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Ethics in Radiological Protection for Medical Diagnosis and Treatment

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CONTENTS

ETHICS IN RADIOLOGICAL PROTECTION FOR MEDICAL DIAGNOSIS AND TREATMENT

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Abstract–*Publication 138* defines the ethical foundations of the system of radiological protection, based on core values (beneficence/non-maleficence, dignity, justice and prudence) and procedural values (accountability, transparency and inclusiveness). The purpose of this report is to propose a practical application of values for the medical radiological protection professions. Because medicine has a long history and strong culture of ethics, this report starts by identifying the shared values and defines a common language between biomedical ethics and radiological protection. The core values are very similar, with the autonomy of biomedical ethics which can be seen as a corollary of dignity, and the precautionary principle which can be understood as the implementation of prudence. In recent years, medical education and training has emphasised the values of solidarity, honesty, and above all empathy. All these values are defined and interpreted in the specific context of the use of ionising radiation in medicine. For those more familiar with radiological protection, the ethical implications of their actions are described. Conversely, for those who already have a good background in ethics, this report highlights the specificities of ionising radiation that also deserve consideration

In order to emphasise the coherence between the values involved in biomedical ethics and those involved in radiological protection, this report proposes to combine them: dignity/ autonomy; beneficence/ non-maleficence; prudence/ precaution; justice/ solidarity; transparency/ accountability/ honesty; inclusiveness/ empathy. This allows a structured review of practical situations from an ethical perspective. For the sake of both example and education, the report proposes twenty-one realistic scenarios (11 in imaging procedures and 10 in radiation therapies), which are all presented and analysed in a one-page format. Sensitising questions are provided to stimulate reflection and discussion.

The ultimate goal is to be able to use ethical values in clinical imaging and therapy situations. Required education and training in ethics is essential for medical radiological protection workers throughout their career span. An example of a framework of knowledge, skills, and competencies is proposed. In order to assist the reader in a theoretically complex subject, key messages are distributed throughout the text, as fixed points that can easily be understood. Although primarily aimed at medical radiological protection professionals, this report is also intended for authorities, patients, and the public.

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Keywords: biomedical ethics; core values; procedural values; radiological protection; medical imaging; radiotherapy; education and training

MAIN POINTS

- **An understanding of the basic principles of radiological protection is an absolute pre-requisite for all health professionals working with radiation for the purpose of diagnosis or treatment. This understanding is necessary but not sufficient without also including ethical training.**
- **In order to establish a common ground and to pave the way for an ethically based analysis of practical situations, the values of biomedical ethics and those identified in Publication 138 are paired: autonomy is linked to dignity, beneficence to non-maleficence, precaution to prudence, solidarity to justice, honesty to transparency and accountability, and empathy to inclusiveness. These values are defined and interpreted in relation to biomedical ethics, professional codes of ethics, and the practice of medicine.**
- **Professionals working in radiological protection in medicine are expected to adhere to their organisation's Codes of Ethics, which may include values of accountability, transparency, safety, and patient-centeredness.**
- **Everyone in the diverse groups of relevant stakeholders in health care is responsible for assuring strong radiological protection and ethical values. Each target group needs to be empowered and educated to ensure that patients are imaged and treated correctly.**
- **Radiation dose estimates should be recorded in a patient's medical record; patients should have access to doses they receive and have the dose explained just as they have access to records for all their care. The degree and approach of dose, benefit and risk communication depends on the needs and cultural background of each patient and family, which is explored in shared decision-making.**
- **Risks should be explicitly defined as those that we know with certainty, those that are potential, and those where there is uncertainty in the scientific community or that we do not yet fully understand.**
- **A method for analysing real or hypothetical situations from an ethical perspective is proposed. It consists of reviewing the conformity and non-conformity of a situation in terms of paired ethical values. This highlights the strengths and weaknesses of a situation and thus makes it easier to identify what could be improved. The method can be used retroactively in a pedagogical setting, but also proactively to solve a problem in progress.**

1. INTRODUCTION AND GOALS

(1) Key Message 1: 'Radiation protection is not only a matter for science. It is a problem of philosophy, and morality, and the utmost wisdom' (Taylor, 1956).

1.1. Why is ethics in medical radiological protection important?

(2) This report discusses the ethical aspects associated with the use of radiation in medicine, with particular emphasis on the radiological protection of patients, and is intended for medical professionals, patients, families, carers, the public, governments, and regulatory authorities. It builds upon *Publication 138* (ICRP, 2018a), which outlines the ethical values foundational to the system of radiological protection. *Publication 138* is intended to serve as a resource for the radiological protection community and relevant stakeholders by providing baseline recommendations for addressing ethical issues in practice.

(3) This report elaborates on the ethical values underpinning the principles of radiological protection to focus on the realm of medical decision-making. It presents, analyses, and discusses scenarios in which clinical teams, patients, and the public face ethical challenges applying the principles of radiological protection given the rights and responsibilities involved in ethical clinical practice (Malone et al., 2019; WHO, 2022b). This report does not address issues related to medical research, as the Commission plans to update *Publication 62* (ICRP, 1992) on this topic.

1.1.1. Successes, problems, and scale of modern medicine

(4) *Publication 138* clarifies the ethical basis of the system of radiological protection and highlights core ethical values of the system (**beneficence/non-maleficence, prudence, justice, and dignity**), along with procedural values (**accountability, transparency, and inclusiveness**). It also, describes its historical development and gives general recommendations for application. However, there is a need for subsequent consideration and elaboration of how the values can be practically implemented in different subfields of radiological protection. Medicine was an obvious discipline for this next step because of its long history in ethics. The specific agenda of the ethics of radiological protection in medicine is relatively new, although some experts have discussed biomedical ethics in the context of radiological protection and the changing expectations from the public and professionals. (Malone and Zölzer, 2016; ICRP, 2018a; Malone et al., 2019)

(5) Whether imaging or therapy, radiological medical procedures have become ubiquitous in the practice of medicine, with the number, variety, and types of procedures continuing to increase (ICRP, 2007b; NCRP, 2019; UNSCEAR 2022). Finding a balance between the benefits of these applications and their potential harms cannot be achieved solely by quantitative calculations. Practical situations often give rise to dilemmas that are best resolved on the basis of ethical criteria.

(6) The art and practice of medicine seeks first the health, well-being, and best interests of patients. Systems and theories of biomedical ethics have been developed accordingly, evolving over the years to reflect the moral relevance of patient-centred care. The origins of biomedical ethics date back, for instance, to the ancient Greek Hippocratic Oath (Miles, 2005).

(7) International consensus around biomedical ethics has been sought since the end of the Second World War, with near universal commitment to never repeat the unethical treatment of

patients and research subjects that marked that era. In 1947, the World Health Organization declared "health" to be a fundamental human right that should be equally assured for every human being (WHO, 2006). In 1948, the United Nations General Assembly released the Universal Declaration of Human Rights (UN, 1948). The same year the World Medical Association (WMA) defined the ethical obligations of physicians in the Declaration of Geneva, which was followed in 1949 by the International Code of Medical Ethics, revised multiple times (WMA, 2018).

(8) Meanwhile, the academic and applied discipline of biomedical ethics developed in parallel to support ethical decision-making in policy and practice. Originally published in 1979, *Principles of Biomedical Ethics* by Beauchamp and Childress would be one of the most prominent and globally influential theory of biomedical ethics (Beauchamp and Childress, 1979/2019; Ten Have et al., 2011; Qiu, 2013; Al-Bar and Chamsi-Pasha, 2015; Ashcroft et al, 2015). Biomedical ethics arose not only from the medical profession's need for guidance but from various patients' rights movements, such as the women's health movement, from which care ethics and relational ethics emerged. It is of note that the latest international agreement of the fundamental ideas of this field is the 2005 Universal Declaration on Bioethics and Human Rights by the United Nations Educational, Scientific and Cultural Organisation (UNESCO, 2005a.).

(9) Managing population exposure from medical technologies is more than a purely scientific and technical matter. For example, today there is a general recognition of the importance of considering societal values – as they evolve – and involving patients, families, and the public in the process of decision-making about benefits, costs, and risks. Risks should be defined as those that we know, those that are potential (or probabilistic), and those where there is uncertainty in the scientific literature (or that we do not yet fully understand). Understanding and acting appropriately on the risks and harms of radiological exposure is important not only for physicians, nurses, radiographers, radiation therapists (RTTs), medical physicists, and other related professionals, but also for patients, citizens, governments, regulators, and other stakeholders. These challenges take place in a world that has moved away from the historical paternalism[1] of the medical professions, which clearly no longer provides an acceptable approach to service delivery, but instead requires shared decision-making, interdisciplinary teamwork, and interpersonal behaviour. Sustainable use of medical radiation must be faced together with the above stakeholders, in addition to the goal of providing the patient and societal level benefit.

(10) The various branches of radiology, nuclear medicine and radiation therapy have made numerous organisational and clinical contributions to enhance radiological protection in medicine. National and trans-national radiological protection campaigns have focused on optimisation of protection in medical imaging for patients (Image Gently, 2022; Image Wisely, 2022; EuroSafe Imaging, 2022). Despite these positive contributions, there are ongoing areas in need of improvement, not the least of which concerns justification of procedures as well as honest communication about dose, benefit and risk with the patient, which can be addressed by increased awareness and more robust understanding of the underlying ethical values (Malone et al., 2019, Chapter 3).

(11) Ethics can also inform situations involving limited resources (WHO, 2022a). There are various, inevitable factors that can have detrimental impact on available resources: special interest groups may divert resources to benefit themselves; health professionals may be under

[1] Medical paternalism refers to a model of care in which professionals interfere in patients' choices about their health by making decisions on their behalf, with a protective intention. In paternalism, staff should only use their knowledge and skills for the benefit of the patient, never do harm (the "primum non nocere" principle) and always act only in the patient's best interest. These principles are still at the heart of contemporary medical ethics, where beneficence and non-maleficence are core values.

pressure to optimise revenue (i.e. financial conflict of interest); the public may have unrealistic expectations of the power of diagnostic and therapeutic applications of radiation; bureaucracies, including regulatory agencies, can be self-serving; politicians may respond to political motivations for the location and level of services. All of these factors and more may limit resources for the provision of high-quality care for the public at large, and service to underprivileged and marginalised communities. In some countries, resources do not support an adequate level of service provision, while elsewhere there is clear evidence of over-utilisation of resources leading to overdiagnosis and overtreatment (Shrank et al, 2019). In these situations, an appropriate underlying ethical framework should guide action.

(12) Ethical conflicts in medical practice are diverse and complex when dealing with radiological medical procedures. This report examines how the ethical values adopted by the ICRP can be applied in solving dilemmas in the medical practice within teams and between a radiological professional and a patient and/or family member. It considers various realistic ethical issues, beginning with a review and reflection on past unethical practices specifically in the field of radiological medical procedures. The report promotes acting always on core ethical values when faced with some dilemma or conflict in daily practice.

1.1.2. When things go wrong

(13) Key Message 2: Review of relevant historical events is important, not to judge per se, but to learn. Practices that complied with the law and the guidelines could already have ethically problematic aspects at the time they were carried out.

(14) A historical analysis of what can go wrong with the collective response of a group in medicine was performed in 2010 by the German Radiology Association and the German Association of Radiation Oncology (Eckert et al., 2018). They coordinated a national project looking into original archival material in order to better understand the specifics of the radiology and radiation oncology community during the Nazi period of German history. More specifically, they investigated the regulatory and academic frameworks around tuberculosis screening and forced sterilisation that eventually led to much suffering and numerous deaths. Practices like forced sterilisation, tissue irradiations and race and x-ray registry of the population were officially encouraged and financially supported, performed in facilities of high reputation, against a background of formal guidelines for new therapy and human experimentation. They were known and understood by the medical community, and the subject of official research, doctoral theses, and academic publications. They had legal, institutional, and professional support, but ignored existing ethical guidelines that had already been published in 1931.

(15) Historically, and in many countries, it was common to use patients as subjects of research without their awareness or consent (ACHRE, 1995). For instance, experiments included the injection of plutonium into hospitalised patients to understand the physiology of excretion and other atomic bomb material for military purpose. In treatment of non-cancer conditions such as intractable pain (Smith and Doll, 1982), skin conditions (Widder, 2014), infections (Salomaa et al., 2020), hearing loss, and in reproductive health (Lafferty and Phillips, 1937), radiation has been used with belated understanding of carcinogenic (Kaick et al., 1991) and cardiovascular implications.

