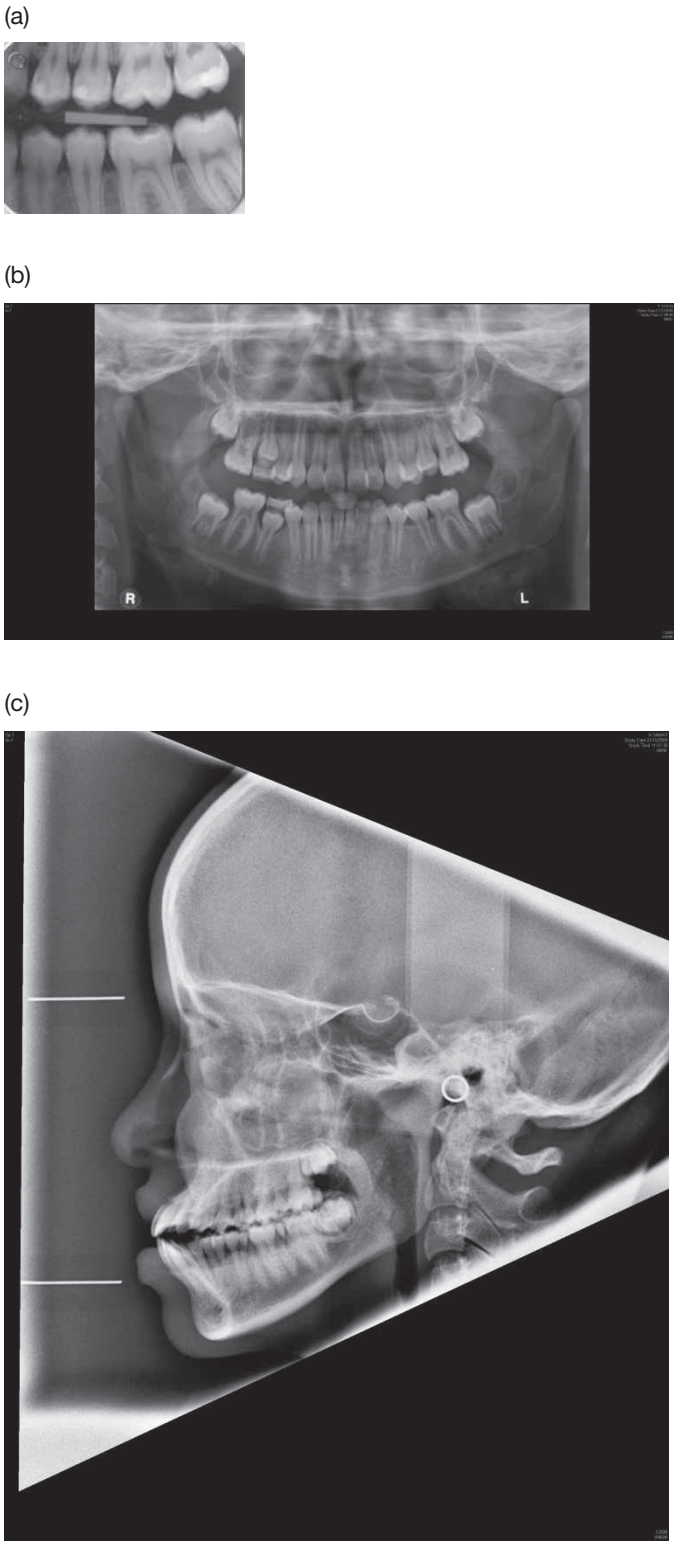

FIG. 1. Traditional dental radiographs: (a) bitewing, (b) panoramic, (c) lateral cephalometric radiographs.

specific weighting factor for the salivary glands, have increased effective doses noticeably but they remain low relative to most medical diagnostic X ray examinations (Table 1). Dental CBCT can, in contrast, be associated with higher effective doses. The dose associated with CBCT varies a lot according to the equipment and the field-of-view; it is generally lower than ‘medical’ CT but greater than conventional dental X ray techniques [4].

TABLE 1. EFFECTIVE DOSES ASSOCIATED WITH DENTAL X RAY EXAMINATIONS

(Most research has been performed prior to ICRP [3], so data are presented prior, and subsequent, to the new method of effective dose calculation. Data derived from Refs [4–6]).

Techniques	Effective dose pre-ICRP 2007 (μSv)	Effective dose post-ICRP 2007 (μSv)
Intraoral radiograph	1–8.3	5
Panoramic radiograph	3.85–30	2.7–24
Cephalogram	2–3	5.6
Cone beam CT 'dentoalveolar'	—	34–652
Cone beam CT 'craniofacial'	—	30–1073

An important difference between dental and medical radiology is the age profile of patients, as shown internationally [1]. Many of the problems that dentists deal with, notably dental decay (caries) and developmental disorders of teeth (crowding and impaction of teeth; dental aesthetics) arise in childhood and early adult life. Thus dental radiology is used to a proportionately high degree in young people. Once again, obtaining accurate objective data is not easy, but a specially commissioned data analysis in England and Wales, carried out for the author, showed that most panoramic radiographs were shown to have been taken of patients in the first two decades of their lives [7]. The frequency of taking this type of radiograph fell with increasing patient age. As the risk associated with X ray exposure is inversely related to age, the risk consequences of dental radiography are somewhat greater than their low dose might initially suggest.

4. JUSTIFICATION IN DENTAL RADIOLOGY

There are several unique aspects to the use of X rays in dentistry that have some impact upon the issue of justification. First, as described above, dental radiology is a 'low dose/high volume' procedure, while the level of risk associated with dental X ray examinations needs to be considered in the context of the younger age groups that are typically examined. Apart from these, there is the fact that the majority of dentists work in independent practice. 'Self-referral', with the dentist acting both as referrer and the person responsible for justification, is the norm. Many are the owners of the establishments in which they work, while others work for corporate bodies; only a small proportion of dentists work in a hospital environment. Although in most countries the regulation of X ray use for dentistry is the same as that for medical applications, the independence of dentists means that there is, inevitably, a greater chance that the justification process is addressed in a superficial way. Dental X ray examination may often become 'routine' rather than a considered choice.

Over and above this, there are non-clinical influences on the use of X ray imaging. There is a pressure to use more expensive items of equipment (panoramic, cephalometric and, more recently, dental CBCT machines) so that costs can be recouped more quickly. Manufacturers may compound this by highlighting the income generation aspects of X ray examinations as well as diagnostic value and can promote inappropriate use. Inevitably, in a competitive culture amongst dentists in marketing their services, more sophisticated X ray equipment can feature as a 'selling point' to patients. Another factor that is influential but not primarily driven by clinical need is medico-legal concern amongst dentists. There is a fear of litigation from patients if something is missed at initial examination. While such fears are almost certainly groundless if clinicians follow accepted practice, this is a background issue that can influence the use of X ray imaging [8, 9].

Justification in radiology can be perceived by dentists as an arcane process. In dentistry, risks from radiation exposure are generally low. Dental disease is almost never life threatening and the benefits of radiology are also low relative to those in most medical care. Thus the philosophy of justification, in which risks are weighed against benefits, is hard to translate into the real world. It has been argued that when risks are low or negligible, X ray examinations may be justified by proportionately low benefits [10]. This argument can be interpreted as giving *carte blanche* to indiscriminate use of dental radiology, particularly where exclusion of disease and screening

examinations are the existing practice of dentists. It is important, therefore, also to see the use of dental radiology as a ‘consumer issue’ for patients who are often paying for their treatment. The financial pressures on dentists to use their X ray equipment have to be balanced by the rights of patients to avoid wasting their money on unnecessary tests.

5. REFERRAL CRITERIA

Referral criteria are a type of clinical guideline. Guidelines have been defined as:

> “Systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.” [11]

A guideline is not, however, “a rigid constraint on clinical practice, but a concept of good practice against which the needs of the individual patient can be considered” [12].

Not all guidelines are equal, however, and attention needs to be given to their method of development. Three levels of sophistication can be identified:

(1) ‘Expert’ opinion — This is the traditional, and weakest, type of guideline produced by one or more (often self-appointed) individuals. It uses the valuable resource of specialized expertise and experience to present an opinion. Such guidelines have a high risk of bias. Even where a panel of several people is involved, there is a danger of one dominant individual influencing a decision;
(2) Consensus opinion — This may have some advantage in that a methodology may have been used to arrive at consensus, but frequently such guidelines represent little more than expert opinion;
(3) ‘Evidence based’ development — This should be the strongest method of producing any guideline. A clear methodology is used, based upon systematic review of literature, critical appraisal and data assessment, culminating in the production of a guideline statement carrying an evidence grade. Methods for performing evidence based guideline development have been published. In medical radiology, the European Referral Guidelines for Imaging [13] is modelled closely on a UK Royal College of Radiologists approach [12].

Regardless of the process of guideline development, it is important to remember that no guideline has an infinite life. Technology undergoes improvements with time and research evidence of clinical efficacy may change. Any guideline should be reviewed at regular intervals to take such developments into account.

6. DENTAL RADIOGRAPHIC REFERRAL CRITERIA

Probably the first set of guidelines dealing with justification on the use of radiology in dentistry were those produced in the United States in 1987 [14]. These ‘expert panel’ guidelines emphasized that individualized radiographic examinations for the asymptomatic, nonemergency patient seeking comprehensive dental care should be prescribed based upon the patient’s signs, symptoms, and history using selection [referral] criteria that increase the likelihood that the patient will benefit from the radiographic examination. These were followed by supportive guidance in Canada [15].

