FULL PAPER

Pragmatic ethical basis for radiation protection in diagnostic radiology

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Objective: Medical ethics has a tried and tested literature and a global active research community. Even among health professionals, literate and fluent in medical ethics, there is low recognition of radiation protection principles such as justification and optimization. On the other hand, many in healthcare environments misunderstand dose limitation obligations and incorrectly believe patients are protected by norms including a dose limit. Implementation problems for radiation protection in medicine possibly flow from apparent inadequacies of the International Commission on Radiological Protection (ICRP) principles taken on their own, coupled with their failure to transfer successfully to the medical world. Medical ethics, on the other hand, is essentially global, is acceptable in most cultures, is intuitively understood in hospitals, and its expectations are monitored, even by managements. This article presents an approach to ethics in diagnostic imaging rooted in the medical tradition, and alert to contemporary social expectations. ICRP and the International Radiation Protection Association (IRPA), both alert to growing ethical concerns, organized a series of consultations on ethics for general radiation protection, and are based on a solid scientific evidential base, combined with value judgments that allow it be applied to practical problems in industry, medicine, education, research and in everyday life. Some of the values on which ICRP relies are articulated, but many are implied and not explicitly present. The source documents in which ICRP values are most clearly articulated are the recommendations of the main commission in publications 26, 60 and 103.1–3 With respect to medical uses, publication 105 is also important, although it adds little, if anything, to the principles.4

In medicine, there is a longstanding system of values stretching back to the Hippocratic Oath, which recognizes the need for care and ethical sensitivity in the way patients are treated and treatments are delivered. The resultant corpus of knowledge and experience is

INTRODUCTION

The system of radiation protection in the great majority of countries in the world is based on the recommendations of the International Commission on Radiological Protection (ICRP).1 The publications of ICRP are specifically designed for radiation protection, and are based on a solid scientific evidential base, combined with value judgments that allow it be applied to practical problems in industry, medicine, education, research and in everyday life. Some of the values on which ICRP relies are articulated, but many are implied and not explicitly present. The source documents in which
impressive. Medical ethics has a tried and tested teaching literature for undergraduates and postgraduates, as well as an active research community throughout the world. Approaches have evolved that are essentially global and are acceptable in most cultures.3–7

For the most part, scholarship in medical ethics does not attend to the problems in radiation protection. In practice, it appears there is an unwritten assumption that matters relating to radiation are dealt with in a separate system and medical/general ethicists have not engaged with it. In consequence, radiation protection in medicine has enjoyed exceptional independence, which allowed it unique access to management and resources. The counterpoint is that the ethical issues in radiation protection have low recognition in the medical world, with the exception of a handful of radiation protection specialists who advise in the area. For example, patients are afforded some protection by advisory diagnostic reference levels. This, in our experience, leads to the mistaken belief among many healthcare professionals that patients are protected by good practices which include limits on total radiation dose. This illustrates the somewhat isolated position that radiation protection has, until recently, occupied vis-à-vis contemporary social and ethical thinking and leaves it exposed on some important matters.

The systems of medical ethics and the ICRP system for radiation protection overlap significantly. However, there is no simple way of mapping one onto the other.7,28 Analysis of the ICRP system identifies different strands of Western utilitarian and deontological ethics, although the impact of some of these has been attenuated with time (Appendix 1). Notwithstanding, it is likely that a widely recognized approach to medical ethics may prove helpful.

Recently, the global nature of radiation protection has been explicitly recognized in ICRP Task Group 94 on Ethics of Radiological Protection.10 This is mandated to identify the basic values behind the system and their mutual relationships. It is not expected to rewrite the principles of radiation protection but rather show how they are compatible with and rooted in a broadly accepted “common morality”. The work of this task group has been informed by a series of workshops/consultations held in Asia, Europe and the Americas which have looked at the ethical basis of radiological protection. These have been organized jointly by IRPA (International Radiation Protection Association) and ICRP.10,11 In addition, the European Commission has supported enquiries into the ethical basis for radiation protection in its wide-ranging Open Project for the European Radiation Research Area (OPERRA), as well as in its earlier project on Safety and Efficacy for New Techniques and Imaging Using New Equipment to Support European Legislation (SENTINEL).9,12

Pending the outcome of these developments, which may take some time, an interim approach is proposed here for the medical area. It is consistent with the ICRP/IRPA consultations. The proposed approach is global in its reach and will help issues arising in radiology be judged and reflected on, not just against the ICRP principles, but also taking on board contemporary thinking on social, medical and ethical concerns.10

The proposed approach in this article is based on a set of principles/values that can be applied to problems in medical radiation protection and that potentially have high recognition in medicine. In our view, the approach to ethical decision-making in medicine proposed by Beauchamp and Childress provides a good basis to this aim.6–7,13 Their Principles of Biomedical Ethics, first published in 1979, is highly regarded and reached its seventh edition in 2012.7,13,14 In it, the authors suggest that ethical questions in medicine can be addressed by referring to four basic principles:

- Respect for autonomy (of the individual)
- Non-maleficence (do not harm)
- Beneficence (do good)
- Justice (be fair).