(16) In some countries, radiation was also used to induce therapeutic abortion (Bushberg et al., 2012). Some countries had also kept a legal framework to support forced sterilisation or

abortion reflecting unscientific eugenics[2] thought to improve the population's genetic quality by excluding "inferior" subpopulations. For instance, in Japan, under the former Eugenic Protection Act (1948–1996), in addition to surgical operation, x ray had been one of the options of authorised procedures of involuntary sterilisation (Mainichi, 2018). In the preamble of the "Law concerning lump sum payment to those who have undergone eugenic surgery based on the former Eugenic Protection Law", enacted in 2019, the Japanese government expressed sincere apology to the victims, for their "great psychological and physical damage", and enacted to pay victims of forced sterilisation 3.2 million yen each (Mainichi, 2019). Actual situations regarding how radiation technology had been used for voluntary and involuntary sterilisations have not yet been systematically analysed. While official eugenics policies are now rare, bias and stigmatisation of particular populations continue to influence decision-making in reproductive health.

(17) Review of relevant historical events is important, not to judge per se, but to learn. The above cases illustrate that ethics guidelines on their own are not sufficient to ensure practice will be morally sound. Taken together they indicate that good intentions and professional consensus will, in retrospect, not always ensure acceptable practice, and learning from these examples should inform current and future practice.

(18) Judgment on if a practice is ethical can diverge when the question is considered in different fora. For example, the consensus of a group of radiological protection professionals may differ to that of a group of healthcare practitioners, which may differ again from that of groups of patients, members of the public, parliamentarians, lawyers or judges. While considering all of these groups, radiological protection in modern medicine must strive to achieve a consensus which is acceptable to patients (WHO, 2015).

(19) When things go wrong, leading to patient harm and to conflict between patients and professionals, the ultimate arbitrator will, in most jurisdictions, be the law courts (although sometimes there will be an ethics committee at a hospital to appeal for help). These will not always favour the consensus of a profession above behaviour deemed to be reasonable in civil society. Hence, in determining the values that must be emphasised in practice, it is wise to be attentive to the legal and judicial environment as well as to what prevails within the professions (Malone et al., 2019, Chapter 1).

(20) The historical nature of the radiation incidents cited above may lend a false sense of security, suggesting that unacceptable radiation practices could not, or do not, occur today. However, current medical practice is rich in events that demonstrate it is still possible for its professional consensus to diverge in important ways, sometimes with lethal consequences, from the expectations of its key stakeholder, i.e. the patient. Health care systems, like every system, involve people to do the work and people invariably make mistakes. Health care systems are increasingly complex and require systems engineering, continuous review and improvement of care, and lifelong education of the health workers. Although not always involving ionising radiation, there are numerous examples in high profile medical events, some global in their reach. These include those around blood products, widely distributed pharma products/ medical devices, and exuberant deployment of software or artificial intelligence (AI). There are others with a more limited reach, involving systemic unacceptable practices in particular regions or institutions (Madden, 2005).

(21) While radiation in medicine has not experienced problems identical to these—there have certainly been global concerns raised over the past 15 years regarding the risk of cancer from CT scans. It harbours echoes of behaviour to standards not shared with its main

[2] Eugenics is a set of beliefs and practices (unscientific and unethical) aimed at "improving" the genetic makeup of a group. Eugenics programmes included positive measures, such as encouraging individuals deemed "particularly fit" to reproduce, and negative measures, such as marriage prohibitions and forced sterilisation of people deemed "unfit for reproduction".

stakeholders, as will be seen later in this report (Sections 6, and 7). Both radiation dose and risk – as we understand them – have not been disclosed to patients: this must change. Imaging is overutilised and not justified in many circumstances. The consequences include both the significant consumption of resources with little return in individual patient or societal outcomes, as well as possible harm to patients (Malone et al., 2012; EC, 2014a; Shrank et al, 2019). In addition, while much more work has been done by the professions and industry regarding dose optimisation, there are still large variations in the dose per examination between countries, between departments in a country, and between procedure rooms/ operators within a department (Marin et al., 2015; ICRP, 2017; Sadigh et al., 2018; Smith-Bindman, et al., 2019). This leaves much to be desired (EC, 2014b; EC, 2021). Both the justification and optimisation issues are systemic and it is possible that review of current practices, in the context of patient or societal ethics expectations, would find them (the practices) unacceptable.

(22) The failure to incorporate evidence-based findings into local and national *radiotherapy* protocols also leads to an inconsistency of practice and a failure to provide optimum treatment to patients. Large variations exist between departments within a country and even amongst clinicians within a department.

(23) Key Message 3: Individual patient radiation dose and risk – as we understand them – have not been disclosed to patients as a routine practice; this must change so that these data become no different from all other patient health information.

(24) Patients have repeatedly reported a desire to know both dose and risk when asked (Larson et al., 2007; Merck et al., 2015) and this has sometimes reduced unnecessary imaging (Merck et al., 2015) and not created fear that causes patients to refuse necessary imaging (Larson et al., 2007). Some clinician surveys have noted a majority favour informed consent for patients that undergo imaging with ionising radiation (Karsli et al., 2009).

1.2. Scope and purpose of this report

(25) Ethics has a long history in medicine, and it is important that the system of radiological protection be consistently applied in practice. As such, this report aims to increase familiarity of radiological protection professionals with biomedical ethics and with the ethical foundations of radiological protection to help them integrate these considerations into radiological protection in medicine. It also aims to assist medical professionals to integrate considerations of radiological protection into their ethical and clinical decision-making. Patients may also find this report helpful, although they are not its primary target audience.

(26) This report starts with a review of historical development of the system of radiological protection and its evolving ethical foundation along with additional key concepts of ethics (Sections 2–4). Based on this background, the report proposes an evaluation method to analyse specific situations from an ethical point of view (Section 5). The method provides the context to gain clarity about the relevance of ethical perspectives to practical clinical situations. This is then put into practice through case-based examples dedicated to imaging (Section 6) and therapy (Section 7). Finally, the implications and importance of ethics in education and training are discussed (Section 8).

2. ETHICS IN RADIOLOGICAL PROTECTION

2.1. Background: Ethics in radiological protection and radiological protection in medicine

(27) As reported in *Publication 138*, the first decades of the use of radiation in diagnosis and treatment were characterised by gradual developments in the understanding of its risks and harms (Clarke and Valentin 2009; ICRP, 2018a, Para. 2.1). In the 1920s, the principle of "do no harm" was the implicit ethical basis for protection of firstly, radiological workers who received high doses and later, of patients by the International X-Ray and Radium Protection Committee (IXRPC; the precursor of the ICRP). The focus of policy at this time was on avoiding what are now called tissue injuries or tissue reactions and the goal was to keep doses below thresholds to avoid those harms.

(28) Key Message 4: This report builds on *Publication 138* by bringing the ethical values that support the principles of radiological protection back into the context of patient care and medical decision-making.

(29) Scientific understanding of the types and extent of radiation-related harms and concerns with broader populations subject to exposure led to an expansion of policy over the following decades to include the idea that cancer and hereditary effects (understood as "stochastic effects") arose at any increment over background radiation (ICRP, 1955). More complex considerations of balancing benefits and harms ("beneficence and non-maleficence"), respecting individual rights ("dignity"), and taking into account patient, professional, and societal concerns were required in an ethical system of radiological protection.

(30) In 1966 the ICRP adopted the linear-non-threshold (LNT) model for *protection*, stating that there is "...no practical alternative, for the purposes of radiological protection, to assuming a linear relationship between dose and effect, and [assuming] that doses act cumulatively" (ICRP, 1966). The goal was to promote reasonable action in the situation of uncertainty, reflecting the value of "prudence". In 1977, the ICRP articulated the three basic principles of radiological protection: justification, optimisation, and limitation (to avoid disproportional allocation of risk, reflecting "justice") (ICRP, 2018a, Para. 2.5).

(31) In 1996 the ICRP further defined the role of justification for patients in *Publication 73* (ICRP, 1996) and, coincident with its statement of general principles of radiological protection in *Publication 103*, the ICRP published *Publication 105*, which interpreted the principles for a clinical context. (ICRP, 2007). The interpretation of the principles for patient care is outlined here in Table 2.1, although this is not without criticism (Malone, 2020).

Table 2.1. Key Principles of Radiological Protection System (ICRPædia Glossary) interpreted for the medical context (*Publications 73* and *105*).

Principle	General description	In the medical context
Justification	The process of determining whether the benefits to individuals and to society from introducing or continuing the activity outweigh the harm resulting from the activity	Level 1: Procedure provides more benefit than harm. Level 2: Procedure follows relevant guidelines for the given condition in the national context. Level 3: Procedure is justified for the individual patient.

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Table 2.1. *(continued)*

Principle	General description	In the medical context
Optimisation	The process of determining what level of protection and safety makes exposures, and the probability and magnitude of potential exposures, as low as reasonably achievable (ALARA) with economic, societal and environmental factors being taken into account	Optimisation applies to 1) equipment and facilities, and 2) to working processes/protocols. Sometimes the best patient protection may involve high occupational doses for staff (ICRP, 2018b). Diagnostic reference levels are used instead of dose constraints for patients. Dose constraints are appropriate for carers.
Limitation	The use of controls (in terms of doses) over the exposure of an individual to ensure that the radiation risk is acceptable	No dose limits for patients. Emphasis is on justification and optimisation.

(32) *Publication* 138 identifies dignity, beneficence/non-maleficence, prudence/precaution, and justice as core ethical values of radiological protection (Table 2.2). In addition, it discusses three procedural values that play a role in the practical implementation of the system: accountability, transparency, and inclusiveness (i.e. stakeholder participation) (Table 2.3). It demonstrates how these core ethical values underpin the principles of radiological protection and how the key procedural values inform requirements for the practical implementation of the system. Finally, *Publication 138* summarises the main implications of ethics for the system of radiological protection. Three annexes address respectively ethical theories, biomedical ethical principles and cross-cultural values relevant to radiological protection.

Table 2.2. Core Ethical Values of the Radiological Protection System (ICRP, 2018a, pp. 11).

Core Ethical Values	Definition	Example in *Publication 138*
Dignity	The unconditional respect that every person deserves, irrespective of personal attributes or circumstances. Personal autonomy is a corollary.	Stakeholder participation and the empowerment of individuals to make their own informed decisions
Beneficence/non-maleficence	Promoting or doing good, and avoiding doing harm	The primary aim of the system of radiological protection: ... an appropriate level of protection... without unduly limiting... desirable human actions
Prudence	Making informed and carefully considered choices without full knowledge of the scope and consequences of an action	Consideration of uncertainty in radiation risks for both humans and the environment

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Table 2.2. *(continued)*

Core Ethical Values	Definition	Example in *Publication 138*
Justice	Fairness in the distribution of advantages and disadvantages	Individual dose restrictions to prevent any individual from receiving an unfair burden of risk

Table 2.3. Procedural Values for the practical implementation of the core values (ICRP, 2018a, pp. 13–16)

Procedural Ethical Values	Definition	Example in *Publication 138* with (paragraph number)
Accountability	The obligation of individuals or organisations who are in charge of decision-making to answer for their actions to all those who are likely to be affected, including reporting on their activities, accepting responsibility, and accounting for actions taken and the consequences, if necessary	Exercising accountability to future generations for waste management and the protection of the environment (68)
Transparency	Accessibility of information about the deliberations and decisions concerning potential or on-going activities, and the honesty with which this information is transmitted	Informing radiological workers of hazards and precautions (70); disclosing all relevant information about radiation risks and benefits to patients in informed consent (71–72); environmental impact assessments (74)
Inclusiveness	Ensuring that all those concerned are given the opportunity to participate in discussions, deliberations, and decision-making concerning situations that affect them	Empowering the public in the wake of an accident (79-80); engaging stakeholders to keep workplace exposures as low as reasonably achievable (79)

(33) This report builds on *Publication 138* by bringing the ethical values that support the principles of radiological protection back into the context of patient care and medical decision-making, as detailed in the following sections.

2.2. The interpretation of ethical values in radiological protection and in biomedical ethics

(34) The four core ethical values identified by the Commission as underpinning the system of radiological protection (beneficence and non-maleficence, prudence, justice, and dignity) are similar to Beauchamp and Childress's classical four principles of biomedical ethics, which are widely accepted in medical and other areas (Beauchamp and Childress's, 2019; Malone et al., 2019, Chapter 2). With the intention to address the practical ethical concerns of radiological protection, the Commission defined these core values and the related procedural values for application to radiological protection at a very general level, addressing all possible exposure situations, whether they are existing, planned, or emergency.