In Europe, national regulatory authorities seem understandably reluctant to interfere with the prescription of radiographs by dentists. Most recommendations relating to justification seem to be general guidance that imaging should be selected on an individual patient basis after a history and examination have been performed, relying on individual dentists’ judgements rather than a set of specific referral criteria [5, 16, 17]. More detailed guidelines have appeared sporadically from European and national dental organizations, notably in the UK [18] and France [19]. Apart from national initiatives, guidelines on imaging have also appeared from supra-national [20, 21, 22] and national [23, 24] specialist organizations. Upon close examination, however, many of these sets of referral criteria are expert panel based, rather than developed using a structured method of literature review. This no doubt explains why different sets of referral criteria may disagree.

In the UK, the Faculty of General Dental Practice (UK) produced evidence-based referral criteria for dental radiography in 1998 [18], revised them in 2004 [25] and is now working on its 3rd edition. Unlike the US and previous European guidelines, these were very clearly 'evidence-based', following a specific SIGN methodology [26] which, at best, included systematic review. These guidelines acted as the model for the development of the European Guidelines on Radiation Protection in Dental Radiology [5]. Using the SIGN method, search strategies were developed to identify relevant scientific literature, previous guidelines and 'grey literature'. Papers were reviewed by at least two individuals using standard methods of critical appraisal and data extraction, with grading of evidence. Material was then collected and reviewed to develop guideline statements which, in each case, were allocated an 'evidence grade'.

7. CHALLENGES IN JUSTIFICATION IN DENTAL RADIOLOGY

What are the key issues in justification of dental radiology? For intra-oral X ray examinations taken for detection of dental decay, the development of evidence based referral criteria [25] has led to a move away from routine biannual bitewing radiographs towards a frequency that reflects caries risk categorization. Thus, while a high risk individual may still be asked to undergo bitewing examination after a six month period, those seen as at low risk for dental decay may not benefit from X ray examination for periods of two or more years. Intra-oral radiographs may also be taken to assess healing after endodontic treatment and arbitrary times and frequencies of examination are used, despite the evidence that the optimal time to assess radiological signs of healing are at 12 months post-treatment only. Both these examples are, however, a matter of modification of current behaviour, rather than involving radical change.

The more important issues for radiation protection in dentistry are twofold: panoramic radiography and CBCT. First, the use of panoramic radiography, particularly for 'screening' new patients, is a practice that is commonplace [9, 27] but unsupported by evidence. A key study [28] showed that screening panoramic radiography of a large sample of new adult patients in primary dental care was unproductive (i.e. identified nothing of significance to treatment) in 56.3% of patients when findings that would be identified on bitewing radiographs were excluded. This proportion rose to 71% when the new patients were asymptomatic at presentation. Another important aspect to consider for panoramic radiography is that its diagnostic accuracy for the detection of the common dental pathoses (dental caries, bone loss due to periodontal disease and periapical inflammation) is inferior to that of intraoral radiography.

Panoramic radiography does have a role in oral surgery, notably where third molar teeth are being surgically removed, but its use for 'checking out' third molar development and position in asymptomatic patients is inappropriate [5, 26]. Similarly, panoramic radiography is an ideal imaging tool for imaging the developing dentition when considering orthodontic treatment, but it should not be used in the absence of clinical indicators of treatment need [24]. A study in Denmark neatly showed that, by applying just four clinical signs as criteria for panoramic radiography in children, 94% of dentally healthy children could be excluded from a radiographic examination, while correctly identifying 97% of those who would benefit from a panoramic radiograph [29].

CBCT has changed the world of dental radiology considerably. As recently as five years ago dental CBCT was in its infancy, but today there are at least 20 different pieces of equipment marketed worldwide and, despite its financial cost relative to conventional dental X ray equipment, its clinical use is burgeoning. The European Directive 97/43/EURATOM Article 3 (1a) states that "all new types of practices involving medical exposure shall be justified in advance before being generally adopted" [30]. What is happening in practice is in conflict with this, as there is a dearth of high quality research addressing the diagnostic efficacy of CBCT. Using the hierarchical model of diagnostic efficacy described by Fryback and Thornbury [31], most research on dental CBCT has been at the 'Level 1 Technical Efficacy' level, with only a few studies of adequate design at the 'Level 2 Diagnostic Accuracy Efficacy' and almost none at the four higher levels. Perhaps reflecting this lack of evidence for efficacy, dentists are undertaking CBCT examinations for their patients based on inappropriate clinical recommendations from manufacturers and specialist practices whose motivation is commercial. One manufacturer recommended in an advertisement in the UK dental press that "in the field of cariology (dental decay) the images generated by the cone beam technique revealed tooth tissue much more clearly than in the case with conventional X rays", in the face of research evidence that artefacts from existing dental restorations make caries diagnosis unreliable. Similarly, three-dimensional cephalography is being recommended by imaging practices in the USA [32], despite little

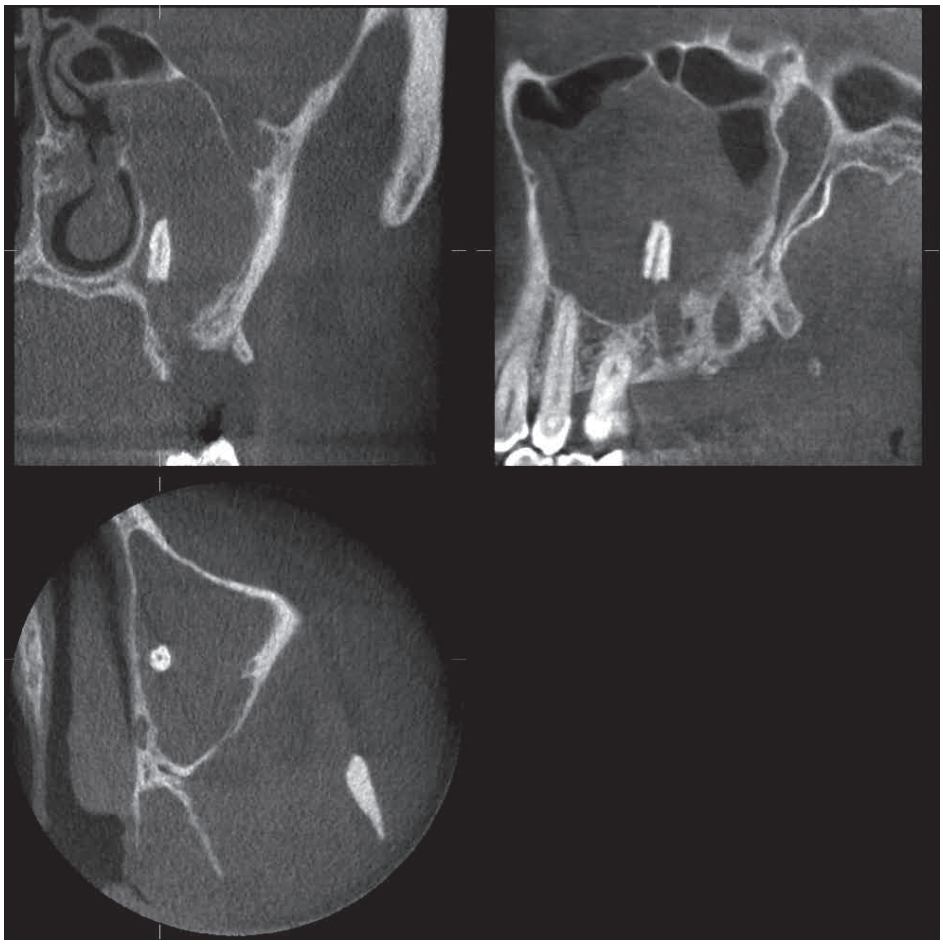

FIG. 2. Cone beam CT image.

research evidence supporting its impact over conventional two-dimensional techniques and good evidence that the latter is not required for many cases of orthodontic treatment planning [24, 33].

Concerns over the rapid take-up of CBCT, higher radiation doses compared with conventional dental radiographic techniques and the younger age profile of dental patients led to the co-funding by the European Commission, under its Seventh Framework Programme of the European Atomic Energy Community (EURATOM) for nuclear research and training activities (2007 to 2011), of a collaborative multidisciplinary project SEDENTEXCT (Safety and Efficacy of a New and Emerging Dental X ray Modality). SEDENTEXCT aims to acquire key information necessary for sound and scientifically based clinical use of cone beam CT. Amongst its objectives is one to develop evidence based guidelines on the use of CBCT in dentistry, including referral criteria. In 2008, however, the project was approached by the European Academy of Dental and Maxillofacial Radiology (EADMFR) with an urgent request to collaborate on producing a set of ‘Basic Principles’ on the use of dental cone beam CT. A set of statements was developed in plenary meetings at the 2008 EADMFR Congress, followed by an online consensus process to refine and agree on wording. This procedure led to publication [34] of 20 ‘Basic Principles’, including seven addressing justification (Table 2). Subsequently, the SEDENTEXCT Guideline Development Panel, following the defined methodology pioneered by others [5, 18], has built on these principles to produce provisional guidelines on cone beam CT, with detailed imaging criteria based on existing research evidence [4].