These principles are rooted in “common morality”. They are of sufficient generality and flexibility to be widely deployed in medicine and, by extension, in radiology.

A closer look at ethics traditions as well as social expectations identifies additional values which are also relevant for ethical decision-making in the radiological context. While these are implied by Beauchamp and Childress’s basic principles, it is valuable to give them the additional emphasis of being specifically mentioned. The most important of these, in our view, are:

- prudence: (keep in mind possible long-term risks of actions) and
- honesty: (share knowledge with those concerned truthfully).

The notion of prudence is respected across cultures and religions. It is generally understood to be at the heart of the Precautionary Principle, which is highly valued in dealing with scientific problems where action is required in the absence of definitive data. Honesty, in the sense used here is often thought as “working in an open and transparent manner”.

All of the principles are described and explored more fully in the Building Blocks section of the Methods and Materials, in the Pragmatic Value Set section of the Results and in the Discussion and Conclusion section. The Methods and Materials section is followed by the Results section, which not just details the pragmatic set of five values, but also provides a set of scenarios illustrating their deployment. The article ends with an extended Discussion and Conclusion section.

**METHODS AND MATERIALS**

The literature on medical ethics and the implicit ICRP ethical values were reviewed qualitatively, with a view to identifying a system, or set of principles/values that will help guide contemporary behaviour particularly, but not exclusively, in radiation protection of patients. The proposed system is designed, as far as is possible, to:
• be presented using accessible language for the values and/or principles
• be based on a small number (five) of core values which would be easy to remember
• have the possibility of achieving more widespread recognition in medicine and
• not be in conflict with the ICRP/IRPA consultations in the area.

Terminology
When referring to justification, optimization and dose limitation, the three “principles” of radiation protection, we continue to use the term “principle” exclusively for those from ICRP, whereas Beauchamp and Childress also use the term “principle”, and we use their term in introducing their principles. However, once that is done, we substitute the term “value” when dealing with concepts or clusters of concepts from medical ethics. This is to assist readability and avoid confusion.

Building blocks for the pragmatic value set
Beauchamp and Childress developed four principles for biomedical ethics. These are the proposed building blocks for an ethics of radiological protection in medicine.

Four principles
Respect for autonomy In the medical context, this value is to ensure that the patient is the main decision-maker in his or her own case. Consideration for the individual’s point of view in some form is probably part of medical professional ethics all over the world. With regard to radiological protection, it suggests that wherever possible, the imposition of a risk has to take account of the individual’s volition, and this is a prerequisite for justification.

Non-maleficence and beneficence “To abstain from doing harm” is one of the central features of the Hippocratic Oath, and so is “working for the good of the patient”. Of course, it has always been understood that there may be situations where pain, or even damage, has to be inflicted to achieve healing, and thus non-maleficence and beneficence need to be balanced. Both principles, and the awareness of the fact that they sometimes work against each other, can be found in European, Arabian, Indian and Chinese traditions.

Justice The “Golden Rule”—“Treat others as you would like to be treated yourself”—is one of the most common ethical guidelines around the world. Even its wording is strikingly similar in different traditions. It can serve as a support for the principles of non-maleficence and beneficence, but its greatest importance is in support of the value of justice, as it asks everyone to consider the interests of the other as if they were his or her own.

Three related values
Several authors have raised the question if, perhaps, additional principles/values might be needed. We reviewed their suggestions, keeping in mind the current needs of radiological protection in medicine. Three are identified as being of immediate importance to the pragmatic value set. All are of well-established importance in the public and/or environmental health literature and, we believe, extending their applicability to radiation protection in radiology will be of value.

Human dignity It could be argued that respect for autonomy is actually based on (a certain understanding of) human dignity and thus the latter does not need to be invoked as an additional value. We nevertheless prefer to explicitly mention it. Human dignity is more easily demonstrable as a cross-cultural concept than autonomy. All great religious and philosophical traditions recognize it. It appears in a contemporary form at the beginning of the United Nations Universal Declaration of Human Rights.

Prudence One of the most discussed additions to the four principles when it comes to public and/or environmental health is prudence or precaution. It is found in various written and oral traditions around the globe and was embraced by several scientific and public meetings over the last few decades. It may be paraphrased by stating that where an action potentially causes a serious irreversible harm, measures to protect against it must be taken even if the causal relationships involved are not fully established scientifically. This is further discussed in the Results and Discussion sections.

Honesty Honesty extends well beyond financial matters and includes openness and transparency with regard to the benefits and risks of procedures. Justice, intergenerational equity and inclusivity require that people are not deceived. Honesty, veracity and truthfulness have therefore been suggested as guiding values for the interaction between specialists and lay people exposed to radiation. Accountability also arises as a matter of honesty that is relevant in the context of radiation protection.

The two sets of building blocks presented here are regrouped and integrated together in the proposed Pragmatic Set of five Values presented in the Results section: we refer to respect for autonomy and human dignity as one joint value, as we do to non-maleficence and beneficence.