(35) In clinical practice, exposures are normally planned and the risks and benefits apply primarily to the individual patient (ICRP 2007b). To facilitate practical understanding of core and procedural values identified in *Publication 138*, the Commission considers it necessary to provide additional interpretations to this set of values, clarifying some especially important notions that have been well discussed in the field of biomedical ethics, and that health professionals are familiar with.

(36) Key Message 5: In the medical application of radiation, biomedical ethics of professional practice are already firmly in place.

(37) Interpretations of the core and procedural values that are especially important in clinical practice are presented as "paired values", as shown in Table 2.4. The following subsections describe why these additional interpretations are important in the medical context. These "paired values" are then used in the scenario evaluation procedure introduced in Section 5 and carried out in Sections 6 and 7 (Table 5.1). The following Section 3 presents the practical implementation of these values in clinical procedures. A table of "sensitising questions", which relates clinical interpretations of these values and their implementation to practical clinical decisions, is provided in Section 5 (Table 5.2).

(38) It should be noted that, although there is no hierarchy among the four core values as they were presented in historical order in *Publication 138*, this report presents dignity and autonomy first, following the order well established in biomedical ethics (Beauchamp and Childress's, 1979, 2019; Malone et al., 2019, Chapter 2).

Table 2.4. Glossary of clinical interpretations of core and procedural values.

Drawn from *Publication 138* pp. 11 and 13–15, except where marked by an asterisk ("*").	**Clinical interpretations**
Core value: Dignity **Dignity** is the value and respect that every person has and deserves regardless of her/his age, sex, health, social condition, ethnic origin, religion, etc., protected by the Universal Declaration of Human Rights. **Additional interpretation: Autonomy** **Autonomy** is the capacity of individuals [or groups] to act freely, decide for themselves, and pursue a course of action in their lives.	An important manifestation of respect for dignity and autonomy is seeking and respecting patients' free and informed consent. Specific clinical procedures (Section 3) address the needs of those with temporary incapacity, waning capacity, or growing maturity. Both dignity and autonomy have culturally specific and patient specific interpretations.
Core value: Beneficence/non-maleficence **Beneficence** and **non-maleficence** refer to the duty to promote or do good, and to avoid harm **Additional interpretation: Balancing benefit and risk** Balancing benefits and risks means assessing procedures with respect to the benefits and risks as they relate to a patient population and an individual patient*.	Beneficence includes the commitment of the health care provider to promote the patient's well-being. Procedures should only be offered or performed where they provide a potential **benefit** that outweighs the **risks** to which they expose patients, and these benefits should be maximised while the risks are minimised and/or mitigated.

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481 Table 2.4. *(continued)*

Drawn from *Publication 138* pp. 11 and 13–15, except where marked by an asterisk ("*").	**Clinical interpretations**
Core value: Prudence To be **prudent** is to make informed and carefully considered choices without the full knowledge of the scope and consequences of an action. **Additional interpretation: Precaution** **Precaution** refers to measures taken to prevent or reduce risk in the absence of scientific certainty*.	Medical decision-making involves the integration of multiple sources and kinds of information with patient values in situations of uncertainty. In decision-making about medical radiation use, the LNT model supports reducing exposures insofar as this is consistent with good clinical care.
Core value: Justice **Justice** is the upholding of what is right, equitable, and fair. It takes several forms. *Distributive justice* refers to fairness in the distribution of advantages and disadvantages among members of communities. *Restorative justice* includes repairing the harm done to victims, communities, and the environment. *Social justice* refers to promoting a just society by recognition of human rights to equitable treatment and assuring equal access to opportunities. **Additional interpretation: Solidarity** **Solidarity** refers to consideration of the common good and the societal structures that ensure it, as well as interpersonal relations of recognition, reciprocity and support*.	Where health care resources are scarce, priority setting and resource allocation procedures balance maximising benefits and ensuring fairness in access to these resources. **Social justice** requires health care professionals and institutions to work to address the health inequities experienced by particular communities, including advocating for improvements in the social determinants of health. **Solidarity** in health care refers to the efficiency and sustainability of the health care system for all and also to social relations of mutual recognition and support, including support for the most vulnerable.

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Table 2.4. *(continued)*

Drawn from *Publication 138* pp. 11 and 13–15, except where marked by an asterisk ("*").	**Clinical interpretations**
Procedural Value: Accountability and Transparency Accountability is an obligation of professionals to answer for their decisions and actions to those who are affected, and to accept the consequences. Transparency is a necessary component of accountability, and it refers to accessibility of information about the deliberations and decisions, and the honesty with which this information is shared. **Additional interpretation: Honesty** Honesty is the professional and personal commitment to candid and truthful sharing of information*.	The patient is often the one most affected by the decisions and actions of the health care professional, but families, caregivers, and the health care team are also affected. **Transparency** and accountability are key to the management of adverse events and to continuing quality improvement and review of performance. Informed consent rests on transparency about the benefits and risks of diagnostic and treatment interventions, and on the disclosure of the patient's diagnosis and prognosis. **Honesty** in health care is the personal and institutional commitment to foster the patient's accurate understanding of their own medical condition, and their diagnostic and treatment options, including the risks involved. This includes when appropriate the understanding of others involved in the patient's care.
Procedural Value: Inclusiveness Ensuring that all those concerned are given the opportunity to participate in discussions, deliberations, and decision-making concerning situations that affect them. **Additional interpretation: Empathy** Empathy can take emotive and cognitive forms: sharing another's emotional response and/or understanding their feelings and perspectives*.	**Inclusiveness** means participation of the patient in decision-making about his or her health care and involving family and carers. **Empathy** for patients and carers is important for the recognition of their feelings and perspectives in their care. It should be developed in professional education and supported institutionally in practice.

*Additional interpretation defined in this Report (see Sections 2.2.1–2.2.5)

2.2.1. Dignity and autonomy

(39) The Commission defined respect for human dignity as "the unconditional respect that every person deserves, irrespective of personal attributes or circumstances" and identified "personal autonomy [as]… a corollary of human dignity." (ICRP, 2018a, Para. 59). The value encompasses respect both for autonomy and for the broader range of human attributes protected in the Universal Declaration of Human Rights (UN, 1948; ratified as UN, 1966), including

civic, political, social, economic, and cultural rights. Dignity is maintained to capture the importance of unconditional respect for persons, whatever their capacity to understand procedures, including, for example, children (UN General Assembly, 1989).

(40) In the clinical context, autonomy, which is derived from dignity, is named as a paired value for the scenario evaluation procedures of Sections 5–8 (Tables 2.4, 5.1, and 5.2). Defined by the Commission in *Publication 138*, "Autonomy is the capacity of individuals to act freely, decide for themselves, and pursue a course of action in their lives." When medical professionals focus on dignity, they may revert to paternalistic assumptions about what dignity means. Patients have their own conceptions of dignity, and these are often culturally specific (Killmister, 2010; Hofmann, 2020). Autonomy has also been subject to various interpretations across cultures, including concepts of "related autonomy" (Kimura, 2014) or family/community-based decision-making (Akabayashi, 2014), which is different from the Western emphasis on the individual's right of self-determination (ICRP, 2018a; Malone et al., 2019, Chapter 2).

(41) Dignity also indicates the need to *adapt* clinical procedures to the specific cultural and medical needs of the patient, such as pregnant women unable to lie on their backs in late pregnancy, or nauseated patients who cannot drink oral contrast for a CT scan. The human rights framework for dignity includes providing disabled persons access to the same range, quality and standard of health services necessary to enjoy "the highest attainable standard of health" (UN, 1948, Article 25; WHO, 1948) and "live independently and participate fully in all aspects of life" (Article 9; UN General Assembly, 2007).

(42) In the history of ICRP, respect for human dignity has been reflected in calls for informed consent in *Publication 62* (ICRP, 1992) on biomedical research. Subsequently, in *Publications 84* on pregnancy and medical radiation (ICRP, 2000) and *Publication 105* on radiological protection in medicine (ICRP, 2007b), the focus was on consent for diagnostic and treatment interventions. Consistent with biomedical ethics, *Publication 84* pointed out that "there are usually five basic elements to informed consent, which includes whether one is competent to act, receives a thorough disclosure, comprehends the disclosure, acts voluntarily, and consents to the intervention" (ICRP, 2000). For vulnerable populations with diminished competency, such as children, or limited freedom, such as those living in institutions and prisons, or for pregnant women considering health effects for the foetus, additional protection both in terms of consent and strict benefit/risk assessment are required (ICRP, 1992, 2000).

(43) From the clinical perspective, the WMA's Declaration on the Rights of the Patient and Declaration of Geneva (WMA, 1981, 2018a) confirms the right of the patient "to self-determination, to make free decisions regarding himself/herself," and the need for physicians to "inform the patient of the consequences of his/her decisions," respecting the right of the patient "to the information necessary to make his/her decisions," including "what is the purpose of any test or treatment, what the results would imply, and what would be the implications of withholding consent." Where the patient lacks capacity for informed consent, substitute decision-makers represent their wishes and values where these are known and their best interests where their specific wishes and values are not known (Williams, 2015).

(44) Personalised criteria for radiological protection in some patients, as in parallel with the current approaches of personalised medicine, should be considered. The opinion of the patient needs to be considered. Some patients may accept additional radiation risks to confirm or exclude a diagnosis. This information may constitute a relevant psychological benefit for the patient (Vano, 2021 and for an example, see scenario 6.8 below).

(45) Key Message 6: Health care professionals respect dignity and autonomy through enabling the patient to participate in informed consent for procedures. They also respect dignity and autonomy through adapting radiological procedures to the specific cultural and medical needs of the patient and ensuring confidentiality in patient-professional interactions.

(46) The right to privacy has not been discussed in *Publication 138*, but it is especially important in medicine. It is derived from "dignity" (UN, 1948), and assured in the constitutions of democratic countries. Recognising this fundamental right, personal data have come to be protected by data protection laws (e.g. EU, 2016) or additional legal instruments for health data (e.g. United States HIPAA, 1996), balancing patients' fundamental privacy rights and the need of society to analyse patient data for improvement of health care and research. The health care provider's obligation not to breach confidentiality and to keep patient's privacy is foundational to trust in the provider-patient relationship, and dates back to many ancient physician oaths. Based on these fundamental demands, patient confidentiality has been protected in the legal systems of many countries.

(47) *Publication 138* states that respect for dignity and autonomy relies closely on the procedural values of accountability and transparency. In this report, the procedural values are interpreted below (Section 2.2.5) for the context of informed consent to medical interventions.

2.2.2. Beneficence and non-maleficence; benefit and risk

(48) *Publication 138* highlights that beneficence and non-maleficence are central to the system of radiological protection, although these technical terms from biomedical ethics had not been previously used by the Commission (ICRP, 2018a, Para. 37). While workers, carers and comforters, and the public may also experience exposure, in the voluntary and planned exposures of medical practice, the risks and benefits of radiation exposure usually accrue to the same person, the patient (ICRP, 2007b). The possibility of societal and environmental harm must also be considered for instance when radioactive materials are used in a hospital setting.

(49) The values in biomedical ethics of beneficence and non-maleficence, or doing good and avoiding and minimising risks of harm, are often understood in clinical practice as balancing benefit and risk in selecting a diagnostic or therapeutic intervention, and maximising benefit and minimising or mitigating risk in how that intervention is delivered. This language of benefits and risk is added as a "paired value" in the scenario evaluation procedure of Sections 5–8 (Tables 2.4, 5.1, and 5.2). The following considerations are specific to beneficence and non-maleficence in the clinical setting.

(50) In radiological protection, the imperative to do more good than harm is reflected in (though not limited to) the principle of justification. Beneficence and non-maleficence can be interpreted together as maximising benefit and minimising risk (NCPHSBBR, 1979). This idea is also reflected in optimisation, where the value of prudence as expressed in the LNT model supports a specific approach to balancing harms and benefits (Section 2.2.3).

(51) Beneficence and non-maleficence in biomedical ethics have additional meanings. Beneficence has referred to the primary commitment or loyalty of the health care provider to the patient's health and well-being (Bloche, 1999; WMA, 2018b; Malone et al., 2019), while non-maleficence is often associated with the so-called Hippocratic obligation to "do no harm" (Gillon, 1985).

(52) The value of beneficence in biomedical ethics includes consideration of the full range of the goals of medicine—promotion of health; prevention of disease; treatment of disease and amelioration of suffering; and/or enhancement or improvement of functional status—for individuals and for populations (Allert et al. 1996). In this respect, it is worth recalling the WHO definition of health: "Health is a state of complete physical, mental and social well-being

and not merely the absence of disease or infirmity" (WHO, 1948). Radiology screening programmes are part of cancer and dental caries preventive medicine; radiotherapy is used in both a curative approach in radical treatment and in improving quality of life in the palliative setting. Radiological procedures also play a role in improving quality of life or aiding functional recovery after trauma, and in youth and adult sports medicine performance (COMARE, 2019).