TABLE 2. ‘BASIC PRINCIPLES’ RELATING TO JUSTIFICATION OF DENTAL CONE BEAM CT
(taken from Horner et al. [34])

Cone beam CT examinations must not be carried out unless a history and clinical examination have been performed.
Cone beam CT examinations must be justified for each patient to demonstrate that the benefits outweigh the risks.
Cone beam CT examinations should potentially add new information to aid the patient’s management.
Cone beam CT should not be repeated ‘routinely’ on a patient without a new risk/benefit assessment having been performed.
When accepting referrals from other dentists for Cone beam CT examinations, the referring dentist must supply sufficient clinical information (results of a history and examination) to allow the cone beam CT practitioner to perform the justification process.
Cone beam CT should only be used when the question for which imaging is required cannot be answered adequately by lower dose conventional (traditional) radiography.
Where it is likely that evaluation of soft tissues will be required as part of the patient’s radiological assessment, the appropriate imaging should be conventional medical CT or MR, rather than cone beam CT.

8. THE WAY FORWARD

One area of concern is, as mentioned above, that one set of guidelines may not agree with another. Even guidelines that, ostensibly, use an evidence based methodology may be apparently conflicting. For example, while one set of guidelines do not support the use of panoramic radiology as a justifiable ‘routine’ examination of a new patient [25], others describe it (author’s translation) as “a fundamental examination of first intention when the clinical examination justifies it” [19]. Among guidelines with a less robust methodology for development, such examples are even more frequent, no doubt reflecting the personal bias of the authors. Any dentist who takes the trouble to read around the subject and who identifies such anomalies will be justifiably confused and skeptical about referral criteria. If guidelines are to be widely accepted, the methodology used should be transparent, with inclusion of references for all material reviewed and a mechanism for external (peer) review similar to that used for other scientific publications.

A perfect set of referral criteria is useless if it is invisible to, mistrusted by or ignored by the key stakeholder group: the ‘high street’ dentists. It has been shown that within American and Canadian Dental Schools, where attitudes to use of radiography and imaging will be instilled, pre-determined routine radiographic examinations are used on most new patients and referral criteria are not accepted [35, 36]. To counter such irrelevance, there is a requirement for, first and foremost, effective dissemination of referral criteria, usually by the active involvement of dentists’ national organizations or specialist societies. Guidelines also need to be available at little or no financial cost. Education, at the undergraduate and postgraduate level, is an essential means of increasing awareness among the dental community of the issues surrounding justification and referral criteria. The International Association of Dental and Maxillofacial Radiology highlighted the importance of these in a recent report [37].

Continuing Professional Development (CPD) programmes are also valuable. It is notable that in the UK, at least, radiology and radiation protection is one of the compulsory subjects included in the CPD requirements for revalidation and continued registration as a dentist [38]. This increases the chance that every dentist will be aware of, if not compliant with, the guidelines that are available.

As discussed above, dentists are usually independent practitioners with a sometimes fierce attitude to external ‘interference’ with their clinical judgement. Nonetheless, where dentists work within public health service frameworks, there is probably more scope for enforcing radiological referral criteria than is currently exploited. Certain types of treatments may already be excluded from publically funded dental health care programmes on economic grounds, so there is no reason why radiological examinations might not be similarly restricted. This would not, however, prevent dentists offering particular X ray examinations on a private basis.

The decision to use X rays for diagnosis in dentistry should be the judgement of the dentist, reached after obtaining a clinical history, conducting an examination, consideration of the diagnostic efficacy of the available radiological techniques and of alternative methods not using ionizing radiation and after obtaining the informed consent of the patient. The process of justification, with individualized prescription of radiological examinations, is

thus as important for dentists as it is for our medical colleagues. Properly developed referral criteria can offer valuable assistance to dentists in making their judgements. Nonetheless, despite several excellent examples of the development of radiological referral criteria in dentistry, their acceptance and impact remain uncertain and much work remains to be done. In particular, there is a need to consider implementation of referral criteria and clinical audit of the justification process in 'high street' dental practices.

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JUSTIFICATION ISSUES IN RELATION TO MEDICAL EXPOSURES OF WOMEN OF CHILD BEARING AGE

G. O'REILLY
St. James's Hospital,
Dublin, Ireland
Email: goreilly@stjames.ie

Abstract

This paper reviews justification issues in relation to medical exposures involving women of child-bearing age. One of the most common radiation protection issues in relation to the use of ionizing radiation concerns the management of the pregnant patient. Instinctively, one might want to avoid the use of radiation with a patient who is or might be pregnant [1]. The perception of risk seems to be heightened by the fact that both the hazard and the unborn infant are unseen and the situation may be perceived to be less amenable to control. The problem can be even more difficult when the female is not sure or does not know whether she is pregnant. In such situations, a risk based approach is appropriate. In evaluating risks and benefits, two individuals need to be considered as part of the justification process and the risks and benefits to both must be balanced. This adds a level of complexity to the problem that requires a well considered approach.

1. JUSTIFICATION ISSUES

A recent IAEA report [2] on justification acknowledges the well established principle that justification must be based on a favourable balance of benefit and risk for the procedure involved. It further recognizes the obligation of physicians and other health care providers to be well informed and to respect the autonomy and dignity of patients. It states that patients should be involved in all decisions that may impact on their short and long term well-being and that whenever feasible, the valid consent of patients should be secured before actions are undertaken. All of these are essential parts of the justification process in practice.

When procedures involve exposure to ionizing radiation, consent must include acknowledgement of the benefits and risks associated with the exposure. This is best accomplished by expressing them in terms that are transparent and understandable from the patient's perspective: a considerable challenge when the risks are uncertain and often presented using arcane terminology. However, this challenge must be met if patients are to be vitally engaged in the justification of medical procedures that expose them to radiation. Only in this manner can the justification process be fully transparent and accountable to patients and to society at large [2].

Within the radiological community, the issue of exposure during pregnancy has been considered within a framework dominated by radiobiological and dose considerations [3]. While these are undoubtedly of critical importance, additional considerations such as legal requirements and the personal view of the individual being irradiated should also be taken into account.

The considerations outlined above help identify a number of steps that should be an integral part of the justification process. These include the assessment of radiation dose and risk, the communication of risk to a patient and the obtaining of informed consent.

1.1. Scientific basis for risk

In order to make a judgement on the risk/benefit ratio of a particular examination, clinical staff and patients must understand the risks that are involved. A recent UK publication [4] on the protection of pregnant patients states that the "radiation dose to the embryo or foetus that is likely to result from any diagnostic procedure in current use should present no risk of causing foetal death, malformation, growth retardation or impairment of mental development". This essentially rules out the risk of deterministic effects arising from diagnostic procedures. However, in their 2003 publication on this topic [5], ICRP confirmed "embryonic susceptibility to the lethal effects of irradiation in the pre-implantation period of embryonic developments". While acknowledging that at doses under 100 mGy, such lethal effects will be very infrequent, the possibility of deterministic effects in the first few hours or days of early pregnancy is not definitively excluded.

As reflected in the HPA document [4], the existence of a small but finite risk in the very early stages of pregnancy is for practical purposes generally regarded as being of no significance. This somewhat subjective assessment of significance may rely to a certain extent on the fact that the loss of the embryo would occur without the mother being aware of the loss. In addition, this very early phase of pregnancy is associated with a high natural rate of loss and so the small additional risk that might arise from diagnostic exposures is not considered to be significant. While this approach is undoubtedly well grounded in both science and statistics, it might not be an approach that would be readily accepted by infertile couples trying to conceive.

In terms of stochastic effects, the HPA conclude that the risks of childhood cancer arising from foetal doses <1 mGy are less than 1 in 10 000. However for foetal doses of approximately 25 mGy, the risk of childhood cancer can double. For exposures during the first three to four weeks post conception, the risks are probably lower. The HPA also concludes that there is negligible risk of inducing heritable effects as a result of radiation doses arising from diagnostic exposures.

The ICRP [1] draws from radiobiological evidence and concludes that 'pre-natal doses from most properly done diagnostic procedures present no measurable increased risk of prenatal death, malformation or impairment of mental development over the background incidence of these entities'.

The HPA have published a summary table of foetal doses from standard diagnostic procedures which serves as a useful reference and source of information [4, 5]. In general, increasing dose and hence risk is observed for higher dose examinations (such as CT) and where the uterus is moved closer or into the primary beam. The table is useful in that it groups exams in terms of dose range and risks. This facilitates both physician and patient comprehension of the magnitude of the risk involved.

Although most diagnostic procedures present no 'significant' deterministic risk to the developing embryo or foetus, ICRP 103 notes that radiation therapy and interventional fluoroscopy procedures can result in foetal doses of 10–100 mGy or more [6]. At these doses the stochastic risk is not insignificant and at the higher end of this range, deterministic effects will begin to be a consideration. For procedures in this dose range, pregnancy should be ruled out prior to treatment. An individual dose and risk assessment is essential and informed consent is required. In order to get fully informed consent, an explanation of risk in terms that the patient can easily understand and use to form a judgement is essential.

1.2. Communication issues and informed consent

In their 2000 document, the ICRP stated that "thousands of pregnant patients and radiation workers are exposed to ionizing radiation each year. Lack of knowledge is responsible for great anxiety and probably unnecessary termination of many pregnancies. For many pregnancies, the exposure is appropriate, while for others the exposure may be inappropriate, placing the unborn child at an unjustified increased risk" [1] . This statement highlights two of the issues that arise in relation to the use of ionizing radiation in pregnancy. First, there is a lack of knowledge among both patients and clinicians in relation to the risks associated with ionizing radiation and, in fact, there is often an exaggerated sense of the magnitude of the risk. The failure of clinicians to understand the hazards or communicate effectively in this area heightens the anxiety that patients already experience. Second, there is a failure on the part of clinicians to properly justify exposures leading at times to inappropriate examinations.