Scenarios
Application of the system is illustrated in six clinical scenarios. Each scenario is described and then scored as complying or not complying with each of the values in the Pragmatic Set. The evaluation of compliance, or otherwise, is the personal judgment of the authors. Compliance with a value is indicated as being strong (Y), weak (y) or neutral (−). Likewise, non-compliance is indicated as strong (N), weak (n) or neutral (−). Some aspects of the scenarios demonstrate compliance with a value, when considered from one perspective, and non-compliance, when considered from another from another. Thus, it is possible to score both (Y/y) and (N/n) for the same value.

RESULTS
Pragmatic working set of values and ICRP principles
We suggest that the approach of Beauchamp and Childress, proceeding from middle-level principles acceptable to different
schools of ethics and demonstrably part of a worldwide "common morality", can be applied in radiation protection. It may be helpful and advantageous to frame ethical dilemmas in radiology in terms of these values, rather than relying solely on the established principles of justification, optimization and dose limitation.

Beauchamp and Childress’s principles are used to provide the first three values in the Pragmatic Set. For the first, we added Dignity, to respect for autonomy for the reasons already mentioned in the methods section (Table 1). A corollary of dignity and respect for autonomy is the requirement of “informed consent”. This idea is widespread in Western societies, although it may encounter with some reservations in cultural contexts which are more paternalistic.

Beauchamp and Childress’s second and third principles, non-maleficence and beneficence, are presented as a single value in the pragmatic set (Table 1). This has been done elsewhere, for instance, in the source ethics document, the Belmont Report on guidelines for protection of human subjects in research. In the context of radiological protection, non-maleficence and beneficence together support the concept of justification as well as that of optimization. In the latter case, application may be somewhat more complicated, as the interests of the wider community become a consideration. Weighing economic and societal factors on the one hand, and individual health on the other, is by no means an easy task, but common morality requires it should not be neglected.

For radiological protection, Beauchamp and Childress’s fourth principle of justice is the main foundation of the concept of dose limitation, as it prevents inequities of harms and benefits. It also implies due concern for fairness, particularly in our treatment of the most vulnerable, such as children, or radiation-sensitive individuals. This provides the third value in the Pragmatic Set.

To these, we added the two additional values Prudence and Honesty. Prudence is taken as a code for precaution and the precautionary principle, although it is generally taken to be a broader concept than precaution. Prudence can be seen as an extension of non-maleficence, with an emphasis on our lack of knowledge about the exact risks; for instance, the risks of small doses of radiation. There is much confusion about its place in radiation protection. Hence, it is included explicitly as the fourth value in the Pragmatic Set (Table 1). For the purpose of radiation protection, which must work out of an incomplete scientific evidence base, a clear and high-level conclusion on the application of prudence is available from the 1998 statement of the Wingspread Conference on the Precautionary Principle. It states that “When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically.” This has a valid resonance in radiation protection of patients and workers and has been reiterated in many and varied forms since.

Honesty and truthfulness are considered virtues around the world, even though the exact degree of openness which should be shown to, say, a seriously ill patient may be debatable. With radiation risks, radiation protection has tended to favour a somewhat closed and paternalistic approach, particularly in dealings with the press, patients and public. However, there is increasing agreement that it is important to communicate openly, even our uncertainties, with honesty. Autonomous individuals have a right to expect this (Table 1). Honesty also carries an implied willingness to be accountable, and it is the fifth value in the Pragmatic Set.

When conflict between the values arises, they need “balancing”, i.e. their relative importance has to be weighed in each case, and their application must be carefully nuanced to take account of all the contributing issues. The values also need “specification”, i.e. concrete rules or guidelines have to be derived for different areas of application. Beauchamp and Childress discuss the practical application of the values and how they may be “balanced” and “specified” at length. Their work in these matters is frequently cited and highly regarded.

Scenarios
Six scenarios are presented involving examinations conducted on individuals exposed in a medical setting. The intention is to illustrate the application of the proposed values in a plausible and diverse set of situations, indicate how the approach might initially be deployed and stimulate work that will be necessary to identify the approach that will best serve radiation protection in diagnostic imaging in the future. This inevitably involves providing examples of situations that might prove problematic when judged against the pragmatic value set. However, it is not our intention to be unduly critical or to offer prescriptive remedies to these situations here. Effective solutions will inevitably have to be subject to evaluation and assessment in the real world of departments delivering a day-to-day service. Instant solutions proposed here might well prove facile.