(53) The Commission recognised that radiological protection faces the challenge of measuring and valuing many dimensions of individual and societal harms and benefits, including psychological, social, and cultural aspects (ICRP, 2018a, Para. 40–41). In biomedical ethics, the health care provider's responsibilities include obligations to equity and sustainability in health systems. Thus, health care providers often face ethical dilemmas between what is "best" for individual patients and what is sustainable and equitable in a health care system that serves everyone. The WMA Declaration of Geneva pledges that the health and well-being of the patient will be the first consideration (WMA, 2018a). Keeping this premise, social trade-offs are sometimes necessary in medical ethics. This is discussed more in depth in the context of value of justice and solidarity (Section 2.2.4).

(54) Key Message 7: Beneficence and non-maleficence (i.e. benefits and risks) cannot be disaggregated for use of radiation technologies in medicine. In justification, sparing the patient radiation exposure but failing to answer the clinical question does not benefit the patient.

(55) The value of non-maleficence in biomedical ethics includes considerations that are relevant to radiation technology in medicine. Excessive use of diagnostic technology or follow-up of incidental findings with the intended goal of prevention can lead to medical and psychosocial harms, called "cascade effects" in diagnosis (Deyo, 2002; Nguyen et al. 2015). Examples include "medicalisation," or defining ordinary human experience as disease (Verweij, 1999) and the harms of false positives and of overdiagnosis, i.e. of identifying clinically insignificant findings as disease (Newman-Toker, 2014; Brodersen et al., 2018; Salerno et al., 2019).

2.2.3. Prudence and precaution

(56) The Commission identified the value of prudence, or "the ability to make informed and carefully considered choices without the full knowledge of the scope and consequences of actions" (ICRP, 2018a) as a core value of radiological protection. They interpreted it as "practical wisdom", rooted in ancient Greek and Chinese philosophy (Kurihara et al., 2016). Health care professionals often make decisions in conditions of uncertainty, i.e. in the face of risks and benefits that cannot be reliably quantified at that moment. It both addresses the challenge of decision-making where multiple and uncertain considerations must be weighed, and specifies more precisely how beneficence and non-maleficence in the context of radiation safety culture should be treated.

(57) Related to the Commission's value of prudence is the concept of precaution (ICRP, 2018a, Para. 47–48). Precaution requires first that we here consider credible risks for which we have no direct scientific evidence, such as the risks estimated with the help of the LNT model for doses below 100 mSv (UNESCO, 2005b; ICRP, 2007a, 2018a, Para. 45–46; see also Shore et al., 2018, for the NCRP's most recent review on the matter). In addition, prudence also requires us to consider the level of effort that is reasonable to avoid those risks. Prudence can therefore be understood as being fundamental to the optimisation principle of radiological protection which stipulates that exposures should be kept as low as reasonably achievable (ALARA) "taking into account economic and societal factors".

(58) Although developed in the context of environmental ethics, precaution has wider applications and is more familiar than prudence in biomedical ethics (Resnik, 2004). Hence in this report precaution is paired with prudence for the scenario evaluation procedure of Sections 5–7 (Tables 2.4, 5.1, and 5.2). The precautionary principle involves two considerations: the probability of a harm and the strength of evidence for that harm. The principle states that when facing a small risk of serious and irreversible harm, policymakers should take preventive action, and that they should do so even in the face of uncertain evidence (Munthe, 2020).

(59) The ICRP has emphasised its rejection of strong interpretations of prudence and precaution: "neither prudence nor the precautionary principle should be interpreted as demanding zero risk, choosing the least risky option, or requiring action just for the sake of action" (ICRP, 2018a, Para. 48). A moderate interpretation of precaution is that we may rely on uncertain evidence in taking action to avoid serious harms for which there is at least some evidence (Munthe, 2011, 2020).

(60) While precaution and the related value of prudence in decision-making are defensible in general, questions remain about their application in terms of optimisation and dose limitation. How exactly are health risks to be balanced with possible economic and societal benefits? What level of certainty is needed for the adoption of certain dose levels as occupational limits or medical diagnostic reference levels? This issue has been identified as a topic for a new ICRP task group, Task Group 114, on "Reasonableness and Tolerability," established in 2019.

(61) In the clinical application of radiation, professionals are expected to apply precaution and prudence in both justification and optimisation, for example by weighing lifetime cancer risks against the clinical benefits of CT (Doria et al., 2006). In radiological and nuclear medicine imaging, for example, it is proposed to use alternative non-ionising radiation imaging where practical, especially for children; to reduce radiation exposure for follow-up exams, especially CT; to promote weight-based nuclear medicine dosing; in addition to a number of relevant steps to participate in quality assurance and dose registries. In radiotherapy, for example, the use of MRI to reduce the additional dose received in image acquisition for planning and in treatment verification is increasing, especially for children.

(62) To achieve optimisation in medicine, the dose must be adequate to answer the clinical question or achieve a meaningful therapeutic response (ICRP, 2013). Optimisation implies keeping patient exposure to the minimum necessary to achieve the required medical objective (diagnostic or therapeutic). In diagnostic imaging and x-ray-guided interventions, it means that the number and quality of images are adequate to obtain the information needed for diagnosis or intervention. In radiation therapy it is delivering the prescribed dose to the tumour whilst keeping the dose to the normal surrounding tissue within accepted tolerance doses. The common radiological protection concept of ALARA has to be interpreted in medicine in the context of a clinical goal. In radiation therapy, ALARA applies primarily to normal tissue. Use of ALARA out of this context may be misleading (ICRP, 2013).

(63) Precaution in the clinical context means taking an elevated lifetime risk of cancer of 1 in 2000 (as a single CT scan of the abdomen might imply) as a serious consideration in individual clinical decision-making. Health professionals may interpret 0.05% as a negligible addition in absolute risk terms to the already substantial lifetime risk of cancer and therefore consider procedures involving such a risk as "safe" (Lin, 2010). However, the fact that many patients will have to undergo repeated diagnostic procedures involving radiation results in a non-negligible population dose and a higher increased individual lifetime risk of cancer (Brower and Rehani, 2021). It should not be assumed that patients share the view that such risks are negligible. It is important to integrate precaution about radiation risk in clinical decision-making and informed consent. Prudence and precaution should not, of course, be misconstrued as stating that avoiding risk is an absolute value. Health professionals must consider justification, that is, the benefits of the medical intervention (in this case, the

diagnostic and management information from the CT scan). In the case discussed here, not performing a CT scan can lead to missed or delayed diagnosis of serious illness, to be balanced with the benefits (no radiation, lower costs, avoiding the diagnostic cascade).

(64) Key Message 8: The use of non-ionising radiation imaging where possible is prudent and good practice but must be balanced in the context of the individual patient needs and should not be detrimental to early diagnosis or accurate treatment.

2.2.4. Justice and solidarity

(65) The Commission recognises in *Publication 138* that justice is a broad concept, and focuses on distributive justice as "fairness in the distribution of advantages and disadvantages among members of communities".

(66) In biomedical ethics, distributive justice is important, for example, in the distribution of limited resources. In resource allocation, different values may govern a just distribution: maximising aggregate outcomes, improving the situation of the worst off, or achieving equality in opportunity or in outcomes, for example. Given these different possible just distributions, fair decision-making procedures must be followed to adjudicate them (Daniels, 1985). Procedural values are discussed in Section 2.2.5.

(67) In addition to distributive justice, different forms of justice come into consideration in biomedical ethics, including relational justice, social justice, and restorative justice. To capture these additional dimensions of justice, "solidarity" is a paired value with justice in the scenario evaluation procedure of Sections 5–7 (Tables 2.4, 5.1, and 5.2).

(68) Habermas described solidarity and justice as "two sides of a coin": "justice concerns the rights and liberties of autonomous, self-interested individuals, whereas solidarity concerns the mutual recognition and well-being of the members who are connected in the life world" (Ter Meulen, 2017). Solidarity, or "consideration of the common good", in health care refers to the efficiency and sustainability of the health care system for all and also to social relations of mutual recognition and support, including support for the most vulnerable.

(69) The health care provider must take into account not only the well-being of individual patients (according to beneficence, Section 2.3.1) but the effects of health care on others, including other patients and the general public, to ensure the efficiency and even sustainability of the health care system. This is an example of solidarity as the consideration of the common good (Prainsack and Buyx, 2012). Efficiency and sustainability are promoted by avoiding the overuse of imaging and addressing the ever-growing costs of overuse of technological improvements outside of the context where they provide clinical benefit.

(70) Interpersonal or relational justice requires recognising and addressing power imbalances between the health care professional and patient. These power imbalances can be due to the prestige of the professional role, imbalance in knowledge, and the medical condition of the patient. They can be exacerbated by additional power imbalances due to gender, class, and racial or ethnic relations of the individuals in the role. This has implications for the relationship between health professionals and patients. "Health care policies and arrangements should go beyond merely meeting needs and rights, by exploring how people's personal dignity and sense of belonging can be sustained within relations of recognition, reciprocity and support" (Ter Meulen, 2017, pp. 107).

(71) Social justice refers to promoting a just society by recognition of human rights to equitable treatment and assuring equal access to opportunities (ICRP, 2018a, Glossary). Considerations of social justice urge that special attention be given to the disadvantaged, as for example in a work of modern political theory that has been very influential in biomedical ethics

(Rawls, 1971), according to which "social and economic inequalities are to be arranged so that they are to be of the greatest benefit to the least-advantaged members of society." In just health care, the least-advantaged are those subject to health inequities, that is, differences in health that are unnecessary, avoidable, unfair, and unjust (Whitehead, 1991). Our responsibility is to take steps to enable disadvantaged groups to access and benefit from care, for example, with mobile imaging units that can reach rural and remote populations or with housing support for persons living with housing insecurity while receiving radiation therapy. As such, justice in the biomedical context also involves recognising and addressing the social determinants of health, such as housing insecurity, that generate health inequities (Daniels, 2007; Marmot, 2015).

(72) "Restorative justice," according to the *Publication 138* glossary, means "repairing the harm done to victims, communities, and the environment." This can include compensation for loss as in the case of medical malpractice, where loss, injury or harm to patients resulting from medical intervention is compensated. While causality between radiation and harm is difficult to define in case of diagnostic radiology, there are cases where the medical professional has to take responsibility to compensate for harm and to respond to claims from patients or their families. Acute reactions and discomfort resulting from radiation therapy are anticipated, and the emphasis is on reducing long term side effects as far as practicable. In the context of patient safety, restorative justice refers to repairing the trust damaged by adverse events through, for example, transparent communication and action to address the structural causes of medical harm (see Section 3.3.5).

(73) Key Message 9: Justice and solidarity reflect a balance between individual benefit, efficiency and sustainability, and equal access to health care for all.

2.2.5. Procedural values

(74) In *Publication 138*, the Commission recognises that a number of procedural and organisational aspects of the implementation of radiological protection are governed by ethical values: accountability, transparency and inclusiveness (stakeholder participation) are highlighted as closely inter-related and common to all exposure situations (ICRP, 2018a, Para. 66). Additional interpretations in the style of "paired values" are also provided for these procedural values (see Tables 2.4, 5.1, and 5.2) and explained in the following sections.

2.2.5.1. Accountability, transparency and honesty

(75) Key Message 10: Accountability is fundamental for clinical quality and safety. It involves continuing review of performance for improvement.

(76) In *Publication 138* accountability is defined "as the procedural ethical value that people who are in charge of decision-making must answer for their actions to all those who are likely to be affected by these actions" (ICRP, 2018a, Para. 67). The concept of accountability explicitly appeared in the general recommendations of *Publication 60* (ICRP, 1991) and was reaffirmed in the general recommendations of *Publication 103* (ICRP, 2007a), addressing hierarchical accountability within organisations and accountability of advisory and regulatory bodies to the parties affected by regulation. The procedural values of *Publication 138* have their clearest meaning in the context of enacting societal and institutional policies, however in clinical care, accountability and transparency are important both at the institutional level and at the level of individual professionals in relation to the patient.

(77) This report takes accountability in the clinical context broadly as an obligation of professionals who make decisions to answer to those who are affected by these decisions, centrally the patient. ICRP 60 states "There is also a retrospective component of responsibility, called accountability, that requires a continuing review of performance to be made so that failures can be identified and steps taken to prevent recurrence. Accountability implies the need to establish a programme of verification to determine how effectively the original objectives are being achieved" (ICRP, 1991).