There is ample evidence in literature that physicians are unaware of radiation risks [7–14]. The evidence would suggest that neither prescribers nor practitioners are well equipped to properly assess or advise on the radiation risks associated with even the most common diagnostic procedures. This poses additional challenges in terms of ensuring that patients are provided with adequate information. The ICRP have stated that the pregnant patient has a right to know the magnitude and type of potential radiation effects that might arise from in-utero exposure. They suggest that the extent and form of communication should be related to the level of risk. For very low dose procedures such as a chest X ray, communication that the risk is negligible is adequate but if foetal doses are higher than 1 mGy, then a more detailed explanation should be given [1]. However, if physicians are not well informed in relation to radiation doses and risks, then it is unlikely that they will be able to adequately inform their patients.

The issue of communication was highlighted in a second IAEA consultation on justification [15] which concluded that there was a need for improved communication both within professions and between professionals and patients. This is closely linked to the issue of informed consent, as adequate communication of risk is a

prerequisite for consent. Earlier IAEA consultation [2] had noted that justification must be responsive to the expressed needs and desires of a patient and is not complete until a patient consents to a procedure.

All of the issues outlined above emphasize the need for well defined protocols, appropriate referral criteria and standardized information leaflets. Without these, a standardized, harmonized approach to patient management will remain elusive.

2. LEGISLATIVE FRAMEWORK

There are provisions within European and national legislation to protect unborn children who might be irradiated as a result of parental exposure. In the protection of pregnant patients, dose limits do not apply and consideration must be given to the interests of both the mother and child. Prior to introduction of the Medical Exposure Directive (97/43/EURATOM) [16], the approach to protection had been governed by professional good practice and recommendations of relevant medical, professional and scientific organizations. With the implementation of the European Directive, protection is further enhanced and underwritten by law.

The Medical Exposure Directive has a number of requirements in relation to exposure of women of childbearing age. Article 10 of the directive places a clear responsibility on both the prescriber and practitioner to enquire whether patients of childbearing age are pregnant. It further requires that if pregnancy cannot be excluded, that special attention should be given to the justification (particularly the urgency) and optimization of the examination, taking into account the exposure of both mother and child. The Directive highlights that these considerations are particularly important if abdominal and pelvic regions are involved. In addition, the Directive imposes a stringent requirement that all individual medical exposures be justified in advance (Article 3).

The Directive also advocates measures that could contribute to increasing the awareness of women in relation to medical exposures during pregnancy [Article 10 (3)].

3. PRACTICAL APPROACHES TO MANAGING PATIENTS

The ICRP statement in 1984 that ‘there would be no risks to the conceptus following irradiation during the first 10 days of the cycle and that subsequent risks in the remainder of the first four week period would be likely so small that no special limitation on exposure was required’ [17] provides the basis for two of the practical approaches that have been used to protect patients. These are known as the 10 and 28 day rules. The 10 day rule restricts examinations involving ionizing radiation to the first ten days of the menstrual cycle. It is assumed that for women with a 28 day cycle, there is no possibility that they could be pregnant in the first ten days. For women with cycles of different lengths, the rule should be modified accordingly. The 28 day rule, also known as the missed period rule, allows medical exposures to be scheduled during the first four weeks following the start of the last menstrual period (LMP). If a period is overdue and the patient can not be certain that she is not pregnant then consideration is given to postponing the examination. The essential difference between the approaches in the 10 and 28 day rules is that in the latter, exposure of a conceptus in the second part of the cycle is possible. However, as outlined earlier, low dose exposure during the first two weeks of gestation is generally regarded as low risk.

The 28 day rule was in widespread use in the UK in the mid 1980s and early 1990s. This approach was outlined in ASP8 [18], published by the National Radiological Protection Board (NRPB) in 1985. However, in 1998, the NRPB and the Royal College of Radiologists (RCR) in the UK advocated the return to the use of the 10 day rule for high dose examinations such as barium enemas and abdominal or pelvic CT [19]. This was based on a statement from the NRPB in 1993 which concluded that while “risks from exposure during the interval between day 10 and the date at which the next menstrual period is due, although still small for most diagnostic procedures, may be significant for higher dose procedures” [20]. They estimated that a foetal dose of about 25 mGy could double the natural risk of childhood cancer to age 15 years. Based on this, the NRPB concluded that there was a need for a modified policy for high dose procedures. The procedures that concerned NRPB were those that gave rise to doses of “some tens of mGy”. In routine practice, this meant abdominal or pelvic computed tomography and barium enemas. The NRPB suggested that one way to avoid irradiation of an early foetus was to restrict these high dose procedures to the first ten days of the menstrual cycle and so a limited return to the 10 day rule ensued.

3.1. Guidance documents

There are a number of guidance documents developed by professional and scientific bodies which provide advice on the management of women of childbearing age undergoing diagnostic examinations. Guidance that has been developed specifically on this topic includes that from the HPA [4], the European Commission [21] and the American College of Radiology (ACR) [22]. Relevant information can also be found in the UK [23] and European [24] referral guidelines. All of these documents provide a useful resource in terms of both information on the health effects of ionizing radiation and also in terms of offering a practical approach to the management of these patients. While the documents are broadly in agreement in terms of the hazards presented and also have many parallels in the approaches suggested, a detailed review of the pathways proposed reveals small but material differences. These differences demonstrate a diversity in practice which illustrates subtle variations in understanding, assessment of hazard and overall approaches to management and scheduling of patients.

All of the documents include recommendations on checking pregnancy status and LMP for higher dose examinations. However, even with something as seemingly straightforward as this there are differences in the exact detail of approaches. Differences also exist in relation to the protocols recommended for low dose examinations.

There are also differences in relation to the use of pregnancy testing. Both the European [21] and the American [22] documents refer to its use to rule out pregnancy. However, neither document elaborates upon the type of test that should be used. Given the significant differences in sensitivity of the various tests available, further clarification would have been helpful. For example, point-of-care urine based tests are generally not sensitive enough to definitively rule out pregnancy in the early part of the second part of the menstrual cycle. Laboratory based tests can provide significantly improved sensitivity although at both a financial cost and increased response time. None of the available guidance documents provide adequate information on suitable testing methodologies. However, the ACR document does note that a negative test should not be interpreted as being conclusive and standard screening procedures should still be followed.

It is clear from earlier discussions that justification should take account of the wishes of the patient. All of the guidance documents, either implicitly or explicitly, acknowledge the importance of the patient in the decision making process. The European document states that the ultimate decision whether to go ahead with an examination or not rests with the mother, placing the patient firmly at the centre of the decision making process. The ACR document reflects a more paternalistic approach, stating that the ultimate judgement rests with the physician or medical physicist. However, the document does highlight the need for effective communication with the patient at all stages of the process, thus recognizing his/her central importance.

While it can be seen that there are many areas of overlap in the approaches taken in the various British, European and American guiding documents, there is no single authoritative consensus document representing best practice in managing pregnant patients. This can lead to confusion among both staff and patients, and contribute to the perception that the diversity of practice represents fundamental differences in assessment in relation to the radiobiological risk. In fact, the variations are probably due more to the complexity of dealing with this issue from a practical point of view and to the fact that the approaches are grounded in radiobiology, rather than other social or individual considerations.

3.2. Exposures involving minors

Excluding pregnancy in minors presents considerable challenges for radiology and medical staff. There are ethical and social objections to questioning on this issue. It may be difficult for staff to question a child on this issue with a parent present and it is perhaps unlikely that the question will always be answered honestly. However, many parents would be very unhappy to have such a question put to a child without their consent. The issue is further complicated by the fact that many young girls will have irregular menstrual cycles so scheduling examinations according to the 10 or 28 day rule may prove difficult.

Both the RCR [25] and the ACR [22] have provided guidance on this issue but on review, while interesting, it adds little in terms of a definite way forward. This almost certainly reflects the difficulties inherent in this issue. National or state law may provide additional guidance or a framework for questioning minors, but in the absence of explicit legislative provisions, it remains for individual paediatric institutions to develop a policy best suited to their own organization. This should be aligned with the institution's own policy on informed consent of minors for other

types of examinations and procedures and take due account of any additional legal provisions that may be relevant in this matter.

4. REVIEW OF EXISTING PRACTICE IN EUROPE

As part of the European Commission funded research project, SENTINEL, 13 European counties were surveyed to gather information on existing practice in relation to irradiation of patients and staff during pregnancy [26]. From the review it was found that practices in the 13 countries surveyed varied enormously and the study concluded that there was no harmonization at the European level. This is in spite of the fact that the European Commission had previously produced their guidance document, Radiation Protection 100 [21]. The study found that the use of the 10 day rule was applied for high dose procedures in five countries. There was considerable diversity of practice in relation to establishing pregnancy status and urine pregnancy tests were carried out in two countries for high dose procedures. In general, special attention was given to justification and optimization for patients known to be pregnant. The study also found that some European countries do not allow X rays during pregnancy unless there is a life threatening condition. The study concluded that the diversity of practice and lack of harmonization at a European level was a cause for concern and required further attention and action.

5. CONCLUSIONS

It can be concluded from literature that there is a general lack of knowledge among clinicians in relation to radiation risks and dose arising as a result of diagnostic radiology procedures. It is reasonable to conclude that this knowledge deficit extends to risks during pregnancy. This lack of understanding among physicians in general undermines their ability to understand and communicate risks to their patients. Without adequate communication of risk, it is questionable whether informed consent can be obtained. Standardized information for patients in a form that they can easily comprehend would assist in the task of risk communication and should be developed and made available.