Table 1. Five pragmatic values/value sets to supplement the principles of the International Commission on Radiological Protection

| Number | Value set                  | Source     | Comments                  |
|-------|---------------------------|------------|---------------------------|
| 1     | Dignity and autonomy      | 5, 7, 8, 15| Of the individual         |
| 2     | Non-maleficence; beneficence | 5, 17     | Do no harm and do good    |
| 3     | Justice                   | 5, 7, 8    | In the sense of fairness  |
| 4     | Prudence/precaution       | 16, 18, 19, 20 | Appears in precautionary principle |
| 5     | Honesty                   | 8, this article   | Particularly in openness and transparency |
Figure 1, Scenario 1
This presents a scenario involving Mr Black, a professor of orthopaedic surgery. He holds a weekly outpatient clinic in a public hospital. He sees both new patients and follow-up cases. His clinic is well resourced and is a model of efficiency, running to time with little waiting around for patients. Prof. Black insists all patients attending have an up-to-date radiology examination of the relevant part before he sees them. This obviously is contrary to the principal of justification. The director of radiology and the medical physics expert advised him against this practice. His response is dismissive, pointing out that radiology in their hospital is home to queues and waiting lists, whereas he runs an efficient patient-friendly service.

He requires that patients bring their film folder or DVD to the clinic. He states it takes too long to get a radiology report which, when received, may not address the issue he wants addressed. So he reads the images himself. Pre-signed forms or authorized referrals on the information system are provided for patients, and they are sent to radiology for the required examination. The Radiology Department are concerned that Prof. Black may bypass the department entirely if they refuse to participate, so reluctantly do so. Prof. Black does not share any of these concerns with his patients. Likewise, he does not discuss benefit/risk information with them, which he dismisses as largely speculative. He feels that as a doctor he is an advocate for his patients’ interests and, in his view, acts accordingly.

Mr Black is obviously of the paternalist school. The two-row table at the bottom of the Scenario 1 panel (Figure 1) indicates how well his practice complies with the five-value pragmatic set. Clearly, the practice fails all five on significant grounds, and he scores a No (N) for each. With respect to Dignity/autonomy, this is not respected in the way the decision to conduct examinations is taken, so this scores N (No). He also scores a small y (a limited yes) in recognition of his efforts to provide a timely efficient service respecting his patients. His practice exposes many patients to unnecessary radiation risk with no benefit, so he scores an N under Non-maleficence. He reads the images himself which, some will argue, adds to the potential for harm. He scores N under Justice as either the patient, in his opinion, is careful to long-established and professionally sanctioned practice. On the negative side, any member of the public could point to time consuming and inconvenient. The hospital has been challenged on the practice by previous patients, and after review, felt it would be too disruptive to alter it.

This approach can be faulted on the grounds of failing to respect the autonomy of both the mother and possibly the embryo/fetus (N); exposing both to potential harm (N); failing to act prudently and follow the precautionary principle when there is possible but unproven risk (N); and not behaving in a transparent way both before and after the examination (N). Under the Justice heading, the behaviour of the hospital might be taken as relatively neutral. A (y) is scored under Dignity/autonomy, Non-maleficence and Honesty, for asking the pregnancy question, being willing to act on it and being open/transparent within the limits of the professional advice available to it.

The hospital’s approach is consistent with much of the practice throughout the world.24,25 However, many of the areas in which medicine has found itself involved in public scandals are those where individual dignity and autonomy has been sacrificed to long-established and professionally sanctioned practices.8,26 Issues around exposure of patients who are pregnant (and pregnant staff) provide many examples of scenarios that might be better resolved in the context of a wider deliberation using the pragmatic value set than on the basis of the legal or ICRP systems alone. Both afford interesting problems for reflection/analysis, but the broader perspective of Beauchamp and Childress’ and the additional
values provide valuable perspectives that help view the problem more holistically.

**Scenario 3**
This scenario deals with the practice of Dr Amber, an interventional cardiologist in private practice. She undertakes individual health assessments for symptom-free patients referred by other practitioners, self-referred or who self-present. Dr Amber explains all the risks of interventional cardiac procedures including the potential radiation risks. She explains the radiation risk is unproven. She conducts the procedures on request and with formal consent. Separate fees are charged for the

**Figure 1. Scenarios and compliance with the pragmatic value set.** The main features of each scenario are described in the panels. Compliance with value is indicated as being strong (Y), weak (y) or non-existent (−) in the small table at the bottom of each panel. Likewise, non-compliance is indicated as strong (N), weak (n) or non-existent (−). Some aspects of scenarios demonstrate compliance with a value from one perspective and non-compliance from another. Thus, it is possible to score both (Y/y) and (N/n) under the same heading.

### Scenario 1: Orthopaedic Clinic
- Orthopaedic surgeon, Mr Black, weekly public clinic in large hospital. New, follow up. Injuries and elective.
- He insists every patient be sent to radiology by the nurse, and will not see a patient without a film folder or DVD from radiology.
- Proud of efficient patient centred service.

| Dignity | Autonomy | Non Malfeasance | Beneficence | Justice | Prudence Preservation | Honesty | Transparency |
|---------|----------|-----------------|-------------|---------|----------------------|---------|--------------|
| Y       | (        | (               | )           | (       | (                    | (       | (            |
| N       | N        | N               | N           | N       | N                    | N       | N            |