(78) The Commission also "considered the accountability of the present generation to future generations" (ICRP, 2018a, Para. 68), which has been discussed above in the form of considerations for the sustainability of the health care system, including access to imaging and radiation therapy, as a matter of justice and solidarity.

(79) *Publication 138* notes that transparency "concerns the fairness of the process through which information is shared intentionally between individuals and/or organisations" (ICRP, 2018a. Para. 69), and that transparency and accountability are mutually supporting (ICRP, 2018a, Para. 75). *Publication 138* appeals to the definition of the International Standards Organisation (ISO), according to which transparency means "openness about decisions and activities that affect society, the economy and the environment, and willingness to communicate these in a clear, accurate, timely, honest and complete manner" (ISO, 2010).

(80) For the clinical context, the value of transparency (along with others) informs the procedure of informed consent (see Section 3.3.1; ICRP, 2018a, Para. 72), addressing the need of the patient for the disclosure of the information necessary for the exercise of their autonomy.

(81) Honesty is discussed in biomedical ethics as truth-telling or veracity. Veracity, as described by Beauchamp & Childress, is the "professional's duty to provide accurate, timely, objective, and comprehensive transmission of information, as well as the truthful ways professionals work to foster a patient's … understanding". The duty addresses not only autonomy but also the patient's vulnerability to the harm of being kept in ignorance about their clinical condition and its prognosis (Beauchamp and Childress, 2019, pp. 327–328; Malone et al., 2019, Sections 2 and 6).

(82) In this report honesty is presented as a "paired value" in the scenario evaluation procedure of Sections 5–7. Honesty is the personal and professional trait of fulfilling the duty of veracity: fostering an accurate understanding of the patient's medical condition on the part of the patient and, as appropriate, others involved in the patient's care. Honesty and transparency are shared responsibilities of professionals and institutions. Honesty is extensively discussed as the obligation to truth-telling in biomedical ethics (Hancock et al., 2007). Professional honesty must be exercised within the scope of protecting the privacy and confidentiality of the patient in discussions with third parties (see Section 3.3.2). Honesty demonstrates the trustworthiness of the health care professional and so supports the patient's trust (Higgs, 2007; Nie and Walker, 2015).

(83) Key Message 11: Honesty and transparency are shared responsibilities of professionals and institutions in all stages of the management and disclosure of adverse events.

(84) The degree and approach of communication will depend on the needs of each patient and family, which is explored in shared decision-making (see section 3.3.1). Although there are cultural norms of truth, it has both guided and been violated by medical practice in different cultures at different times (Nie and Walker, 2015). Patient and family perceptions of the culturally appropriate degree of disclosure may differ, and so it is important to inquire with the patient themselves (Freedman, 1993). In the disclosure of radiation risks and complications, it is important to consider the cognitive and emotional burden that inappropriate or excessive detail may have on a patient. Truth-telling includes empathy in attending to the manner of the

disclosure of information, by for example, having an appropriate degree of confidence in what is disclosed, preparing an appropriate setting for the patient to hear what is disclosed, ensuring the patient has the opportunity to have supporting friends and family present or available, being prepared for discussion of follow-up, and also being prepared to delay decision-making until the patient has absorbed information and is ready to make decisions (Beauchamp and Childress, 2019).

(85) Key Message 12: The degree and approach of dose, benefit and risk communication will depend on the needs and cultural background of each patient and family, which is explored in shared decision-making.

(86) Both transparency and accountability are important in continuous clinical quality improvement and the management of adverse events in health care (see Section 3.3.4). For example, disclosure of patient radiation dose estimates (already recorded in electronic medical records in developed nations) as a routine practice in diagnostic procedures and radiotherapy, as well as diagnostic reference levels at regional or national levels would serve transparency. Safety events (e.g. wrong patient dose, wrong protocol, wrong body part exposed) and near miss events are increasingly tracked for learning and systems improvement, including action and investigation by a radiation safety team (see Section 3.3.5). When appropriate, the information is available both at a population level and to the patient and their family.

(87) The most recent European Directive provides such guidance on the responsibilities '...wherever practicable and prior to the exposure taking place, the practitioner or the referrer, as specified by Member States, ensures that the patient or their representative is provided with adequate information relating to the benefits and risks associated with the radiation dose from the medical exposure." (European Directive of the Basic Safety Standards, 2013, Art. 57)

(88) Key Message 13: Radiation dose estimates should be recorded in a patient's Electronic Health Record (EHR). Patients should have access to doses they receive and have the dose explained just as they have access to medications, procedures, and health carer information in their health record.

2.2.5.2. Inclusiveness and empathy

(89) *Publication 138* describes inclusiveness as implemented by stakeholder participation, or "involving all relevant parties in the decision-making processes related to radiological protection" (ICRP, 2018a). It also describes the core values (justice and dignity) that are supported by stakeholder participation: it "is an effective way to take into account their cultural values, concerns and expectations as well as their knowledge about the issues at stake. It is also an opportunity for dialogue between professional and patient and/or public stakeholders to better understand what is at stake with the exposure situation. This in turn enables adoption of more effective, sustainable, and fair protective actions promoting empowerment and autonomy of stakeholders. Participation of all stakeholders in the operation and maintenance of medical facilities, among others, has proven to be an effective way to keep occupational and patient exposures as low as reasonably achievable (ALARA)" (ICRP, 2018a).

(90) Meaningful participation of stakeholders is based mainly on inclusiveness; the value of inclusiveness requires that affected individuals or groups are brought into the process and that active steps are necessary to include those whose voices may be excluded by systemic biases and by marginalisation.

(91) Empathy is introduced in this report in relation to inclusiveness because of its critical importance in understanding the needs and perspectives of the patient and their families and in building trust. Involving the patient and family in decision-making is one way to be inclusive; this is already emphasised with the paired core values of dignity and autonomy. Empathy for patient and carers' perspectives is another path to inclusiveness that is particularly relevant in the clinical context.

(92) In the clinical context empathy has been defined as "the competence of a [health professional] to understand the patient's situation, perspective, and feelings; to communicate that understanding and check its accuracy; and to act on that understanding in a helpful therapeutic way" (Derksen et al., 2013).

(93) This definition encompasses affective, cognitive and behavioural components. "The affective component refers to one's ability to perceive subjectively another person's inner experiences and natural feelings. The cognitive component of empathy relates to the capacity to understand and view the outside world from the other person's perspective. The behavioural component includes the predisposition and competency to adequately create a bond with the other person together with the ability to communicate these understandings and feelings to reassure and comfort the other." Recent research shows lack of correlation between patient assessment and physician self-assessment of empathy, emphasising the importance of patient feedback. This research also looks at trainees and highlights the importance of early education in these skills (Bernardo et al., 2018; Bernardo et al., 2019). An institutional commitment to empathy in clinical care is important to allow radiological professionals the time and flexibility to respond to patient's emotions and perspectives.

(94) In the context of radiological protection in medicine, empathy means that the concerns of those affected, their needs and wishes should be taken seriously and discussed with them, even if they are considered unfounded or exaggerated (Zölzer, 2016; Zölzer and Zölzer, 2020). Empathy can be taught and learned (Platt and Keller, 1994; DasGupta and Charon, 2004; see also Section 8), so that it is possible to frame it as something which should be expected of a health professional and which every professional should continuously strive for. Empathy has also been shown to improve patient satisfaction with care, diagnostic accuracy, and outcomes (Derksen et al., 2013).

(95) Key Message 14: Empathy improves patient satisfaction with care, diagnostic accuracy, and treatment outcomes. Empathy can be taught and learned and every health professional should continuously strive to achieve it.

(96) Empathy is also a corrective to a possible over-emphasis on rights and obligations in traditional ethical theory, which has been emphasised in the ethics of care, arising from feminist bioethics (Gilligan, 1993; Beauchamp and Childress, 2019). Care ethics highlights the perspectives of comforters and carers, which "center… on responsiveness in an interconnected network of needs, care, and prevention of harm …. [and] stress an empathic association with others and a strong sense of responsibility" (Beauchamp and Childress, 2019). It also highlights the concerns and needs of comforters and carers for societal acknowledgement and support (Tronto, 1993). This can extend to the needs and concerns of radiological professionals.

(97) Empathy is a window into beneficence and non-maleficence from the perspectives of every involved person. It has been considered as the starting place for solidarity (Prainsack and Buyx, 2012).

3. THE PRACTICAL IMPLEMENTATION OF BIOMEDICAL ETHICS

(98) In providing patient care and managing clinical services, health care providers often face questions not just about their technical skills and scientific knowledge but about values, rights, and responsibilities (Williams, 2015). The previous section relates the core values of radiological protection to how these values are understood in current biomedical ethics, the relationship between the health professional and the patient, and the organisation of health care systems at a societal level. This section describes key developments in clinical practice that implement the core values of biomedical ethics. The values of biomedical ethics are implemented by institutional, national, and international ethics committees and through Codes of Ethics that have been adopted by national and international professional societies. They are also implemented in clinical practice developments such as in shared decision-making and in movements for the improvement of patient care. Health care professionals navigating scenarios such as those presented in Sections 6 and 8 should reference their Codes of Ethics and relevant guidance produced by ethics bodies. They may also benefit from assistance from institutional clinical ethics committees.

3.1. Professional oaths and codes of ethics

(99) The values and approaches to practice required by biomedical ethics are essentially global, rooted in a long-respected tradition, and predicated on the need for ethical sensitivity in the way patients are treated and how treatments are delivered (Zölzer, 2013; Malone and Zölzer, 2016; Malone et al., 2019, Sections 2, 3, and 6). Compliance with a mature system of biomedical ethics expressed in Codes of Ethics is a non-negotiable starting point for medical care in fields such as medical imaging procedures and radiotherapy.

(100) Historically, biomedical ethics was expressed in physician oaths in many cultures (Baltussen, 2015). The Declaration of Geneva developed by the WMA brings a modern perspective to the medical oath (WMA, 2018a). It emphasises the humanitarian aspects of medicine, enjoins respect for the individual patient, the community, and the environment, and advises doctors to also look after their own health. The document was first adopted in 1948, and amended several times over the years. Its latest version, published in 2018, introduced well-being of both patients and physicians for the first time (WMA, 2018a). The WMA has also issued a series of ethical and social policy documents on various topics, e.g. patients' rights, patient safety, end of life care, and emerging new issues. These have been summarised in their biomedical ethics Manual (Williams, 2015).

(101) Key Message 15: Professionals in radiological protection in medicine are expected to adhere to their organisation's Codes of Ethics, which may include values of accountability, transparency, safety, and patient-centeredness.

(102) Many national bodies maintain Codes of Ethics that serve as a foundation for professional regulation, whereby governments work with or entrust professions to ensure discipline and maintenance of standards of practice of their members, as well as their accountability to public concerns. Professionals in radiological protection are increasingly adopting Codes of Ethics. International models include the Code of Ethics of the ICRP (ICRP, 2014) and of the International Society of Radiographers and Radiographic Technologists (ISRRT, 2022) and the ESTRO Radiation Therapist Code of Ethics and Conduct (ESTRO RTT, 2022). National associations are following suit or leading the way, such as the New Zealand Medical Radiation Technologists Board (MRTB, 2019), the Canadian Organisation of Medical

Physicists (COMP, 1997) or the American Association of Physicists in Medicine (Skourou et al., 2019).

(103) Modern Codes of Ethics typically articulate the profession's responsibility to patients, to society, to colleagues, and to oneself. There is a commitment to lifelong learning and to service to others. Some themes in the radiological protection professions' codes of ethics include maintaining competence, advancing the scientific basis of practice, practising within scope[3], supporting sustainability of the health care system, protecting patient confidentiality, intervening in unsafe or abusive practice, collaborating with the medical team for patient-centred care, and avoidance of conflict of interest, for example. When addressing an ethical dilemma is the context of team care, appeal to the responsibilities enshrined in Codes of Ethics can often ground practitioners in shared commitments. However, ethical dilemmas arise when responsibilities conflict; hence practitioners need a deeper understanding of the values behind codes of ethics. Recourse to ethics committees and advisory bodies can also assist where the application of Codes of Ethics is not straightforward.

(104) Key Message 16: Consult national or international Codes of Ethics for your profession for a concise statement of the core ethical values guiding practice.