It is also clear that there is little harmonization of practice at the European level. This is unsurprising when one considers that available guidance documents show variations in approach and subtle differences in relation to dealing with patients who are or might be pregnant. While the legal requirement to establish pregnancy status ensures some level of consistency in approach, the lack of a precise definition as to when that requirement is ‘relevant’ gives rise to differences in interpretation and approach. Electronic request systems can assist in ensuring adherence to protocol and can be useful, as they can be linked to standardized referral criteria, thus ensuring an appropriate patient pathway is selected to answer the diagnostic question posed.

Excluding pregnancy in minors presents particular challenges for clinical staff. Clear authoritative advice in relation to dealing with the questions of minors in relation to pregnancy status is needed. However, for each institution this should be framed to take due account of local cultural, social and ethical considerations.

All medical exposures of women of child-bearing age must be justified in advance. Medical needs must be balanced against risk, the judgement of which should not rely solely on numerical calculations but should take account of the individual involved. An effective justification process requires the use of appropriate referral criteria and a complete understanding of the inherent radiation risks, coupled with an ability to communicate these risks to the patient in a manner that facilitates informed consent. Without this, the involvement of the patient, which is essential to the process, can not be assured.

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UNJUSTIFIED CT EXAMINATIONS IN YOUNG PATIENTS

H. OIKARINEN
Department of Diagnostic Radiology,
Oulu University Hospital,
Oulu, Finland
Email: helja.oikarinen@ppshp.fi

Abstract

This report will mainly concentrate on the retrospective study of justification of computed tomography (CT) examinations done in the Department of Diagnostic Radiology of Oulu University Hospital, Oulu, Finland. The study was started as an audit of CTs done on patients under the age of 35 years in 2005. The audit finally became an article in European Radiology in 2009 [1]. The following text also includes information about the new interventions undertaken in our hospital after the study and about follow-up regarding justification. Finally, there is a discussion on the justification of radiological examinations in children.

1. THE STUDY REGARDING JUSTIFICATION

1.1. Introduction

Shortly after publication of the European Commission's directive 97/43/EURATOM, justification was considered to be the challenge of the decade, with large implications for prescribers, practitioners and their training. Ten years later, it has been speculated that the process of justification is sometimes weak or even non-existent.

Radiation doses from CT examinations are among the highest in diagnostic radiology, yet CT is being increasingly utilized. According to referral criteria for imaging recommended by the European Commission, imaging methods without ionizing radiation, such as ultrasound (US) and magnetic resonance imaging (MRI), or methods with low dose radiation should be considered whenever justified. Particular attention should be paid to young patients, since the radiation induced lifetime risk of cancer mortality is higher from younger ages until approximately 35 years of age.

The aim of our study was to determine whether previous CT examinations conducted at our university hospital on patients under the age of 35 years had been justified, and if not, whether other, more justifiable imaging modalities had been available, or if any modality at all was needed.

1.2. Materials and methods

Altogether, 148 988 examinations were performed in the Department of Diagnostic Radiology of Oulu University Hospital, Oulu, Finland, in 2005. Of these examinations, 16 975 (11%) were done using CT, and 2367 (14%) of the CT examinations were done on patients under the age of 35 years. CT examinations were mainly done on the head, thorax or lungs, lumbar (and sacral) spine, abdomen or upper abdomen, trauma, cervical spine, nasal sinuses and body (thorax and abdomen) (Table 1).

The examinations analysed in this study were CTs of the head (50 patients), lumbar (and sacral) spine (30), abdomen or upper abdomen (30), trauma (30), cervical spine (30) and nasal sinuses (30) (Table 1). The final study thus included 200 examinations. Images falling into these categories were extracted from the electronic patient files of our hospital consecutively from the beginning of the year 2005. CTs of the thorax or lungs and body were excluded from the study because there is no good alternative for these examinations.

Patient files, clinicians' referrals and indications of the examinations were analysed by a specialist in radiology with good experience. Using that information and the referral criteria for imaging recommended by the European Commission, it was determined whether the examinations had been justified, and if not, whether some other, more justifiable imaging modalities would have been available. After that, other specialists in radiology went through the information collected and expressed their opinion; if necessary, consensus was used.

TABLE 1. DISTRIBUTION OF CT EXAMINATONS ANALYSED

CT examinations (in 2005, < 35 years)	Number of CT examinations N	CT examinations analysed N
Head	1063	50
Thorax or lungs	241	
Lumbar spine	130	30
Abdomen	123	30
Trauma	117	30
Cervical spine	110	30
Nasal sinuses	100	30
Body	80	
Other	403	
Total	2367	200

TABLE 2. UNJUSTIFIED EXAMINATIONS AND POSSIBILITY OF USING OTHER MODALITIES

CT examination	Unjustified/All	Possibility of other modalities to replace CT			
		MRI	US	Fluoroscopy	No. of examinations needed
Lumbar spine	23/30 (77%)	20			3
Abdomen	11/30 (37%)	5	4	1	1
Head	18/50 (36%)	18			
Nasal sinuses	6/30 (20%)	5			1
Cervical spine	1/30				1
Trauma	0/30				
Total	59/200 (28%)	48	4	1	6

1.3. Results

Twenty eight per cent of all the 200 examinations evaluated were not justified (Table 2). Twenty three of the 30 CT examinations of the lumbar spine (77%) were considered not justified. Twenty cases could have been replaced by MRI, and three patients would not have required any radiological examination (Table 2). Symptoms of disk syndrome, suspicion of spinal stenosis and control of spinal lymphoma in young patients may indicate MRI. Trauma and control of fixation indicate CT.

Eighteen of the 50 CT examinations of the head (36%) were not justified. All of them could have been replaced by MRI. MRI should have been performed in elective cases. CT is indicated in trauma or some other acute cases, such as suspicion of intracranial bleeding or acute stroke.

CT was not justified in 11 of the 30 CT examinations of the abdomen or upper abdomen (37%). Five of the cases could have been replaced by MRI, four by US and one by fluoroscopy. One patient would not have needed any radiological examination. Two patients had unspecific hepatic lesions at US, which should have indicated MRI instead of CT. Other patients in this group were so variable that no classification could be made; the analysis had to be done on a case-by-case basis.

Six of the 30 CT examinations of the nasal sinuses (20%) were not justified. Five of them could have been replaced by MRI, while one would not have needed any other examination but CT of the head. CT was considered to be justified especially if operation of the sinuses was being planned, since there is a need for accurate delineation of the bony structures for functional endoscopic sinus surgery (FESS). However, five of the unjustified cases also had rhinitis or sinusitis, but there was no information about plans to operate in the referral.

Only one of the 30 CT examinations of the cervical spine was not justified. The patient would not have needed any CT examination of the cervical spine in addition to the one done on the lumbar spine. Other cases were traumas and a control of fixation, which indicated CT. All the 30 CT examinations of trauma were justified because they were high energy traumas.

2. NEW INTERVENTIONS

After we found that a high percentage of the CT examinations undertaken on young patients had not been justified, we wanted to change our practice through various interventions. The interventions were mostly introduced in 2006–2007.

We provided education for the staff of the department of radiology, other personnel working with ionizing radiation in our area and the referring practitioners in our hospital. The education consisted of the risks and doses of radiation, indications of different examinations, the process of justification and legislation on radiation protection. Through videoconferences the radiology staff in other hospitals in Northern Finland could also be reached. We also provided info cards containing information on radiation and justification to referring practitioners in the Oulu area and to people working with radiation in our hospital, and the cards will be handed out to medical students every year.

The referral criteria for imaging recommended by the European Commission were distributed in the different areas to the departments of radiology. We also made some new recommendations for the use of CT for the referring practitioners and radiologists of our hospital:

(1) MRI is the primary examination of the head. CT examination is only indicated in acute cases;
(2) MRI is usually the primary examination of the lumbar spine in young patients;
(3) Clinicians are recommended to consult a radiologist before sending a request form for abdominal CT in the case of a young patient.

A new recommendation for the use of conventional X rays of the spine was created at the same time, as we also had an audit showing unjustified X rays of the spine.

Our CT study revealed that most of the unjustified cases could have been replaced by MRI. A shortage of MRI capacity may have partly contributed to the poor results of justification. We addressed this by purchasing a new MR system. We also discussed the project at a Finnish conference and at ECR in Vienna, and published an article in the Finnish Medical Journal and European Radiology.

3. FOLLOW-UP

After introducing the interventions, we have followed up justification in our hospital, especially in the area of the lumbar spine. There has been a decreasing number of lumbar spine examinations (both CT and conventional X ray) in patients under the age of 35 years (Table 3). The number of conventional X rays of the spine in all age groups has also decreased.

The justification of CT and conventional X rays of the lumbar spine in patients under the age of 35 years has improved year by year in different wards of our department (Table 4).

The ratio of examinations with and without ionizing radiation also improved in our department in the follow-up (Table 5).

TABLE 3. LUMBAR SPINE EXAMINATIONS FOLLOWING INTERVENTIONS

	2005	2006	2007	2008
CT	132	91	37	38
X ray	485	418	345	342

TABLE 4. UNJUSTIFIED LUMBAR SPINE EXAMINATIONS FOLLOWING INTERVENTONS

	2005 Unjustified	2007 Unjustified*	2008 Unjustified*
CT	77%	2/4** 11/19** (58%)	2/4** 5/20 (25%)
X ray	3/11 (audit)	20% 20% 65%	5% 10% 2/16** (13%)

* In different wards of the department.

