

## NEW ETHICAL ISSUES FOR RADIATION PROTECTION IN DIAGNOSTIC RADIOLOGY

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The ethical basis for many medical practices has been challenged over the last two decades. Radiology has seen enormous growth during the same period. Many practices and equipment types, now commonplace, did not exist a generation ago. Yet the fundamental ethical basis for these practices has not seen a corresponding level of development. This is possibly an oversight, and may be particularly important given that these innovations have taken place over a period of changing social attitudes. Areas of concern include, for example, issues around justification, consent/authorisation, inadvertent irradiation of the foetus/embryo during pregnancy and the place of paternalism/individual autonomy in the structure of practice. This paper provides the background to a workshop on these issues held in late-2006 and presents a summary of its findings.

### INTRODUCTION

The ethical basis for many medical practices is being challenged. This is possibly most evident in events leading to public controversy, such as those related to the infant organ retention scandals, concerns about the sourcing and use of blood products, self-regulation of medical practice in the wake of the Harold Shipman Enquiry in the UK, problematic clinical trials and many other happenings of greater and lesser importance. In many of these controversies, it has become obvious following investigation and/or public enquiry that a gap has opened up between what is acceptable to the public, on the one hand, and what appears reasonable to, or is at least accepted by, the various medical professionals involved, on the other. The background issues have been more fully discussed elsewhere<sup>(1,2)</sup>.

### BACKGROUND CONSIDERATIONS AND THE DUBLIN WORKSHOP

#### Medical progress and change

It is obvious that the enormous technological successes of medicine are running in parallel with equally innovative social challenges to the way it is practiced. Both are proceeding together, almost hand in hand in developed countries. Instances of medical progress are too numerous to mention, but in this context perhaps minimally invasive surgery and cardiac interventional procedures, such as stenting and electrophysiological treatments, are apt examples. Examples of challenge to medical progress and the way it is practiced, that would have been difficult to anticipate a generation ago, are listed in Table 1.

The scandals surrounding the behaviour of Harold Shipman, a GP in the UK, or the damage to patients arising from use of blood products in many countries are good examples of occasions where the trust between the medical professions and the public visibly and unequivocally fails, leading in turn to a revision to the terms of the relationship between the two<sup>(1–6)</sup>. In some countries, the change in the relationship is such that the politicians have come to the view that the medical professions can no longer be self-regulating, and bodies such as the General Medical Council in the UK will in future have a majority of lay members. This movement is by no means confined to the UK and is also evident elsewhere. The revision of the basis for trust in the professions is also evident in judicial conclusions. For example, the agreement of a peer group within a profession that a treatment is the norm within a profession is not now sufficient to establish that it is acceptable. If it can be established that it does not conform to common sense judges may find against an action even if it is common practice within a profession<sup>(7,8)</sup>.

#### Aspects of development in radiology

Radiology has seen enormous growth since the 1960s. Many practices and types of equipment that are now commonplace did not exist a generation ago. Yet the fundamental ethical basis for these practices has not seen a corresponding level of engagement. This is possibly an oversight, and may be particularly important given that these innovations have taken place over a period of changing social attitudes.

Radiology occupies an exceptional place in hospitals and has been the focal point for the successful introduction and dissemination of high-technology imaging devices into medicine throughout the world.

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**Table 1. Some problems with medical practice.**

Organ retention, blood, foetal tissue, organ donor and infection scandals
High level of politicisation
Distrust of authority
Damaged (possibly collapsing)
Self-regulation processes
Challenges to many aspects of practice
Consumerist and medical tourism

This has been an extraordinary exercise in technology transfer going right back to Roentgen and the first reported human radiographer. It has not received the attention it deserves. Notwithstanding this, the image of radiology within medicine was relatively ambiguous, although it may recently have become more glamorous<sup>(2)</sup>. While there are many commendable aspects of the contributions of radiology to the implementation of a good radiological protection agenda, there are also some weaknesses, which are raised below.

#### Aspects of radiological protection

The defining aspects of radiation protection, as exemplified by the agencies whose main responsibility it is, are a strong legal and an apparently strong scientific basis. It is important to be aware that standards, legal framework and thought processes employed have been developed mainly outside of medicine, in disciplines whose fundamental driving impulse is different from that which drives medicine. Thus, for example, the agencies with responsibilities in the area like the International Atomic Energy Agency (IAEA) and some European Union (EU) institutions, as well as those charged with implementation of the relevant directives, generally have primary briefs that are related to energy provision, environmental concerns or creating a framework for peace. All of these are worthy but, unsurprisingly, the organisations involved are not always a good fit to the needs of medical practice. This might also be said of the International Commission for Radiological Protection (ICRP). Indeed this lack of a good fit is often witnessed to by the appearance, in many countries, of *ad hoc* or secondary bodies for radiation protection in medicine.