3.2. Role of international, national and institutional ethics committees

(105) International ethics committees have been established by some inter-governmental or non-governmental scientific and professional bodies, such as the WMA (WMA, 2015, 2022b), Council of Europe (Council of Europe, 2022), and UNESCO (UNESCO, 2010a). They are platforms for coming to an international consensus on foundational and emerging issues in bioethics. Similarly, the WHO ethics office undertakes this work (WHO, 2022a).

(106) UNESCO recommends establishing national and institutional ethics committees after its 2005 Universal Declaration on Bioethics and Human Rights, and it supports countries to do this with educational and policy resources (Ten Have et al., 2011).

(107) National ethics committees advise government, national bodies/institutions, and inform the general public about biomedical ethics. They provide national policy on newly arising ethical issues in the context of the cultural background of the country. They analyse and offer conclusions and recommendations about bioethical issues and the ethics of health more generally, especially as such issues influence potential needs to develop national policies and to adopt legislation (UNESCO, 2010b).

(108) Health care facilities and systems may have "clinical ethics committees" or ethicists (sometimes called "ethics consultants") who formally consult on ethical dilemmas, with the possibility of referral to the interdisciplinary discussion of the full clinical ethics committee. Ethics committees are independent, interdisciplinary, and pluralistic teams that provide education, policy development and case consultation to enhance the capacity of professionals and institutions to deal with common ethical situations and novel ethical dilemmas in their practice (Pegoraro and Petrini, 2016).

(109) It is useful to understand the basic procedure used in ethics consultation, to inform readers in working through the sensitising scenarios of Sections 6 and 7. Ethics consultation commonly proceeds by gathering medical and psychosocial facts relevant to a dilemma, including identifying people for whom the ethical decision has an effect and involving them in

[3] 'Scope of practice' refers "…to those activities that a person licensed to practice as a health professional is permitted to perform, which is increasingly determined by …rules adopted by the appropriate licensing [or regulatory] entity" (https://www.ama-assn.org/practice-management/scope-practice/what-scope-practice).

the process. Then the specific ethical issues arising in the scenario and the values at stake are identified and analysed. Ideally, more than one possible solution to the problem is developed, to address the risk of confirmation bias. These are then evaluated, soliciting the perspectives of those affected by the decision, to refine the options and arrive at a solution. (Pedersen et al., 2009). The process of clarifying values, finding common ground, and discovering clinical possibilities that had not previously been considered, leads to satisfactory resolutions, learning, and growth in ethical understanding. Sometimes the solution is difficult to implement because not everything that matters to those involved in the dilemma can be fully addressed. Addressing the "moral residue" through education or policy change may also be a function of ethics consultation (Fiester, 2015).

(110) Consultation can also be valuable even when it does not change what the clinicians consider to be the correct course of action. It can provide reassurance, build consensus, and improve communication with those who might otherwise think that the decision was inappropriate (McLean, 2007).

(111) The perspective of radiological protection should also be represented in national and international policy work when they comment on relevant developments in the use of radiation in diagnosis and treatment. If ethical issues concerning the medical use of radiation arise in local clinical practice, specific technical support can be requested on an "ad hoc" basis. If such issues are common, the Commission strongly recommends including a radiological protection expert in the committee. This report can serve as a resource to ethics committees and to radiological protection professionals joining ethics committees.

(112) Key Message 17: National and international ethics committees provide policy guidance for emerging ethical issues. Local institutional ethics committees provide guidance and education on specific dilemmas in practice.

3.3. Clinical practice developments

(113) In the last decades, specific clinical approaches to the practical implementation of ethical values have been developed (Malone and Zölzer, 2016; Malone et al., 2019). Each of the Principles of Radiological Protection integrates and balances several ethical values (ICRP, 2018a). In a similar way, clinical approaches to informed consent (Section 3.3.1), privacy and confidentiality (Section 3.3.2), end of life care (Section 3.3.3), professionalism (Section 3.3.4), and patient safety (Section 3.3.5) involve integrating and balancing ethical values. These developments are often specific to clinical and national contexts. Understanding the broad outlines of these clinical developments assists in the ethical evaluation of clinical scenarios. Considerations drawn from these clinical approaches are given as examples in Table 5.2 of Section 5, which presents "sensitising questions" to assist in the interpretation and application of ethical values (Table 5.1) in the clinical scenarios of Sections 6 and 7.

3.3.1. Informed consent, incapacity, shared decision-making, and patient-centred care

(114) Legally, the requirement of respect for autonomy (considered by *Publication 138* to be derived from respect for dignity) has been specified in the requirement to seek and respect patient's informed consent or refusal of medical interventions: that patients be informed of the risks and benefits of a proposed intervention (treatment or diagnosis) and its alternatives, including the alternative of doing nothing, that they understand and appreciate the information provided, and that they are free to make a decision without coercion. Informed consent is

supported by the procedural value of transparency. In different national settings, law has established different standards of disclosure (for example, physician-centred or patient-centred standards) and possibilities for considering consent to be "implied," for example when the patient presents for diagnostic studies and a general understanding of their risks and benefits can be assumed.

(115) In the contemporary shared decision-making model in patient-centred care, patients are asked their preferences for their role in decision-making, and clinicians actively elicit patient values and help to interpret medical information in light of the patient's values and context, through a two-way exchange of information (Charles et al., 1999). This exchange of information helps to ensure that transparency is balanced with empathy, while empathy is informed by a clear understanding of the concerns of the individual patient.

(116) Shared decision-making for diagnostic and therapeutic procedures is often a key element in radiological protection in the clinical context (IAEA, 2011; Malone et al., 2012). Consent for diagnostic procedures is sometimes considered "implicit," but there is little evidence that patients can be assumed to have prior knowledge of the risks of different diagnostic procedures (Ribeiro et al., 2020). There is discussion in radiology about the appropriate manner of achieving transparent understanding of benefit/risk for diagnostic exams (Picano, 2004; Brink et al., 2012; Semelka et al., 2012). There is growing awareness that ethics and law support improving transparency by communication and education (IAEA/WHO, 2014; Doudenkova and Bélisle Pipon, 2016). The Imaging Wisely and Imaging Gently campaigns provide materials to assist in communicating risk in the context of clinical benefit (Image Gently, 2007; Image Wisely, 2014). This includes improving consent for radiation exposure in interventional radiology (Zener et al., 2018).

(117) Informed consent in radiotherapy is complex. As the majority of patients referred for radiation therapy have been diagnosed with cancer they are at a vulnerable point in their lives. Research has shown that a significant percentage of patients have a negative perception of radiation therapy partly as a result of media reporting of radiation incidents in the past and partly historical reports of severe side effects and poor outcomes. However, research reveals post treatment the vast majority of patients were more positive with regard to treatment and felt that more information would have eased their concerns. Whilst the radiation oncologist is key in providing information, initially it is important to bear in mind that radiation therapy is delivered over many weeks and that the concerns and information needs of patients evolves over that time period. It is important therefore that the health care team responsible for treatment preparation and delivery address patients concerns and information needs on an ongoing basis until treatment is completed and during the initial follow up period (Gutiontov et al., 2021).

(118) Practical approaches to respect for autonomy in situations where patients lack the capacity for informed consent have been defined by law in many countries. Health care professionals must be aware of their local legal and cultural context. They should also be aware of the evidence that patients with psychiatric conditions (Okai et al., 2007) even in the in-patient setting often retain capacity for medical decision-making.

(119) A woman who is already pregnant presents a substantial ethical dilemma particularly in the case of high dose diagnostic procedures or radiation therapy (ICRP, 2000). A woman of childbearing age should be provided with full information on the risks associated with radiation exposure or, in the case of high dose imaging procedures or radiation therapy, the risk to the ova and possible implications for future childbearing. Where a pregnancy is known or suspected the woman should be provided with information on the risk associated with radiation to the foetus, the possible effect on the continued pregnancy and the long-term well-being of the child. The information given should be relevant and in accordance with the level of risk. For instance, it is important to note that foetal doses below 100 mGy should not be considered

a reason for terminating pregnancy and poses little risk to the foetus (ICRP, 2000). The question of involving the pregnant person's partner or the father of the foetus in decision-making can be a sensitive issue, especially in contexts where women's rights are not well respected. In any case, shared decision-making with the family and the medical team, including radiation experts, is particularly important (IAEA, 2011; IAEA, 2018).

(120) The developing capacity of children is recognised in the process of seeking their "assent," or expression of agreement, for medical procedures (WHO, 2016). This approach recognises that the capacity of children and adolescents to understand and appreciate health choices is partially equivalent to that of adults before they reach a formal/legal age of majority (Grootens-Wiegers et al., 2017). Seeking paediatric assent involves providing age-appropriate information and seeking agreement, even when full informed consent is not yet possible. It involves addressing paediatric patients directly, rather than through their caregivers. The extent of the parent involvement in consent for paediatric patients depends on the age and maturity of the patient. The manner and scope of this may differ in different jurisdictions. In some, there is a specified age at which minor patients provide their own consent; in others, there is no formal minimal age and the health care team must judge the adolescent patient's maturity.

(121) The values of patient dignity and autonomy continue to inform medical decision-making when patients temporarily or permanently lose decision-making capacity. In an emergency situation in which it is not possible to ascertain the patient's wishes or goals of care, the value of human life takes precedence and treatment is initiated to restore the patient to a state in which they can participate in decision-making or family and carers can be found and involved in care decisions. When the patient is unable to take in information or communicate, the healthcare team must decide which treatment decisions if any can be delayed until the patient can take part. Where the patient's own values and prior expressed wishes for medical treatment are known or available, these should guide decisions that are made on their behalf. The WMA Declaration on the Rights of the Patient expresses the duty of the health care professional to consult the patient's legally entitled representative. An advance directive document can also detail the patient's specific treatment choices and general values. Where the patient's own choices and values are not known, a medical "best interests" judgment may be required (Williams, 2015, pp. 47–51).

(122) Key Message 18: Shared decision-making for the use of medical radiation underpins patient-centred care and involves transparency about the nature of radiation and its benefits and risks. All stakeholders should play a role.

3.3.2. Privacy, confidentiality, and the stewardship of health information

(123) Patient privacy and confidentiality are expressions of respect for human dignity and autonomy and have a long history in biomedical ethics. In radiotherapy and imaging, respect for privacy is also expressed in techniques that minimise positioning discomfort and partial uncovering of a patient's body while achieving the clinical goal of the procedure in a safe manner, the presence of a family member or a language translator, and in the distance between the changing room and the treatment room. The general physical layout of the imaging/radiotherapy clinic should ensure the patient's bodily privacy, provide adequate bathrooms, waiting areas, and also the opportunity to answer questions and receive clinical information in a discreet setting without other patients and staff unrelated to their care being privy to information exchange (Dilauro et al., 2016).

(124) In caring for adolescents, failure to provide paediatric patients with privacy can be a barrier to full disclosure of medically important information about substance use and sexual

activity. At all ages, failure to respect children's privacy can be a barrier to disclosure of parental abuse (WHO, 2017a).

(125) The traditional medical practice's commitment to the sanctity of patient confidentiality, the commitment to share this patient information only to the extent necessary (e.g. consultation, family discussion, billing) has been adapted in the modern world through health privacy laws that address the ownership of and right to access health information, the need for sharing health information within the clinical team for care and increasingly, within the institution for quality assurance and improvement, and the implications of electronic health records. The use of health information including images for education and research requires special procedures of anonymisation and/or consent (Draper and Rogers, 2013). The use of artificial intelligence and machine learning are rapidly developing in both diagnostic imaging procedures and radiotherapy. These areas show improvement in standardisation and optimisation of imaging protocols (Mukherjee et al., 2020; Pinto et al., 2021) yet specific national validation and ethical oversight have yet to be put in place (Larson et al., 2021; Elmore 2022). As technology and research practices evolve, and the integration of imaging databases with inherently non-anonymisable genetic data, the stewardship of patients' private health information continues to require careful thought and consideration of basic ethical values.

(126) Key Message 19: Respect for privacy that is consistent with achieving diagnostic and treatment aims and respect for confidentiality in handling all patient information, including images, are important for respect for dignity and autonomy.

3.3.3. End of life care

(127) Dilemmas arise at the end of life around when to continue and when to cease medical diagnostic or therapeutic interventions aimed at a cure (Santos et al., 2022), and what degree of imaging is appropriate to diagnose and monitor disease progression when the goals of care have shifted to palliative, with absolute respect for the autonomy and dignity of the patient. Clarification of the patient's goals of care is an increasingly important aspect of informed consent.