### Scenario 2: Pregnant Patient
- Department policy: ask patients at reception if patients are pregnant.
- Does not have more rigorous approach for high dose exams as these are "time consuming etc."
- Patient has elective pelvic CT and turns out to be pregnant.
- She is happy to be pregnant, but is distressed about the radiation, does not trust the advice she receives and considers seeking a termination.

| Dignity | Autonomy | Non Malfeasance | Beneficence | Justice | Prudence Preservation | Honesty | Transparency |
|---------|----------|-----------------|-------------|---------|----------------------|---------|--------------|
| Y       | Y        | (               | (           | (       | (                    | (       | (            |
| N       | N        | N               | N           | N       | N                    | N       | N            |

### Scenario 3: IHA/Self Referral
- Dr Amber, Interventional Cardiologist. Private rooms with imaging facility.
- Explains the radiation (and other) hazards of procedures.
- Explains radiation risk is unproven.
- Accepts IHA and unreferral worried well.
- Procedure on request and consent.
- Fee for consultation + for imaging.
- Dr Amber is shareholder in facility.

| Dignity | Autonomy | Non Malfeasance | Beneficence | Justice | Prudence Preservation | Honesty | Transparency |
|---------|----------|-----------------|-------------|---------|----------------------|---------|--------------|
| Y       | (        | (               | )           | (       | (                    | (       | (            |
| N       | N        | N               | N           | N       | N                    | N       | N            |

### Scenario 4: Follow Up Assessment
- Mr Grey is referred for a routine follow up CT scan, following a cancer which was treated and from which he has been free for some time.
- The risk from the scan is explained and consent is obtained. The benefit is also explained.
- A full examination is conducted, the same as that when Mr Grey was originally referred prior to diagnosis. The dose is the same as the original examination and a contrast phase is included. This is the routine protocol normally employed.

| Dignity | Autonomy | Non Malfeasance | Beneficence | Justice | Prudence Preservation | Honesty | Transparency |
|---------|----------|-----------------|-------------|---------|----------------------|---------|--------------|
| Y       | (        | (               | (           | (       | (                    | (       | (            |
| N       | N        | N               | N           | N       | N                    | N       | N            |

### Scenario 5: Paediatric Patient
- Child; Age 2 (old boy), presents for whole body CT examination.
- Dr Brown, well qualified paediatric radiologist, assesses situation and believes examination is justified and should be performed immediately.
- Parents request information on cancer risk. Dr Brown states there is nothing to worry about. She :reflects further questions, explaining her department is the best in the country for this type of case.
- Her reasons for doing so are that full explanation takes too much time, and a fear the parents may withdraw the child from a necessary examination.
- A technically excellent examination is performed.

| Dignity | Autonomy | Non Malfeasance | Beneficence | Justice | Prudence Preservation | Honesty | Transparency |
|---------|----------|-----------------|-------------|---------|----------------------|---------|--------------|
| Y       | Y        | Y               | Y           | Y       | (                    | (       | (            |
| N       | -        | -               | -           | -       | (                    | (       | (            |

### Scenario 6: Non Medical Exposures
- Ms White (28) at Airport. Smoker finds small amount of drugs in hand luggage. Suspicion she may be mule. Refuses permission and potentially pregnant. Customs officer insists and hospital does the scan. She is pregnant and no drugs.
- New ECSS and non medical exposures.
- Issues around justification, benefit to individual, confidentiality, consent, and governance arrangements.
- Hospital based scan and lack of clarity on who justifies

| Dignity | Autonomy | Non Malfeasance | Beneficence | Justice | Prudence Preservation | Honesty | Transparency |
|---------|----------|-----------------|-------------|---------|----------------------|---------|--------------|
| Y       | (        | (               | (           | (       | (                    | (       | (            |
| N       | N        | N               | N           | N       | N                    | N       | N            |
consultation and for the procedure. The procedures are undertaken in the associated imaging centre, in which she is a shareholder. The financial interest is not disclosed to the patient.

In terms of compliance with the pragmatic value set, the scores are presented in the bottom of the panel of Scenario 3 (Figure 1). Dr Amber scores highly on respecting the autonomy of the individual (Y) and on Honesty (Y) as she takes a lot of trouble to inform the patient and get consent. She also scores an (n) for Dignity/autonomy as she does not share the uncertainty about risk with the patient and an (n) for Honesty—arising from non-disclosure of her shareholder interest in the imaging facility. On the other areas, including Non-maleficence, Justice, and Prudence, she scores (N) owing to the probability that harm may flow from the unjustified and unnecessary examinations.

**Figure 1, Scenario 4**

This scenario deals with a case in which Mr Grey is referred for an examination as part of his follow-up for previous cancer, from which he appears to be in remission. A full abdominal CT including a contrast phase is undertaken; no change is reported since the last scan. The risk of a CT scan is explained to Mr Grey and consent is obtained. The dose noted for Mr Grey is the same as that in the original diagnostic investigation. This is not warranted, as a simpler procedure could have elicited the information required in the follow-up study. The problem here is a failure of both justification and optimization. It might arise from inadequate information provided in the referral, or inadequate radiology protocols that fail to distinguish between the follow-up and the initial more demanding and exploratory diagnostic investigations. Unacceptably high dosage for examinations can arise from many sources including inadequately differentiated protocols that do not distinguish between initial referrals and follow-up investigations.