The foundational principles of radiation protection in diagnostic radiology include justification, ALARA and the use of dose limits or constraints as appropriate. The implementation of justification, in practice, is not satisfactory in medicine, although some excellent work in the area has been undertaken by both the Royal College of Radiologists and the EU<sup>(9)</sup>.

Radiation protection has also taken its lead from the physical sciences and shows little sensitivity to or concern for the social/political sciences or the humanities. In addition, it has devised a language and system of units and quantities for measurement that, to say the least, are arcane and impenetrable to those outside the field<sup>(10,11)</sup>. This creates major problems for transparency and accountability, which are key values for any issue for which there must be advocacy in the public domain.

#### General ethical/social concerns and public discourse

There is presently much public discourse on bioethical issues arising from a mixture of issues surrounding the potential for human cloning, stem cell research and allied pharmaceutical possibilities. The extent of concern about these issues and the level of political engagement with them may seem unprecedented. However, the fact that there has been an ongoing engagement with ethical issues in the public domain over the last two generations on more conventional questions is simply illustrated by reference to the list of issues in Table 2. Some of these have been discussed in more detail elsewhere, and many of them regularly feature in public debate, literature or TV soap operas<sup>(1,2,12-17)</sup>. However, it is clear that the position of the philosophical and social consensus on these issues was completely different 30-40 years ago. For example, compare the present view of single parenthood, euthanasia or the treatment of special needs children with what prevailed in the 1970s, and the point is made.

**Table 2. Features of life and attitudes that have changed dramatically since the 1970s.**

Features	Attitudes
Right to life	Suicide
Right to bodily integrity	Euthanasia
Individual choice	Marriage and divorce
Consent	Single parents
Equality	Religion and race
Equity	Equality
Special needs	Special needs
Ageism	Disability
Trust of authority	Gender issues
Trust in professions	

## FORM OF THE SENTINEL DUBLIN WORKSHOP

The ethical issues that presented themselves as obviously requiring attention included concerns with medical ethics in the general and research domains, irradiation during pregnancy, issues with screening procedures and mammography, medico-legal and non-medical exposures, expensive and high-dose procedures and a number of other topics. These required some attention and/or development/confirmation of the existing consensus to provide a sound basis for the future. Studies in each of these areas have been undertaken<sup>(1,18)</sup>. During these studies, it became clear that the systemic issues referred to in earlier sections were likely to have a real impact on the theory and practice of radiation protection. Therefore, it was decided to address the problem at this level also.

This was achieved by convening special workshops that would look at the questions involved from broader perspectives. Two were organised, one in Dublin and the other in Glasgow. The latter dealt with the justification of high-dose and expensive procedures and is reported fully elsewhere<sup>(19)</sup>.

The Dublin program was designed in a way that dealt with the broad societal impact of the matters raised as well as the scientific and medical questions involved. To provide a basis for discussion, three sets of authoritative overviews were provided dealing with:

- some aspects of current practice within radiology;
- concerns related to ethical issues from other professions, such as law, social and political sciences, theology and philosophy;
- concerns from those involved with the formation and response to public opinion, such as patient groups, politicians and the media.

### Workshop participant groups

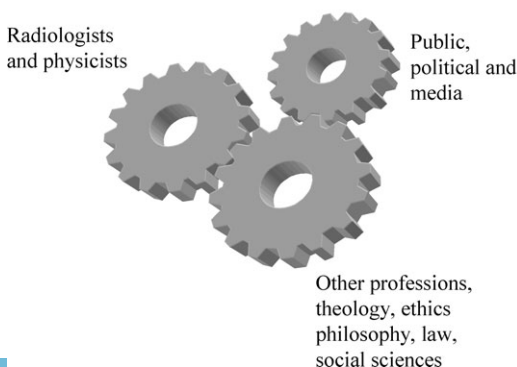


Figure 1. Participants in the Dublin workshop.

Approximately, 40 invited attendees were present drawn from: physicists, radiologists, radiographers, philosophers, theologians, social/political scientists, members of the press, the womens' movement, parliamentarians and patients/patient advocacy groups. The workshop achieved an exceptional level of good exchange and lively discussion in most of the sessions (Figure 1).

## AREAS IDENTIFIED FOR ATTENTION DURING THE WORKSHOP

Seven major issues, listed in Table 3, were identified during the workshop. It will be noted that this list is different from that used as the starting point for the discussion (Form of the Sentinel Dublin workshop above). Most of the areas in Table 3 require elaboration, which will not be possible here. However, a few points will be made in respect to some of the headings. Further initiatives are required to fully address the questions involved, and additional areas will almost inevitably emerge as work progresses and deepens.