(128) At the end of life, reducing stochastic effects of radiation becomes less important. Imaging may be useful to help patients and families understand the medical prognosis. At the same time, imaging that is painful and disruptive for very ill and dying patients should be avoided when it will not benefit the patient by affecting clinical management. The values of non-maleficence and prudence in these cases point us to considerations of minimizing patients' physical and psychological distress.

(129) Treatment that does not directly benefit the patient but avoids or delays communication of a poor prognosis is unacceptable. As an example, a long course of palliative treatment based on reimbursement is unacceptable when a short course would give equal benefit. Patients cannot make their own treatment decisions without a realistic understanding of their own disease trajectory and the availability of palliative options. Where direct communication of imminent death is culturally inappropriate, there are often culturally appropriate ways (e.g. through the family) to communicate the harmfulness of continuing intervention (Nie and Walker, 2015). Truthful disclosure should be offered, given the risk of stereotyping in inferring an individual patient's preference from their cultural identity (Freedman, 1993).

(130) Patients and families may require time to come to the understanding that treatment options have been exhausted. Efforts at supportive communication should be extensive before

unilateral judgments of so-called "medical futility" (interventions that provide no benefit for the patient in any sense, whatever their values) are made.

(131) Medical decision-making in end-of-life care often involves patients and their support networks including families and carers. Those who at first support patients in making their own decisions sometimes transition, when patients can no longer speak for themselves, to carrying the legal responsibility for representing the patient's values and wishes. "Advance care planning (ACP)" has recently been formalised in various regions as a process where patients can develop an explicit plan considering a future where they come to be incapable of expressing their own will. In some settings the palliative care physicians are part of the initial multidisciplinary team easing the transition from cure to palliation for the patient if this situation arises.

(132) When families and carers do carry legal responsibility, empathy for the challenges of their role and transparency in the information needed for them to make decisions are important. Collaboration and referral help to ensure that end of life decision-making is voluntary as patients and their families/carers can be fully informed of the risks and harms of pursuing the goal of extending life, and the availability of palliative care options. Knowing that the family's or carer's role as legally entitled representative (Williams, 2015) is to represent the wishes and values of the patient, and knowing what these wishes and values are, mitigates their distress (Su et al., 2020). Even where the family and other carers do not have legal responsibility for decision-making, they can provide the medical team with crucial information about the values and life situation of the patient.

(133) The determination of brain death becomes important when treatment options are exhausted or when organ donation is contemplated. This determination may involve imaging. Current international consensus indicates the ancillary, but not diagnostic, role of digital subtraction angiography (conventional 4-vessel cerebral angiography) and alternative radionuclide or Doppler transcranial ultrasonography exams in confirming and communicating clinical determination of brain death (Greer et al., 2020).

(134) Key Message 20: Developing a shared understanding of shifting goals of care is especially important to good shared decision-making in end-of-life care.

3.3.4. Professionalism and financial influences on medical decision-making

(135) Medical professionalism has been rooted in ancient physician's oaths and their modernised versions (WMA, 2018a; see Section 3.1). The commitment of a health profession to the primary good of the patient is the basis for "clinical autonomy" and "profession-led regulations" (WMA 1987, replaced by WMA 2018b, 2019).

(136) In the 1990's worldwide concerns about the role of financial influences in medical decision-making led to the professionalism movement, which sought to re-affirm the primary medical commitment to the well-being of the patient, and the importance of transparency around these influences. In radiological protection, avoidance or management of conflict of interest may include guidance for or tight control on physician ownership of diagnostic and treatment equipment. It also includes prohibition of personal benefit from referral relationships. In radiation therapy the increased financial benefit at the institutional level can result in patients having an extended course of treatment, for instance if payment is by treatment fraction rather than treatment course. While the specifics vary across jurisdictions, the common ethical goal is to ensure that clinical decisions are made in the best interests of the patient and not for the gain of health care professionals and institutions, for trustworthiness, accountability, and transparency (WMA, 2019). Ten years of public disclosure of industry payments to physicians

as required by the US Physician Payment Sunshine Act has not reined in the use of so-called consulting fees to influence physician judgment and practice, raising questions about the burden this approach places on patients to research and evaluate their physicians' financial arrangements and the effectiveness of this approach (Adashi et al., 2022).

(137) These concerns about professionalism grew into a movement in medical education to inculcate a core commitment to maintaining life-long professional standards (Brennan et al., 2002), along with other practice-based "competencies," such as practice-based learning and improvement, systems-based practice, and communication skills (Amis, 2008).

(138) The understanding of competence as "the habitual and judicious use of communication, knowledge, technical skills, clinical reasoning, emotions, values, and reflection in daily practice for the benefit of the individual and community being served" (Epstein and Hundert, 2002) is reflected in the value of prudence as defined in *Publication 138*. The definition of competencies not only informs health care education, but also practice evaluation. Professionalism also provides a way of internalisation of ethical values and safety culture during education and training (see Section 8).

(139) Key Message 21: Avoiding and managing conflict of interest contributes to medical services and decisions that are focused on the good of the patient.

3.3.5. Radiological safety culture and patient safety

(140) *Publication 138* defines radiological protection culture as "the knowledge and skills enabling each individual to make well-informed choices and behave wisely when directly confronted with radiation" (ICRP, 2018a, Para. 80), focusing on the aspect of decision-making shared by experts and lay people, reflecting on planned, existing, and emergency exposure situations.

(141) Image Gently and Image Wisely as radiation protection campaigns predated the broader Choosing Wisely movement, "to promote conversations between clinicians and patients by helping patients choose care that is: supported by evidence, not duplicative of other tests or procedures already received, free from harm, and truly necessary" (Choosing Wisely, 2012) This reflects both beneficence and solidarity, or the efficiency and sustainability of the health care system.

(142) This has led to a growing number of regional and national radiological protection campaigns, geared toward radiation professionals, referring physicians, institutions, and the public (EuroSafe, 2014; Image Wisely, 2014; ArabSafe, 2017; CanadaSafe, 2017; AfroSafe, 2018). These campaigns promote appropriateness in radiological imaging, contribute to the promotion of the concept of clinical diagnostic reference levels, promote the use of up-to-date equipment, and improves communication with patients.

(143) The IAEA have facilitated a "radiation safety culture" through the Bonn Call to Action and by providing a handbook to facilitate this concept (IAEA/WHO, 2014; IAEA, 2021). It defines "safety culture" as "The assembly of characteristics and attitudes in the organisations, its managers and workers which assures that, as an overriding priority, safety issues receive the attention warranted by their significance."

(144) In the early 2000s international organisations declared "patient safety" in health care settings to be an obligation of health care professionals (WHO, 2002; WMA, 2022a), and incident reporting systems fostering a cultural framework has been recommended (Aspden et al., 2004). The patient safety movement integrates core and procedural ethical values, including non-maleficence, dignity, accountability, transparency and honesty, into an approach to

avoiding and remediating adverse events. This movement is highly pertinent to radiological protection workers (WMA, 2022a).

(145) The 1999 US Institute of Medicine (IOM) (Kohn et al., 2000) spurred quality and safety policy leaders internationally to begin a series of initiatives to address errors in health care that continues today. The advent of intensity-modulated radiation therapy (IMRT) in the 1990s posed risks of accidental exposure whose consequences went beyond previous radiation therapy modalities (Bogdanich, 2010) and required a comprehensive response with a patient safety lens (ICRP, 2009). The patient safety perspective identifies adverse events that arise from systems factors, and proposes a 'fair and just culture' to prevent blaming of individuals and encourage workers to report safety concerns or events so that managers can effectively review and improve processes of care for future patients (Frankel et al., 2006). This requires moving away from health care's traditional hierarchical culture toward new collaborative structures. All stakeholders learn some level of skill in team building and in qualitative and quantitative approaches to quality/process improvement. Further, a fair and just culture is an environment where workers feel emotionally safe to speak about safety concerns, and both leaders and workers are willing to examine their own role in safety events and how to improve systems of care.

(146) The patient safety movement promotes hospital safety metrics tracking and public reporting. These data should be sufficiently detailed to enable learning and to inform practice improvement (ICRP, 2009; IAEA-SAFRON, 2012; IAEA-SAFRAD, 2019). Patient Safety also promotes a transparent approach to communication with patients and informal carers in both adverse events and when appropriate, "near misses" as a matter of accountability (Evans and Decker, 2011; Brown et al., 2012).

(147) Radiation safety culture is harmonious with the broader concept of patient safety. Radiation safety culture is integral to delivery of quality and safe health care (WHO/IRPA/IOMP/IAEA, 2022). It can be understood as a combination of habits and knowledge of "radiological protection in all its aspects for workers, patients, population and the environment, and in all exposure situations, combining scientific and social dimensions" (IRPA, 2014). Culture "is the product of individual and group beliefs, values, attitudes, perceptions, competencies, and patterns of behaviour that determine the organisation's commitment to quality and patient safety" (U.S. Joint Commission, 2021). It is important also to recognise that culture is learned, passed on and changed by a pattern of basic assumptions, cultural paradigm, and by groups of people who share significant problems, have solved them, observed the effects of their solutions, and who have taken in new members (IRPA, 2014). In order to provide radiation safety for workers, the public, and patients, a strong safety culture based on ethical principles is foundational.

(148) Health professionals working with radiation have contributed to defining the elements and traits of a radiation safety culture that includes a pattern of knowledge (embracing scientific, technical, ethical, historical and practical elements) together with behaviours on the basis of questioning attitude, personal responsibility, integrity, modesty, involvement with interested parties, openness and adaptability, transparency and exemplary behaviour (Cantone et al., 2018). Radiation safety culture is present in medicine when health workers take an active role in ensuring safe and appropriate use of radiation, when the facility supports these cultural values, and takes into account additional factors such as:

- the alternative use of non-ionising radiation imaging where practical, for example when imaging children;
- the accreditation of all medical equipment;
- establishing an internal reporting and learning system from incidents/near miss incidents and sharing information with the wider radiation community;

- in reporting incidents of defined severity in medical radiation dose or equipment, to national incident databases;
- in considering inspections to evaluate the status or radiation safety culture in the facilities, as diagnostic imaging, nuclear medicine, and radiotherapy (EC 1996; IRPA, 2014).

(149) The U.S. National Regulatory Commission (NRC) stated that all organisations and individuals should take the necessary steps to promote and maintain a positive safety culture and developed a summary table of necessary elements (Table 3.1). (U.S. Nuclear Regulatory Commission, 2011). NRC identified nine behavioural elements of a positive safety culture in its *Safety Culture Policy Statement* that could help the professionals to focus their actions by knowing which elements are weak or missing.

Table 3.1. Nine behavioural elements of radiological protection culture according to the US Nuclear Regulatory Commission (NRC). Available at: https://www.nrc.gov/docs/ML1528/ML15280A097.pdf.

Leadership Safety Values and Actions	Problem Identification and Resolution	Personal Accountability
Leaders demonstrate a commitment to safety in their decisions and behaviors.	*Issues potentially impacting safety are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance.*	*All individuals take personal responsibility for safety.*
Work Processes	**Continuous Learning**	**Environment for Raising Concerns**
The process of planning and controlling work activities is implemented so that safety is maintained.	*Opportunities to learn about ways to ensure safety are sought out and implemented.*	*A safety conscious work environment is maintained where personnel feel free to raise safety concerns without fear of retaliation, intimidation, harassment or discrimination.*
Effective Safety Communications	**Respectful Work Environment**	**Questioning Attitude**
Communications maintain a focus on safety.	*Trust and respect permeate the organization.*	*Individuals avoid complacency and continually challenge existing conditions and activities in order to identify discrepancies that might result in error or inappropriate action.*

(150) It should be noted that "patient safety" is not only the issue of minimising risk (non-maleficence). In the decision-making process, health professionals have to consider and integrate all the aspects of ethical values to promote patients' well-being. *Publication 138* clarifies the ethical values that informed the principles of justification, optimisation and limitation. Their integration is a continuous process in which professionals "act virtuously while taking into account the uncertainties associated with the effects of low dose, and to evaluate the criteria for judging the adequacy of these actions. In practice, the search for reasonable levels of protection (the principle of optimisation) and tolerable exposure levels (the principle of limitation) is a permanent quest that depends on the prevailing circumstances in order to act wisely – in other words, with the desire to do more good than harm

(beneficence/non-maleficence), to avoid unnecessary exposure (prudence), to seek fair distribution of exposure (justice), and to treat people with respect (dignity)" (ICRP, 2018a).

(151) As ethics is therefore clearly a part of radiological safety culture, appropriate education and training in ethical values for health professionals is necessary. In addition, the patient, the public and other stakeholders require information and engagement from professionals in sustaining a radiological safety culture.