** Less than 20 patients were included in the audit.

TABLE 5. EXAMINATIONS WITH:WITHOUT IONIZING RADIATION SINCE 2005

	2005 %	2006 %	2007 %	2008 %
Ratio	77:23	76:24	74:26	74:26

4. DISCUSSION

It is estimated that about 50% of the global collective radiation dose is caused by CT, due to its relatively high doses of radiation. There were about 3.9 million medical X ray examinations performed in Finland in 2005. About 7% were CT scans, and there were 30% more CT examinations in Finland in 2005 compared to 2000. At Oulu University Hospital, there were 19% more CT examinations in 2005 compared to 2000. It has been assumed that although the risk of radiological examination to a single individual is small, the exposed global population is large and increasing, which may result in significant long term public health problems. It is therefore important to have good indications for CT and to utilize US or MRI or examinations with lower doses whenever possible.

The utilization of radiology is accepted as part of medicine, especially after careful justification. Despite the rules and recommendations defined in the legislation on medical radiation, suspicions of inappropriate use of radiological examinations and less selective use of diagnostic CT have been reported. Some paediatric radiologists have estimated that about one-third of CT examinations are unnecessary. With the help of the retrospective analysis we wanted to find out whether the number of CT examinations undertaken on young patients could have been reduced with better justification. For the analysis, we chose CT examinations that could be replaced by other investigations, including those not involving any radiation.

Most of the unjustified examinations, 77%, appeared to fall into the group of lumbar CT. The dose of radiation from lumbar CT is about 170 times the level of a thorax PA X ray. Most of these unjustified cases could have been replaced by MRI. Thirty-seven per cent of the cases in the group of abdominal CT were unjustified. The dose of radiation from abdominal CT examination is about 500 times that of a single thorax PA X ray. Five of the unjustified cases could have been replaced by MRI, four by US and one by fluoroscopy. Thirty-six per cent of the cranial CT studies were deemed unjustified. All these 18 examinations should have been replaced by MRI. The dose of radiation from CT of the head is also about 115 times that of a thorax PA X ray. There were fewer

unjustified cases in the group of CT examinations of the nasal sinuses or the cervical spine, and all cases in the trauma group were justified.

To our knowledge, there are only a few other studies about the justification of examinations using radiation. In 2001, Clarke et al. reported about the possibility of MRI to replace many types of CT examinations. This team had more patients and sub-groups than we did, and more than 70% of the CT examinations could have been replaced by MRI; of the examinations of the head and the lumbar spine, more than 90% could have been replaced by MRI [2]. In another report concerning CT examinations of the abdomen, pelvis and lumbar spine, it was often recommended that the last of these be replaced by MRI [3]. One study reports a 60% justification rate of CT examinations according to request forms; in particular, US could have been useful as a preceding or alternative investigation [4]. According to the Swedish national survey on justification of CT examinations, approximately 20% of all examinations were not justified. The degree of justification varied strongly with the organ examined, moderately with prescriber affiliation and weakly with geographical region [5].

Based on the results of our study, we wanted to change our practice by introducing new interventions. It is known that awareness of radiation is often deficient and that radiation risks are frequently underestimated. We provided education and an info card containing information on radiation and justification to the staff of the department of radiology, other personnel working with ionizing radiation in our area and referring practitioners.

Regular use of referral guidelines can also lead to a reduction in the number of request forms and ultimately to a reduction in patient exposure to ionizing radiation. The referral criteria for imaging recommended by the European Commission were distributed to different areas of the department of radiology. We also made some new recommendations for the use of CT for the referring practitioners and radiologists of our hospital.

Our study revealed that most of the unjustified cases could have been replaced by MRI. Because a shortage of MRI capacity may have in part contributed to the poor results, we addressed this by purchasing a new MR system. In order to give other centres an opportunity to make use of our conclusions and interventions, we presented the project at a Finnish conference and at ECR in Vienna, and published a paper in Finnish Medical Journal and in European Radiology.

The follow-up has so far mainly concentrated on the justification of examinations of the lumbar spine, as the justification was poorest in that area. The number of lumbar spine examinations (both CTs and conventional X rays) has decreased in patients under the age of 35 years, as has the number of conventional X rays of the spine in all age groups. The justification of CTs and X rays of the lumbar spine in patients under the age of 35 years has also improved. The ratio of examinations with and without ionizing radiation improved in the hospital as well during the follow-up.

We expect that in the future, greater awareness of justification in other areas of imaging will be achieved by both the personnel working in the area of radiology and referring practitioners. We also hope that the project will have an impact on other hospitals and health care centres in Northern Finland, other units in Finland, and other countries.

The attitude of referring practitioners towards our audits and new interventions has mainly been positive. When necessary, there has been cooperative discussion about individual patients between radiologists and practitioners.

In the near future, we plan to follow up indications for CT examinations. We also plan to make a control study of the justification of various CT examinations in patients under the age of 35 years.

In conclusion, justification of CT examinations in young patients seemed to be inadequate. However, justification could be improved by interventions — education, use of referral guidelines and increased MRI capacity. The main goal of the whole project has been radiation protection of both individuals and the population, and the results have been promising.

5. JUSTIFICATION IN CHILDREN

Ionizing radiation always increases the statistical risk of cancer mortality. The risk is higher at younger age because the expected lifetime is longer than at older age. Division of the cells is also fast and the organs are particularly sensitive to radiation at a younger age.

In our study, 21 out of the 200, or 11% of patients were children (15 years old or less). There were three unjustified cases in this group (3/21, 14%).

To my knowledge, there are only a few published audits of justification of radiological examinations in children. The Swedish national survey on justification of CT examinations reported that the degree of justification is lower for younger patients. However, the total number of paediatric examinations was small [5]. There has also been an audit of CT for the evaluation of mild to moderate paediatric trauma. Paediatric patients had significantly more CT scans than adults, mostly because of a more liberal use of abdominal CT. CT scans of multiple body areas on the same patient were also used more frequently in children but failed to identify more injuries when compared to adults [6]. On the other hand, another study reports of too few CT scans in minor head injuries in a study group of adults and children in a district general hospital [7]. According to a fourth publication, the implementation of guidelines that are acceptable to all specialities will reduce unnecessary skull radiographs following paediatric head trauma [8].

According to personal communication with the heads of paediatric radiology at Finnish university hospitals, referrals for paediatric CT seem to be carefully controlled today at university hospitals in Finland. However, because of the small number of published audits of justification in children, no conclusions can be made. In order to know the actual level of justification in children, this issue should be systematically evaluated in the near future, both in different countries and in different types of hospitals.

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IS MAMMOGRAPHY AND POPULATION HEALTH SCREENING USING RADIATION JUSTIFIED?

K. FAULKNER
Quality Assurance Reference Centre,
NHS North East,
Wallsend, United Kingdom
Email: keith.faulkner@nhs.net

Abstract

Population screening is an established approach in public health. Before a population health screening programme using ionizing radiation is introduced it must be justified in both public health and radiation protection terms. The International Commission on Radiological Protection has recognized that, in radiation protection terms, a population screening programme must be justified on both an individual and population basis. The main radiation protection issue is that the screening programme delivers more benefit than the risk associated with the use of ionizing radiation. This view is reflected in the International Basic Safety Standards and the European Union's Medical Exposures Directive. In this paper, the justification of a breast cancer screening programme is contrasted with the use of computed tomography scanning for lung cancer screening. Ethical concerns regarding the use of the latter technique will be raised, as well as potential implications for the process of justification of medical exposures in general.

1. INTRODUCTION

The public health benefits of various population screening programmes are widely recognized. Various health programmes have been introduced including ante-natal, breast cancer, bowel cancer and cervical cancer screening. Only breast cancer screening using X ray mammography uses ionizing radiation as the primary screening test. The benefits of breast cancer screening have also been recognized at a European level, as there is a council recommendation for Member States to establish an organized programme [1]. In the United Kingdom's Breast Cancer Screening programme, operated as part of the National Health Service, women between the ages of 47 and 73 are invited at 3-year intervals.

Before a population based health screening programme such as breast cancer screening which uses ionizing radiation is introduced, it must be justified in both public health and radiation protection terms [2, 3]. Fundamentally, this means that the population screening programme must produce more benefit than harm.

In this paper, the public health justification process will be described. In addition, the process of justification in radiation protection terms of population screening using ionizing radiation will be outlined by using evidence from the breast cancer screening programme. Finally, the process of justification of breast cancer screening using X ray mammography will be compared with lung cancer screening using computed tomography scanning, which is offered by some private clinics.

2. JUSTIFICATION IN PUBLIC HEALTH TERMS

Screening is a public health intervention within a population to detect unrecognized disease. The key principles of health screening were defined by Wilson and Jungner [4, 5] and cited in the Forrest Report [5].

The key principles are:

(1) The disease should pose an important public health problem;
(2) The natural history of the disease should be well understood;
(3) There should be a recognizable early stage;
(4) Treatment of the disease at an early stage should be of more benefit than treatment started at a later stage;
(5) There should be a suitable test;
(6) The test should be acceptable to the population;
(7) There should be adequate facilities for the diagnosis and treatment of the abnormalities detected;

(8) For diseases of an insidious onset, screening should be repeated at intervals determined by the natural history of disease;
(9) The chance of physical or psychological harm to those being screened should be less than the chance of benefit;
(10) The cost of a screening programme should be balanced against the benefit it produces.