### Background issues for ICRP

The first two issues identified are of systemic importance for radiation protection in medicine. There was an overwhelming consensus that ICRP has been working on a philosophical basis which was assumed in ICRP 26 and 60. The philosophical basis for the work of the commission has not altered radically since publications 26 and 60 and still reflects paternalistic views that were common and acceptable when they were drafted. Since then society has moved on and now operates in a mode that draws more on the idea of individual autonomy. While ICRP revisions since the 1960s are, in a scientific and medical sense, excellent, timely and needed, they overlook this central development<sup>(20,21)</sup>. In addition, there has been a philosophical comment which takes issues with the present ICRP approach to risk and its management between individuals and society<sup>(22)</sup>. Finally, the level of trust formerly

Table 3. Concerns identified at Dublin workshop.

Philosophical assumptions underlying ICRP recommendations
Major issues around justification
Medico-legal issues and non-medical exposures
Population screening issues
Issues around consent, authorisation, personal choice, self-referral, etc.
Pregnancy issues
Non-transparent language for discourse (e.g. quantities and units)

enjoyed by the ICRP has been challenged and somewhat eroded, particularly in the environmental field, but also elsewhere<sup>(23)</sup>.

This creates unnecessary distance between the concerns of the radiation protection community and those of the wider community, which are reflected in the public attitudes and popular culture of the time. At present, popular culture in the west is highly individualistic, consumerist and media-driven. None of these influences are evident in the documents of the ICRP or the IAEA<sup>(24,25)</sup>. They are sometimes marginally evident in the Medical Radiation Protection Series issued by the EU. Likewise, there is little evidence that evolving aspects of the arrangements for delivery of health care are reflected in the new arrangements for radiation protection in medicine (Table 4).

### Justification

The next major issue identified deals with justification (Table 5). This gave rise to one of the more extended discussions. Much concern was voiced by some practitioners that the justification process is sometimes weak, or non-existent, or at the very least lacks transparency in practice. In addition, the scientific and audit bases for justification are underdeveloped. While excellent work has been produced by the Royal College of Radiology in London, the EU and the American College of Radiology, in terms of referral criteria and guidance on the use of radiology services, there is some question on the extent of the use of this information in practice<sup>(9)</sup>. It is clear that in some individual departments compliance with justification is excellent — but how widespread this remains to be determined.

**Table 4. Items raised in discussion of ICRP philosophy.**

Problem identified for radiation protection arising from a shift in dominant values in society since ICRP 26 and 60
Dominant values in society have moved along the continuum from paternalism towards individual autonomy
Deeply underlying assumptions have not been visited or articulated and are of the 50s and 60s
Discourse lacks engagement with many defining features of medical practice, public attitudes and popular culture
Basis for some radiation protection is now removed from the concerns of the public, and lodged almost exclusively with professions
Desensitisation of the professions involved to concerns of the public, eventually giving rise to ethical issues
Recent philosophical challenge to basis for dose limits
Reduced trust in ICRP, both on environmental and medical issues

**Table 5. Issues with justification.**

Sometimes weak or lacks transparency in practice
Seriously underdeveloped scientifically
Issues around consent, individual choice and self-referral
Is exemption from dose limit always warranted?
Whistle blower concerns raised at length on justification issues

There was a useful discussion around the question of self-referral and as to whether or not such should be allowed in a society that allows individuals to indulge in many self-harming practices. In addition, it was noted that society tolerates the use of highly active pharmaceuticals and surgery for lifestyle as opposed to strictly medical purposes. This discussion also focused on issues associated with consent, information and on whether the dose-limit exemption needs to be universal for medical procedures.

The absence of dose limits for medical procedures is entirely reasonable to ensure that regulation does not inhibit whatever is necessary for the care of individual ill patients. However, the context for this is one in which the procedures involved are medically justifiable, and we have seen this may not always be the case. Hence the problem with justification may be strongly linked to the dose-limit exemption. In practice, there has been an attempt to introduce a system of using dose constraints and reference levels for practices without a dose limit. While this seems like an excellent approach, there is very little evidence on how effectively it is applied.

There was a lengthy discussion on the situation of radiographers who may find themselves in the position of whistle blower when untenable justification practices become common place. It was recognised that even bonafide whistle blowers generally suffer in such situations if a structural framework is not provided to support them. It was also felt that this situation is exacerbated by the role conflict that arises when a radiologist has responsibility for, or a vested interest in both safety and 'production'. This could be hard to defend as *reasonable* to the average man.

In addition, there were some concerns, under the heading of justification, about consent/authorisation; irradiation of potentially pregnant females; and criteria for selection of patients for high dose or expensive procedures.