In Scenario 4, the Dignity/autonomy of the individual is recognized through explaining the risk and obtaining consent (Y). However, there is also a failure in this area as the same protocol is applied to all patients where important differences exist (n). The consequences of this are inadequately recognized and give rise to additional problems. These include failures under the headings of Justice (n) and Non-maleficence (N) owing to unnecessary exposures. An (N) is also scored under Prudence and Honesty.

**Figure 1, Scenario 5**

This scenario concerns Dr Browne, an experienced well-trained paediatric radiologist. A 2-year-old boy is referred for a whole-body CT examination. Dr Browne believes the examination is justified. She advises the child’s parents, his legal proxies, that the examination should proceed. The parents enquire about the risks, if any, from the examination. She (Dr Browne) reassures them that there are none they need consider. She deflects further questioning by explaining that the hospital is the leading one in the country for this type of examination in young children (which is true) and it will not be better performed elsewhere. Her reasons for deflecting the question, which she does as a matter of policy, are two-fold. First, it takes too much time to respond to detailed requests for further information. Second, and more important in her mind, that informed parents may withdraw their children from the examination. The examination is clearly justified from the history provided by the referrer and is technically well performed and reported on efficiently and promptly.

This scenario raises interesting problems. Clearly the dignity/autonomy of the child is respected in ensuring the examination is justified (Y). However, the radiologist’s behaviour towards the parents does not respect their dignity/autonomy and their role as legal proxies for the patient (N). Behaviour with respect to the Honesty category was also unsatisfactory. Patients or their legal proxies are entitled to, and should receive, honest transparent information, when they request it (N). The other categories, Non-maleficence, Prudence, and Justice were all exemplary and hence each scores a yes (Y).

**Figure 1, Scenario 6**

Many issues arise in a subset of human exposures that appear like medical examinations, but are not conducted for the benefit of the person involved, i.e. they are not medical procedures in the normal sense of the term (e.g. drug searches, weapon searches, screening of migrants etc.).

Scenario 6 deals with Ms Whyte, age 28 years, who arrives at the airport after a long-haul flight. She is behaving nervously, and sniffer dogs alert the authorities to check her baggage. They find a small amount of cannabis in one of her bags, and she continues to behave suspiciously. After some deliberation, the authorities decide that she may be a drug mule and request an abdominal/pelvic CT scan. She is healthy with no symptoms and referred to a local hospital with which the customs service has a contract to provide scans in such circumstances. She is not apprised of the radiation or any other risks and permission is not sought. She strenuously objects to the procedure, but eventually allows it to be performed so that she can go home, as she knows she is innocent.

The scan is performed promptly, competently and with optimized dose. The report is made available to the customs service. It shows no sign of concealed drugs in body cavities, but also shows Ms Whyte to be pregnant. She is promptly advised accordingly by the customs officer, who also advises her of her pregnancy. Ms Whyte had thought she might be pregnant but was not sure. She is distressed by the situation, but the customs officer is unable to offer her any advice on the pregnancy or possible radiation damage to her foetus.

The hospital assumes this scan is justified by the customs service which, in turn, assumes the hospital deals with this issue. In the ICRP system, it has no value to Ms Whyte as a medical procedure, and hence is not medically justified. The requirements for consent and possibly for confidentiality are also dispensed within the process described here. In the circumstances, the hospital should have robust authorization processes to mandate such departures from normal practices and ensure public confidence cannot be undermined. Likewise, the customs service must have an open and transparent protocol detailing how such scan requests are justified and who the authorizing officer is.
In some countries, a judge must underwrite the request for a non-medical radiological examination, as the risks and benefits involved are essentially social rather than medical.\textsuperscript{8,27,28}

This scenario appears as negative under all the headings in the table at the bottom of Scenario 5 (N). Ms Whyte’s dignity/autonomy are put to one side in the performance of the examination and perhaps even more clearly in disclosing the scan results to third parties, particularly in connection with her pregnancy. All of these are compounded by a justification process that falls between stools, and fails to establish the subject is pregnant before the examination is performed. There are also problems under the headings of non-maleficence, justice, prudence, and honesty. On the positive side, there is a social benefit, which is shown as a (Y) under justice accompanying the (N) already scored there on Ms Whyte’s behalf. The customs officers treat her as well as the situation allows, allowing a small (y) under dignity/autonomy. This scenario illustrates the problems encountered in reaching a balanced judgment in these situations, but the pragmatic value set helps flag the issues involved more clearly.