These points were all considered before the UK breast screening programme was introduced in 1986. More recently, the International Agency for Research on Cancer (IARC) has confirmed the benefits of breast screening and has concluded that mammography screening reduced mortality from breast cancer. IARC estimated that there is a 35% reduction in mortality amongst screened women aged 50–69 years old [6].

3. JUSTIFICATION IN RADIATION PROTECTION TERMS

Justification is a well-established principle of radiation protection and is included in the last two sets of recommendations of the International Commission on Radiological Protection (ICRP) [7, 8]. In basic terms, justification means doing more good than harm.

The International Atomic Energy Agency (IAEA) defines justification as: “Medical exposures should be justified by weighing the diagnostic or therapeutic benefits they produce against the radiation detriment they might cause”. In relation to population screening, the International Basic Safety Standards [9] state: “Mass screening of population groups involving medical exposure is deemed to be not justified unless the expected advantages for the individuals examined or for the population as a whole are sufficient to compensate for the economic and social costs, including the radiation detriment. Account should be taken in justification of the potential of the screening procedure for detecting disease, the likelihood of effective treatment of cases detected and, for certain diseases, the advantages to the community from the control of the disease.”

In the Medical Exposures Directive (MED) [10], justification of medical exposures “shall show a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefits it produces, including the direct health benefits to an individual and the benefits to society, against the individual detriment that the exposure might cause, taking into account the efficacy, benefits and risks of alternative techniques having the same objective but involving no or less exposure to ionizing radiation”. The MED [10] requires that “all individual medical exposures shall be justified in advance, taking into account the specific objectives of the exposure and the characteristics of the individual involved.” It also requires special attention where there is no direct health benefit for the person undergoing the exposure. Moreover, the MED states that if an exposure cannot be justified, it should be prohibited.

Consequently, the use of ionizing radiation as part of a health screening programme should be justified on both an individual and population basis. Both the International Basic Safety Standards [9] and the Medical Exposures Directive [10] require justification to be for both the individual and the population. When considering justification, economic and social costs should be considered as well as the benefit the individual or screened population may derive from the screening programme.

4. JUSTIFICATION OF BREAST CANCER SCREENING USING MAMMOGRAPHY

One approach to the justification of breast cancer screening in radiation protection terms is to estimate the benefit/risk ratio. A simple approach to this process is to consider the benefit of screening to be the number of breast cancers detected. Data on breast cancer detection rates for the UK breast screening programme are collated on a national basis and published by the Department of Health.

Risk may be considered to be the number of breast cancers induced by the use of X ray mammography. Induced breast cancers may be estimated from the mean glandular dose to a typical woman attending the breast screening programme by multiplying this value with an age specific risk factor for the induction of breast cancer using ionizing radiation.

Preston et al. [11] have reviewed the evidence for breast cancer induction using ionizing radiation. In their review paper they considered eight cohorts of women who had been irradiated. In their pooled analysis they investigated the application of the excess relative risk and excess absolute risk models to the data. Law et al. [2]

have calculated breast cancer radiation risk factors using both models specific to the UK population. These risk factors take into account a 10 year delay between exposure and any induced breast cancer. Where applicable, the underlying breast cancer incidence to the UK population has been used. A correction factor for other causes of death has been applied using data obtained from life tables applicable to the UK population.

Estimated detection/induction ratios are provided in Table 1 for women aged 50–70 years, assuming two view screening at three year intervals [2]. It may be deduced from Table 1 that the cancer detection/induction ratio is large for women of all ages irrespective of which radiation risk model is applied. The benefit risk ratio is always higher for a particular age band for the excess absolute risk model. The cancer detection/induction ratio is very age dependent being higher for older women due to a combination of the higher breast cancer incidence and the radiation risk factor being lower for older women due to reduced life expectancy.

An alternative approach to estimating the benefit/risk ratio is to consider the improvement in mortality due to breast cancer screening. Of the breast cancer detected by screening, a percentage (A%) will survive five years. If the cancer is not detected by the breast screening programme, then it would be detected by the symptomatic service, which would have a five year survival of B%. An estimate of the improvement in mortality achieved by the screening programme is the number of cancers detected multiplied by the improvement in mortality (i.e. A-B%). This is one estimate of the lives saved by screening.

The number of fatal cancers induced by breast cancer screening may be deduced from the number of induced breast cancer cases by allowing for survival. It may be assumed that most women with radiation induced breast cancer are likely to have their breast cancer detected by the symptomatic service, with a five year survival of B%. Hence the number of fatal cancers at five years is deduced by the dose multiplied by the risk factor and the percentage mortality (M%). It is given by;

$$M = 100\ B$$

Data on the five year relative survival of women with breast cancer detected in 2001–2002 by the screening programme has just been published by the NHS Cancer Screening Programmes and is 97.4% [12]. The five year relative survival for women in the symptomatic service is 77.6% [12].

It is possible to convert the data in Table 1 to benefit/risk ratios in terms of lives saved by breast cancer screening to fatal cancers induced by multiplying the values in Table 1 by a correction factor C which takes into account the improvement in mortality resulting from breast screening and the number of fatal cancers induced.

The factor C is given by;

$$C = \frac{A - B}{100 - B}$$

In the United Kingdom, the five year relative survival for screening detected and symptomatic breast cancer may be used to provide a value for C, which is 0.88.

TABLE 1. ESTIMATED BENEFIT/RISK RATIO FOR BREAST CANCER SCREENING IN TERMS OF CANCERS DETECTED TO CANCERS INDUCED, ASSUMING TWO VIEW SCREENING AT THREE YEAR INTERVALS [2]

Age at exposure (years)	Model [11]	
	Excess absolute risk	Excess relative risk
50–54	240	87
55–59	445	135
60–64	950	220
65–70	2200	315

Values for the benefit/risk ratio in terms of cancer saved by screening at five years to the number of fatal cancers induced are provided in Table 2. If however, the induced breast cancers are detected by the screening programme, then the conversion factor C will change. One approach to estimating the number of fatal breast cancers induced by breast screening is to take an average five year survival for all invasive cancers irrespective of whether they were screen detected or not. The five year relative survival for all invasive cancers in the UK is 82.0% [12] making the correction factor 1.1.

5. DISCUSSION

Breast cancer screening using X ray mammography as the initial screening technique is justified on both a public health and a radiation protection basis. In public health terms it fits the criteria for a population screening programme [4] and it is estimated to reduce mortality in screened women aged 50–69 by 35% [6]. In radiation protection terms, the breast screening programme is also justified, as the benefit exceeds the risks by a large degree, irrespective of the definition of benefit and risk and the choice of radiation risk projection model used. The justification of breast cancer screening may be compared and contrasted with that of lung cancer screening.

Lung cancer screening using CT scanning has been proposed by some as a population health screening programme. The National Cancer Institute in the USA is conducting a large scale study to discover if the use of spiral CT or chest X rays as a screening tool can reduce deaths [13]; the results are awaited with interest. While CT scanning can detect early tumours it has not been proven to reduce the likelihood of dying from lung cancer. One of

TABLE 2. BENEFIT/RISK RATIO FOR BREAST CANCER SCREENING IN TERMS OF LIVES SAVED AT FIVE YEARS POST SCREENING TO FATAL CANCERS INDUCED, ASSUMING TWO VIEW SCREENING AT THREE YEAR INTERVALS AND THAT INDUCED CANCERS ARE DETECTED IN THE SYMPTOMATIC SERVICE

Age at exposure (years)	Model [11]	
	Excess absolute risk	Excess relative risk
50–54	212	77
55–59	393	119
60–64	840	194
65–70	1945	278

TABLE 3. BENEFIT/RISK RATIO FOR BREAST CANCER SCREENING IN TERMS OF LIVES SAVED AT FIVE YEARS POST SCREENING TO FATAL CANCERS INDUCED, ASSUMING TWO VIEW SCREENING AT THREE YEAR INTERVALS AND THAT INDUCED CANCERS HAVE THE SAME SURVIVAL RATE AS ALL INVASIVE CANCERS IN THE UK *(i.e. an average across the breast screening and symptomatic screening services)*

Age at exposure (years)	Model [11]	
	Excess absolute risk	Excess relative risk
50–54	264	96
55–59	490	149
60–64	1045	242
65–70	2420	347

the problems with the use of CT scanning for lung cancer in smokers or former smokers, is that 25–60% of examinations reveal abnormalities which are not cancer [13]. Despite these reservations about the use of CT scanning for lung cancer, a number of private clinics are offering these examinations [14]. It is even possible to exchange points from the UK's largest supermarket loyalty card for a reduction in the price of a private CT scan [15] which has stimulated a debate about CT scanning in the media. Lifescan, the private provide, offers a lung check which includes a CT lung scan for £215. This is aimed at people over 40 who have either smoked in the past or been exposed to secondary smoke at home or work, or who have worked with asbestos and hazardous chemicals [16]. Lifescan stresses the importance of detection. Lifescan also offers other types of CT scan as part of a range of health checks. The website describes the benefits of CT scanning for lung cancer but fails to mention the risk. Typical effective doses for CT lung scans are in the range of 6.0–9.0 mSv, with a mean of 7.1 [17], a significant dose of radiation when compared with natural background radiation. It is interesting to reflect on the application of the justification process given the effective dose levels for CT lung scans and the absence of results from the National Cancer Institute's trial [13].