### Irradiation and pregnancy during diagnostic imaging

Likewise, there are justification aspects to the questions of irradiation of women who are pregnant or possibly pregnant. However, there are many other aspects to this, including the great diversity in practice throughout Europe that was identified in the

**Table 6. Some pregnancy issues in diagnostic imaging.**

Basis for recommendations
Diversity of practice throughout EU and wider
High-dose procedures need a more consistent approach
Consent or authorisation issues?

ethics session<sup>(26)</sup>. This was a surprising finding and one that needs attention. In addition, the discussion highlighted that the basis for the ICRP recommendations in this area is not regarded as being well developed. Finally, with respect to the pregnancy issue, but also in connection with many of the other issues discussed, there was a strong feeling that the matters of consent, patient information and authorisation for procedures might not be sufficiently well developed. Further attention was felt to be required to this area as well as new models of how to proceed (Table 6).

#### Medical exposure, the law and medico-legal issues

The precise definition of medical exposure is not completely determined. For example, the EU MED Directive and IAEA documents frequently list medical exposures to include medico-legal ones and also include the exposure of comforters and carers<sup>(8, 27)</sup>. There are in addition many other types of human exposure undertaken for a variety of reasons, including determination of demographic data, security monitoring, theft detection, public health surveillance, drugs searches, forensic enquiry and many more. While these activities involve procedures that are similar to medical radiology, their justification is seldom based on the benefit to the individual being irradiated, and hence they are questionable in the medical context. It is particularly important that this issue be dealt with, as the credibility of the exemption of medical exposures from dose limits depends critically on their not being confused with some of these activities.

#### Other issues

Many other concerns emerged and are summarised in Table 3. All require attention, and some mask multiple additional concerns that will require quite protracted study. An extended discussion returned on a number of occasions to how collegiality and undue deference within professions may become self-serving, part company with common sense and damage the public interest. This discussion was informed by the recent tribunal of enquiry into behaviour of an obstetrician<sup>(28)</sup>. In this context, the

direct language of the judge and the press were compared with the oblique quality of comment by professional peer groups. The judge stated that she had found 'severe management deficits, personality problems, internal conflicts, no transparency at any level, no discussion, no analysis, no audit — questionable training of some consultants, and flawed judgments in one consultant in particular'<sup>(28)</sup>. The press account of the judges report noted "how a culture of deference — permitted the consultant obstetrician — to conduct 129 'peripartum hysterectomies' — at a time when most obstetricians would have conducted no more than eight to ten such procedures in their entire careers. She [*the Judge*] makes the point eloquently that while this despoliation of women's bodies was taking place, no consultant, no registrar, no junior doctor, no midwife, no nurse, no pathologist, nobody — [from the] — the order which owned and controlled the hospital, complained or even questioned".

An underlying issue that may contribute to many of the above problems was also identified. It is desensitisation within professions to issues that the public may find shocking. This was well illustrated in the response of both the public and the professions to the scandals surrounding retention of infant organs that occurred in both the UK and Ireland. In these events, it is widely agreed that there was no intention to do harm and nobody benefited improperly, yet individuals were deeply hurt and continue to seek settlement. One of the papers dealt very ably with this issue<sup>(29)</sup>.

#### WHY THE PHILOSOPHICAL BASIS IS IMPORTANT IN PRACTICE

It may seem that the philosophical basis for radiation protection is something remote from practitioners and that they do not need to be concerned about. The case against this is compelling, and will be developed more fully elsewhere. Here it is possibly sufficient to point out that it is arguable that self-referred radiology might be permitted in a system based on individual autonomy, even where it could be harmful to the individual. It is likely that a dose limit or strong dose constraint would be applied to the procedure and that full information would have to be provided to the individual. Such a scenario is difficult to imagine in our present version of a paternalistic system. There are many other examples of how a change in the basic framework would reverberate through the system to give conclusions different from those we presently enjoy. In addition, there is more likely to be accepted by the public of the conclusions of a system more closely related to the best in public attitudes.

## CONCLUSIONS

There are many conclusions from this work, principally that there are major ethical questions underlying the theory and practice of radiation protection that need to be revisited and brought into line with the prevailing philosophy in the early part of the 21st century. The philosophy underlying the recommendations of the ICRP is squarely placed in the middle of the last century. It has served us well, but it is time for a review and to consider moving on. In addition, there are a number of practical and operational aspects of radiation protection that require attention, over and above that provided in the recent welcome new recommendations.

A further important conclusion, with a high level of consensus, is that ethicists, philosophers, theologians, social scientists, the public, patients, media and politicians will not tell us where we should move to. They will help us identify and articulate the arguments for or against particular positions. We should invite and welcome their contribution to this and it is clear that we have been working without them for too long. Finally, we need to consider how to educate the various professions involved in the radiation protection to be ethically sensitive, as it is clear that they bear the responsibility and are called to be accountable to the public for the approach they adopt and foster. These professions, though strong and disciplined on scientific and medical aspects of their role, could be strengthened with regard to ethical sensitivity and responsiveness to public attitudes.

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