**DISCUSSION AND CONCLUSION**

A pragmatic set of five values is proposed to help guide evaluation of day-to-day activities in diagnostic imaging. The need for such a practical set of values arises from the high levels of social expectation with respect to behaviour of health professionals in the area, particularly in the event of accidents or other events that become the subject of public scrutiny. Three of the values are derived from the well-regarded Beauchamp and Childress’ approach, which are independent of ethical theories and cultures. The other two, prudence and honesty, are derivable from the Beauchamp and Childress’ approach, but are explicitly included to help address practical concerns in areas where the day-to-day culture of radiation protection may be somewhat distanced from contemporary public values. This is particularly so in the case of prudence and precaution, when dealing with the uncertainties around radiation risks; likewise with honesty and transparency, and when dealing with matters of consent and communication with patients. All of these will require nuanced application that also addresses balancing the competing demands of the values in an intelligent, sensitive and skilled manner.

As to the origin of the Beauchamp and Childress system, the authors believe it is rooted in “common morality”, i.e. “not relative to cultures or individuals, because it transcends both.”\textsuperscript{7} This is one of the strengths of their approach.\textsuperscript{7} Initially, Beauchamp and Childress were not speaking about different cultures. They were trying to find middle-level principles that both could agree on. Beauchamp was a utilitarian, i.e. for him the consequences of one’s actions were the only thing that counted, while Childress based himself on deontological arguments and was thus mainly concerned with an individual’s duties towards other individuals (Appendix A). These two approaches are usually considered incompatible, as their fundamental criteria for moral good are different. Nevertheless, the authors saw that they could find common ground. It was not that the utilitarian and the deontologist each contributed one or more principles which the other had to match. Rather, both could fully agree with all four principles, albeit for different reasons.

As the world shrinks to a “global village”, there is a need to develop approaches to decision-making that are acceptable for people from different cultural backgrounds. The enterprise of radiology is, more than most medical activities, truly global in its clinical application, research base, industrial infrastructure and regulatory framework. Thus, it is now important to have a matching global framework for ethics to guide its practice in medicine, into the future.\textsuperscript{7,8} Patients travel and will find themselves in the presence of doctors brought up in a different cultural context. Doctors travel and will encounter patients and peers from radically different cultures in different cultural contexts. International organizations such as the World Health Organisation, International Atomic Energy Agency, European Commission and ICRP and numerous professional bodies have to present their findings in language that is not alien to large groups of health professionals and lay populations throughout the world.

The point can be made, however, that it is not enough to refer to a “common morality” and merely claim that “all persons committed to morality” would agree with Beauchamp and Childress’s principles. Rather, we have to base our reasoning on principles that can be shown to exist and demand respect in different cultural contexts and indeed be backed by, or consistent with, the time-honoured written and oral traditions that people around the world refer to for moral guidance. There is not space here to go into detail on this approach. Suffice to say that we are of the opinion that the principles proposed by Beauchamp and Childress can indeed be demonstrated in a wide range of cultural, religious and philosophical contexts.\textsuperscript{5,7,8}

The importance of the two additional values (prudence and honesty) is often overlooked in discussions of radiation protection in the radiology. At this stage, they may be viewed as buttresses for the core Beauchamp and Childress values.\textsuperscript{8} When a fully developed and widely agreed system is well embedded in radiology, the need to state these explicitly may decline.

With regard to prudence, ICRP appears to support the Precautionary Principle, particularly in adopting the linear no-threshold (LNT) model for extrapolation to low doses. Yet, it also states “… calculation of the number of cancer deaths based on collective effective doses from trivial individual doses should be avoided”. This is justified by saying that such calculations would be “biologically and statistically very uncertain”.\textsuperscript{1,29} As the Precautionary Principle applies precisely to those cases involving uncertainty, the ICRP position here seems to be somewhat self-contradictory. The United Nations Scientific Committee on the Effects of Atomic Radiation position, discouraging population risk calculations for small doses, also requires more robust justification with respect to prudence and the Precautionary Principle.\textsuperscript{30}

An equivocal approach to prudence has been adopted at a surprisingly high level in some professional bodies and is also favoured by some well-regarded experts in medical physics and radiation protection.\textsuperscript{1-33} For example, an American Association of Physicists in Medicine statement appears to favour, on the surface at least, emphasizing the benefits of diagnostic investigations without reckoning the risks.\textsuperscript{34} A more extreme version of this is encountered among some practitioners who are linear no
threshold sceptics, do not advise patients about risk and disregard it in their approach to diagnosis or treatment. Behaving as though there is no risk is inconsistent with the precautionary principle, even though doing so may have professional advocates and may, as noted above, appear to be endorsed in some publications. Thus, the value of prudence needs to be re-emphasized in medical radiation protection and to be applied with conviction.

The culture of radiation protection in medicine has come to rely heavily on professionals avoiding talking to patients about the uncertainties involved, and assuring them that everything is fine. This is no longer acceptable, both as a purely practical matter and, more important, as a consequence of the emphasis placed on the autonomy of the individual in contemporary thinking.