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CONCLUSIONS AND RECOMMENDATIONS

(Session 6)

Chairperson

R. CZARWINSKI
IAEA

Rapporteur

K. FAULKNER
United Kingdom

CLOSING REMARKS

D. Ristori
Deputy Director General,
Directorate General for Energy and Transport
European Commission,
Brussels
Email: dominique.ristori@ec.europa.eu

Ladies and Gentlemen,

I am very delighted to be with you this afternoon on the occasion of the closing session of this very interesting seminar. First of all, I would like to express my thanks to all organizations involved in the preparation and conduct of this meeting and especially to the International Atomic Energy Agency, in particular Ms. Renate Czarwinski, and also to our services in the European Commission in charge of this matter, under the responsibility of Mr. A. Janssens, the Head of the Unit for Radiation Protection.

I would like to present to you some comments regarding the global nuclear context and then, more specifically, regarding medical exposure.

Today the world is going through important changes in the use of nuclear energy and ionizing radiation. We see more and more a new interest in the development of nuclear energy everywhere in the world, including in the European Union — this is the case not only in France or Finland but also today in the United Kingdom, in Italy, in Sweden and in the great majority of the new Member States from Central and Eastern Europe. We also note the rapid developments regarding the use of ionizing radiation in medicine. All these changes have the potential to contribute to a better life for European citizens, providing a cleaner environment, sustainable economic development and improved health care.

However, developments in the nuclear arena also create safety and non-proliferation challenges that need to be tackled on national, regional and international levels. We have seen in the context of the last G8 summit new proposals, in particular the proposal from the new President of the United States of America to organize a Global Summit on nuclear security in Washington in April next year. We will also have in 2010, in the context of the United Nations, a review of the Non-Proliferation Treaty. And we, as Europeans, have a special responsibility because we have the largest number of nuclear power plants (over 140 in operation today), and we have the lead on more advanced technologies regarding modern reactors, but also on the nuclear enrichment process and on reprocessing.

In this context, it was possible in the last couple of years, first of all, to elaborate a new Directive on Nuclear Safety, adopted at the end of June this year under the Czech presidency and, importantly, with the full support of the 27 Member States and a very large majority at the European Parliament. For the first time we will introduce legally binding provisions regarding nuclear safety in Europe. We will give legal force to the main international standard, that of the Safety Fundamentals of the International Atomic Energy Agency, and also to the obligations of the International Convention on Nuclear Safety. We will also strongly reinforce the independence and resources of the national regulatory authorities. This will be important not only for us, as Europeans, but also in order to provide a good example for the rest of the world.

We have also decided to present to the Council and the Parliament a new Communication on non-proliferation. This is extremely important, particularly in the context I mentioned before regarding the preparation of the Global Summit on Nuclear Security. There we will have a common responsibility to facilitate a new common position regarding those countries not respecting key provisions of the Non-Proliferation Treaty and refusing access of the International Atomic Energy Agency inspectors to some nuclear plants. We will also have to work out a position on those parties deciding to leave the Non-Proliferation Treaty, as was the case with the Democratic People's Republic of North Korea. Accordingly, I think that now there is a new clear understanding at the top level in many countries — in particular in the United States of America and in Europe but also in Japan, China and the Russian Federation — regarding the need to increase strongly international cooperation in this sector.

We will develop cooperation with our partners including, as a first priority, the signing of bilateral agreements with the Russian Federation, Australia, Canada and all our other key partners.

We also take part in the revision of the International Basic Safety Standards for radiation protection, in which the European Commission envisages becoming a cosponsoring organization. We are in parallel working on the update of the EURATOM radiation protection legislation with the aim of ensuring coherence with international standards; the Commission proposal for revising and recasting the EURATOM Basic Safety Standards should be finalized by the end of 2010.

The European Union is at this moment in a process of important transition from the current Commission to the new one. President Barroso just presented his views regarding the priorities of the Commission for the next five years. The new Commission could take office at the beginning of next year. Also, after the Irish referendum planned for 2nd of October, we could have the new treaty coming into force and providing us with more possibilities to act, including in the field of energy.

Ladies and Gentlemen,

Be assured that nuclear energy, including radiation medicine, will remain at the top of our priorities — because of the importance of public health as well as our global quality of life.

As it was clearly indicated during the IAEA General Conference in Vienna in September last year, medical applications of ionizing radiation have gone through a revolutionary development over the past decade. Today, every year, throughout the world, ionizing radiation is used in four billion diagnostic procedures, in thirty five million nuclear medicine procedures and in eight million radiotherapy treatment courses, and it keeps expanding, affecting a growing portion of the global population.

Development in this area, which as a whole is very positive, has also caused several challenges, from the prevention of accidents in radiotherapy through the training of medical personnel, to avoiding the overuse of radiological equipment. Especially impressive are the figures on justification of medical radiological procedures, where there are indications that, in economically developed countries more than 20% of examinations may not be appropriate; this can be as high as 45% in special cases and up to 75% for some specific techniques.

In view of this situation, the International Atomic Energy Agency initiative to launch these series of meetings on justification regarding medical exposure in diagnostic imaging is extremely important. In this context, the European Commission is very pleased not only to host today the present workshop but also to decide to consider this matter is a priority. I am confident that on the basis of your work and conclusions, we will have a better basis for developing a real strategy in order to improve justification in practice and, if necessary, to improve regulation and accountability.

Ladies and Gentlemen,

This workshop is only one of the areas of cooperation between the European Commission and the international organizations. I would like to stress the importance of our present collaboration with the Agency in Vienna and the need for enhanced cooperation in other areas, including non-proliferation, safeguards, nuclear safety and radiation protection. In this context, the first meeting organized here, in Brussels last year, between Commission President Barroso and the Director General of the International Atomic Energy Agency Dr. El Baradei, was extremely important in order to open new doors of cooperation.

We will now carefully examine the conclusions of this seminar and we will take, at the right time, the necessary initiatives in order to support our new actions.

Let me conclude by once again thanking all those who actively participated and contributed to this meeting and I wish all participants a fruitful future cooperation for the good of the public.

Thank you very much.

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LIST OF PARTICIPANTS

AUSTRALIA
Wallace, A.

AUSTRIA
Deutschmann, M.
Ditto, M.

BELGIUM
Eggermont, G.
Engels, H.
Jamar, F.
Malchair, F.
Mol, H.
Pringot, H.
Smeesters, P.
Van Bladel, L.
Vanhavere, F.

BRAZIL
Dias, S.K.

BULGARIA
Dimov, A.
Vassileva, Z.

CANADA
Chen, J.
Mayo, J.

CZECH REPUBLIC
Novak, L.
Zachariasova, I.

DENMARK
Waltenburg, H.

FINLAND
Järvinen, H.
Kettunen, E.
Oikarinen, H.

FRANCE
Durand-Zalenski, I.
Kiffel, T.
Tirmarche, M.

GERMANY
Akbarian, G.S.
Griebel, J.
Regulla, D.

GHANA
Inkoom, S.

GREECE
Balougias, C.
Dimitriou, P.

HAITI
Michel, G.

HUNGARY
Pellet, S.

INDIA
Guleria, R.
Srivastava, A.

IRAN, ISLAMIC REPUBLIC OF
Seifi, K.S.

IRAQ
Al-Khalissi, M.M.J.A.

IRELAND
Butler, M.-L.
Craven, C.
Dempsey, E.
Lowe, J.
McCoubrey, B.
O'Reilly, G.
Sia, S.

ISRAEL
Kravel, A.
Shelly, E.
Vaknin, S.

ITALY
Picano, E.

JAPAN
Ban, N.
Ono, K.

KENYA
Shadrack, A.

KOREA, REPUBLIC OF
Jung, H.
Lee, C.

LITHUANIA
Ziliukas, J.

MALTA
Bhikha, T.
Gruppetta, E.
Samuel, A.

MEXICO
Delgado, J.L.

MONACO
Bondouy, M.
Serrano, B.

NETHERLANDS
Van de Wiel, A.
Zuur, C.

NORWAY
Friberg, E.
Widmark, A.

OMAN
Al-Tai, S.

PERU
Bussalleu, A.

POLAND
Dabrowska, A.
Kluszczynski, D.

ROMANIA
Neamtu, D.

SLOVAKIA
Adamek, P.
Ragan, P.

SLOVENIA
Tomše, P.

SPAIN
Pedraza, S.

SWEDEN
Leitz, W.

SWITZERLAND
Theiler, T.

TANZANIA, UNITED REPUBLIC OF
Mrema, G.

UNITED KINGDOM
Chell, I.
Corbett, R.
Ebdon-Jackson, S.
Faulkner, K.
Horner, K.
Horton, P.W.
Remedios, D.

UNITED STATES OF AMERICA
Hendee, W.R.

EUROPEAN COMMISSION
Baranczyk, R.
Janssens, A.
Jouve, A.
Ristori, D.
Simeonov, G.
Walerius, H.

EUROPEAN SOCIETY OF RADIOLOGY
Vock, P.

EUROPEAN FEDERATION OF RADIOGRAPHER SOCIETIES
Paulo, G.

INTERNATIONAL ATOMIC ENERGY AGENCY
Amaral, E.
Chhem, R.
Czarwinski, R.
Holmberg, O.
Malone, J.
Rickwood, P.

INTERNATIONAL ORGANIZATION FOR MEDICAL PHYSICS
Vaño, E.

WORLD HEALTH ORGANIZATION
Dora, C.
Gamhewage, G.
Hendaoui, L.
Neira, M.
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