The value of autonomy of the individual implies that patients have the right to know of possible risk, so that they can make good informed decisions about their own healthcare. This, in turn, implies that radiologists, other healthcare providers and radiation protection professionals have a duty to inform patients on benefits and risks, on the basis of the best available estimates and the associated uncertainties. This is even further emphasized by the related value of human dignity. The message should be that there may, or may not, be a significant risk; we do not know the exact size, but the best estimates of the scientific and medical community are conservative and are discounted in the decision to recommend an examination. Excessive reassurance is not appropriate in the face of real uncertainty and ultimately damages credibility. Furthermore, patients constantly encounter and cope with larger uncertainties in other aspects of the medical interventions they experience.

Because of their basis in medical ethics and social expectation, the pragmatic value set could reasonably be expected to achieve a higher level of recognition in medicine than the ICRP principles. They might, thereby, help facilitate the transfer of core messages of radiation protection more effectively to its largest area of application. They should help move towards a style of behaviour in radiation protection that is consistent with contemporary social and ethical thought. Health professionals should more easily and fluently relate to them, and apply them, with greater ease. They are less likely to allow issues be missed, be overlooked or be opportunistically neglected. This applies even where the professionals involved are not experts in ethics, as the language involved is mainly intuitive and familiar to those in medicine. On the other hand, the language of radiation protection often seems arcane and mysterious to those not deeply involved. Radiology is essentially a medical activity and is likely to benefit from sharing in the safety/ethics culture and language with the rest of medicine.

The pragmatic value set proved to be an effective roadmap in the evaluation of six scenarios. It helps reaching decisions that are likely to be socially acceptable and respected. The set is not intended to replace the well-established and legally mandated principles of justification and optimization championed by ICRP and by governments in legislation. Rather, they will supplement these and add considerably to them in aiding decision-making in socially sensitive areas. Pending the outcome of the current ICRP/IRPA initiatives, the values give an intuitively clear and credible basis for assessing events, protocols and behaviour of health professionals in radiological imaging. In addition, the value set may find application in areas such as nuclear medicine and radiotherapy which are not explored here.

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APPENDIX A BRIEF EXPOSITION OF “WESTERN” ETHICAL THEORIES

The recommendations of the ICRP obviously presuppose certain elements of moral philosophy, but these are not always made explicit. Individual authors, A1,2 among them members of the commission itself, A3,4 have identified influences mainly of utilitarian and deontological ethics.

Utilitarianism has arguably had the stronger impact at least during the first few decades of the ICRP. It is a concept developed by the British philosophers Jeremy Bentham (1748–1832) A5 and John Stuart Mill (1806–1873). A6 Both considered the outcome, or “utility”, of our actions as the only valid criterion for their moral goodness or badness: if what we do causes more benefit than harm, it is good; if it causes more harm than benefit, it is bad. This is nicely captured in the phrase, “It is the greatest happiness of the greatest number of people that is the measure of right and wrong”. The clearest reflection in the ICRP system of this kind of thinking is certainly the principle of justification: “Any decision that alters the radiation exposure situation should do more good than harm”. When it first appeared in 1977 (Publication 26), it was worded differently, but equally utilitarian: “No practice shall be adopted unless its introduction produces a positive net benefit”. A7 The second principle of radiological protection, optimization, is also based on a consideration of outcomes: “The likelihood of exposure, the number of people exposed and the magnitude of their individual doses shall be kept as low as reasonably achievable, taking into account economic and societal factors”. It was introduced by ICRP in as early as 1958, although it was worded a little differently at the time: “as low as readily achievable” (ALARA). A8 Either way, it became known as the ALARA principle. It is generally understood as urging not only a net benefit, but a maximum of good over harm. In 1973, ICRP explicitly recommended cost–benefit analysis as a tool for optimization, strengthening the notion that the underlying concept was utilitarian. A9

The second influence, deontological ethics, considers as morally valid nothing else than our “duty” (Greek: “deon”), and thus insists that we should never, even if we expected our action to cause more good than harm, neglect the respect for the individual person. And thus, according to the German philosopher Immanuel Kant (1724–1804), we should act in accordance with the Categorical Imperative, which, in one of its formulations, says, “Act in such a way that you treat humanity, whether in your own person or in the person of any other, never merely as a means to an end.” A10 It seems that during the 1970s, the ICRP recognized that focusing only on the principle of “as low as reasonably achievable” did not offer enough protection for the individual. If the “reasonable” is judged on the basis of a cost–benefit analysis only, we cannot rule out that somebody would be treated as a means for somebody else’s ends. For instance, we might find it reasonable, or even imperative, to expose one individual to a relatively high risk in order to save many others from a relatively low one, so that the collective risk can be kept at a minimum. But, that would be unfair to the one highly exposed person. ICRP therefore introduced dose limitation as a third principle of radiation protection in 1977: “The total dose to any individual from regulated sources in planned exposure situations… should not exceed the limits specified.” A11 The recommended dose limits were supposed to keep the risk for professionally exposed radiation workers in line with the occupational risk in other industrial sectors, namely those that have been classified as relatively safe. Apart from dose limitation, the influence of deontological ethics on radiation protection has been slow to gain ground, but is now the subject of much discussion.

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