(152) Key Message 22: Radiological safety culture incorporates the knowledge, skills, attitudes and behaviours that underpin informed choices and shared decision-making by experts and lay people in the context of "radiological protection in all its aspects for workers, patients, population and the environment, and in all exposure situations, combining scientific and social dimensions" (IRPA, 2014).

4. MEDICAL USE OF IONISING RADIATION AND ETHICAL CLINICAL DECISION-MAKING

4.1. Basics of medical radiological protection and its links to ethics

(153) This section is particularly dedicated to people with knowledge in clinical ethics who want to learn about the types of health effects of ionising radiation and their potential influence on decision-making processes involving ethical issues. It starts by describing stochastic effects, which can appear after any dose, and involve cell transformation that can lead to cancer or hereditary effects. Next, tissue reactions are discussed, that only appear above a certain dose threshold when cells death affects tissue functions, becoming clinically observable. Finally, the main factors that can cause different individual responses to radiation and the uncertainty associated with radiation risk assessment are discussed.

4.1.1. Stochastic effects

(154) Despite efficient DNA repair mechanisms, radiation exposure can induce mutations that might result in the development of disease after a long latency period (years to decades, or even generations). Effects of this nature are termed "stochastic" and include radiation-induced cancer and hereditary effects. In the case of cancer, epidemiological and experimental animal studies provide evidence for a dose-dependent increase risk, albeit with large uncertainty at absorbed doses of about 100 mGy or less (Rühm et al., 2022). In the case of hereditary effects, there is no direct evidence of radiation risks to humans, but animal experiments (mainly with drosophila flies and mice (Muller, 1927) suggest that such risks for future generations should be considered. The decision to accept a stochastic risk made by patients or by somebody else on their behalf may, at certain life stages, have implications in relation to possible descendants, depending on patients´ reproductive intentions and potential.

4.1.1.1. Linear-non-threshold model

(155) At low dose and low dose rate, the dose-effect relationship that could be deduced solely from epidemiological evidence is too uncertain to be unequivocally defined. However, based on a conjunction of epidemiological, animal, and cellular data, it appears increasingly reasonable to linearly extrapolate the high dose and high dose rate risk to the low dose and low dose rate region. In general, the result is adjusted by a dose and dose-rate effectiveness factor (DDREF). Currently, the Commission recommends to apply a DDREF = 2. In other words, the associated risk at low doses and low dose-rates is two times lower than what it would be with a simple linear extrapolation from high dose and high dose rate domain.

(156) This approach is known as the linear-non-threshold (LNT) model (ICRP, 2005). In practice this means that the Commission (ICRP, 2007a) assumes for radiological protection purposes that a given increment in dose will produce a directly proportionate increment in the probability of incurring cancer or hereditary effects attributable to radiation. It may well be that the LNT model does not truly reflect the biological reality, but the Commission considers the LNT as the best practical approach to managing risk from radiation exposure at low doses and low dose rates. This reasoning is based on the ethical value of prudence which, in the context of medical exposure does not oblige one to choose a procedure associated with the lowest dose. Rather, the prudent professional makes informed and carefully considered choices without the full knowledge of the potential risks. This is commensurate with the "precautionary principle",

which can be invoked because low dose radiation exposure concerns a large number of people and the number of medical procedures during the lifetime can be numerous.

(157) The validity of the LNT model as used in radiological protection has been substantiated in 2018, in a commentary report from the United States National Council on Radiological Protection and Measurement (NCRP), based on the most recent epidemiological cancer data, which concluded that "no alternative dose-response relationship appears more pragmatic or prudent for radiological protection purposes than the LNT model" and that the LNT model should continue to be used for radiological protection purposes (NCRP, 2018a). However, this explicit reference to the ethical values of non-maleficence and prudence is questioned by certain authors who claim that LNT is overly conservative (Ulsh, 2018).

(158) Key Message 23: ICRP considers the linear-non-threshold (LNT) model as the best practical approach to manage stochastic risks from radiation exposure. This is based on the ethical values of prudence/precaution.

4.1.1.2. Radiation detriment

(159) The Commission defines the radiation detriment as the overall stochastic harm to health incurred by an exposed group and the descendants of that group because of exposure to radiation. Detriment is a multidimensional concept that excludes tissue reactions. Its principal components are probability of attributable cancer, weighted by lethality and length and quality of life lost if the harm occurs, and weighted probability of severe hereditary effects. The choice of these components derives from a value judgment, which is assumed as such by the Commission, and which again can be linked to the ethical values of non-maleficence and prudence.

(160) The detriment calculated in *Publication 103* (ICRP, 2007a) averages the values associated with exposure of males and females and defines two broad categories of population: the general population with an age at exposure between 0 and 89 (90 years of lifespan) and the working population with an age at exposure between age 18 and 64 (47 years of lifespan). For both categories, the calculation is performed for a maximum attained age of 94 (ninety-fifth anniversary) (ICRP, 2022).

(161) Even though the detriment is explained in *Publication 103* (ICRP, 2007a) and analysed in detail in *Publication 152* (ICRP, 2022; Ban et al., 2022), its complex definition is such that many radiological protection professionals do not always understand what its full scope and extent are. Because the calculation of detriment considers a nominal risk averaged over sex, adjusted for lethality, quality of life and years of life lost, the word "detriment" tends to mask the range of severity of harm. This report will therefore rather use the terms benefit and harm when dealing with the general consequences of radiation exposure. For those involved in clinical decision-making about justification and optimisation of patient imaging, the concern is often about the risk of developing fatal cancer. The approximated overall lifetime fatal risk coefficient of 0.5% per 100 mSv from *Publication 103* (ICRP, 2007a) on which International Radiation Safety Standards were based (IAEA, 2014), continues to be appropriate for the purpose of radiological protection (ICRP, 2022) as it expresses the correct order of magnitude of both the detriment and the risk of developing fatal cancer.

4.1.2. Tissue reactions

(162) At absorbed doses much higher than those of typical diagnostic imaging exams, but commonly encountered in radiation therapy and regularly in interventional radiology

procedures, ionising radiation can induce death of a sufficient number of cells to affect tissue functions and become clinically observable (e.g. skin necrosis, hair loss, or fistulae). These effects were previously called "deterministic effects" but are now referred to as "tissue reactions" for two reasons. The first reason is that they are not determined solely at the time of irradiation but can be modified at later times after radiation exposure. The second reason is that a given tissue reaction is not solely determined by a given level of dose but varies according to the individual radiosensitivity. *Publication 118* (ICRP, 2012) reviews tissue reactions in detail, both in terms of morbidity and mortality.

4.1.2.1. Threshold dose in radiological protection

(163) Tissue reactions occur only if the radiation dose exceeds a certain threshold. The Commission does not define it for the average population, but provides it at the level of 1 % incidence for a given dose, and a given tissue (ICRP, 2012). For example, for every 100 patients exposed to 6 Gy maximum skin dose during fluoroscopically guided interventional procedures, one patient may develop a main erythema reaction within 1.5 weeks from this treatment; this is how the ICRP defines the threshold dose for a tissue injury—it is a low threshold in order to be prudent. Moreover, and in order to be relevant for members of the public and young workers, the threshold doses are defined for very long follow-up times; for example, the occurrence of tissue effects is still assessed in atomic bomb survivors with more than 50 years of follow-up. This can be seen as a reflection of the ethical values of prudence because of the impact of these effects on the one hand, and respect for the dignity of the most vulnerable on the other.

(164) Threshold doses can be highly dependent on the temporal delivery of the exposure. For instance, 15 Gy delivered in a single fraction are sufficient to induce fibrosis or necrosis of the bladder, for acute exposure, whereas the same effect appears with a higher threshold dose of 55 Gy for a 2 Gy fractionated exposure in radiation therapy (ICRP, 2012). Temporary sterility in males has the lowest threshold dose (about 0.15 Gy). For temporary sterility in females, depression of haematopoiesis, or cataracts, a threshold dose of around 0.5 Gy is a good estimate. For other tissue reactions, with exception of in utero exposure, the thresholds are generally higher or much higher.

4.1.2.2. Tolerance dose in radiation therapy

(165) According to ICRU Report 50 (ICRU, 1993), an organ at risk (OAR) is a normal tissue that has a lower tolerance to radiation than the tumour in radiation therapy. Over-dosage may result in severe complications, and treatment planning must ensure that the dose to the OAR is below a certain tolerance dose. The ICRU defines two such doses for the OAR: TD5/5 and TD50/5 (Rubin and Casarett, 1972). TD5/5, the minimal tolerance dose, represents the radiation dose that would result in a 5 % risk of severe complications to an OAR within 5 years after irradiation. TD50/5, the maximal tolerance dose, represents the dose that would result in a 50 % probability of developing severe complications within 5 years after irradiation. A compilation of the normal tissue tolerance doses for various critical structures can be found in the QUANTEC Guidelines (Bentzen et al., 2010).

(166) The tolerance dose of radiation therapy is defined at a higher level of incidence (5–50 %) and for a shorter time (5 years) than the threshold dose of radiological protection (respectively 1 % for more than 50 years). This can be justified by the ethical value of beneficence because in therapy, the higher the dose to the tumour the more likely the patient benefits but may also increase radiation side effects. Requiring a lower tolerance dose could therefore impair the probability of curing the patient. This approach is intended to be tolerable to most patients. However, it has not been empirically established and shows some paternalism because it does not explicitly ask the patients which level of risk they accept to take. Another

concern about tolerance doses is that toxicity, like medication toxicities, is often underreported and under investigated (Papanikolaou, 2004). However, giving this information about the benefits and risks (including short and long term side effects) of radiation therapy to the patient is not straightforward and requires balancing the ethical values of autonomy (the patient has the right to know), prudence (there is a lot of uncertainty for a given patient) and empathy (not all information is useful for each patient). The process of shared decision-making can help establish clarity about individual patients' desire for information.

4.1.3. Impact of sex, age, and individual radiosensitivity on radiation response

(167) The effects of ionising radiations described in the previous two sections apply to general populations. When a particular person is exposed, it is desirable to take into account the characteristics of that person that may modify the risk of radiation effects. The following text is dedicated to the role of sex, age or other specificities. Inevitably, inclusion of these additional parameters gives rise to additional ethical issues to be considered.

4.1.3.1. Age at exposure

(168) Age has a significant impact on the potential harm from radiation exposure. The detriment at birth per unit of dose is up to three times higher than for the general population, whereas at 60 years of age at exposure, the risk is approximately a factor of 3 lower than for the general population. A key aspect of children regarding the development of stochastic effects is their longer life expectancies, resulting in a longer available time for manifesting long-term radiation-induced health effects. The sensitivity of children to radiation-induced cancer has been a focus of interest for over half a century.

(169) The evidence that children are significantly more sensitive than adults to develop a radiation-induced cancer is especially clear for breast, brain, thyroid and non-chronic lymphocytic leukaemia. It is moderate for stomach and skin (non-melanoma), and weak for colon and myelodysplasia. The only tissue for which children present relatively weak evidence for less radiosensitivity than adults is the lung (UNSCEAR 2013).

(170) There is moderate evidence that suggests no differences between children and adults for bladder cancer and weak evidence for liver cancer. Insufficient evidence to decide whether children are more sensitive than adults can be found for a large number of other tissues (oesophagus, small intestine, rectum, pancreas, uterus, cervix, ovary, prostate, kidney, parathyroid, Hodgkin's and non-Hodgkin's lymphoma, myeloma) (UNSCEAR 2013). This may be explained by a lack of statistical power of the studies.

(171) As mentioned above, tissue reactions have a wide range of threshold doses depending on the effect and the tissue, but most of them are above 0.5 Gy. A notable exception is the appearance of cognitive defects following exposures of fetal and infants' brains (< 18 months) with an absorbed dose of 0.1–0.2 Gy (Hall et al., 2004). This is generally explained by the development of synaptic connections between the neurons during the first years of life.

(172) All this evidence shows that the ethical values of non-maleficence and prudence are strong arguments in favour of developing specific protocols for paediatric exposures. The fact that the pregnant patient, the foetus and children are more sensitive than adults should be translated into putting more effort into delivering the adequate dose to obtain the diagnostic information or to treat the patient (i.e. applying the optimisation principle). This is, in particular, necessary because children do not have the same anatomy as adults and may have different pathologies.

4.1.3.2. Sex

(173) Sex also has a significant impact on the potential harm from radiation exposure. For instance, the detriment for female workers is approximately 40% higher than male workers (5.1% per sievert for females and 3.7% per sievert for males, according to *Publication 103*).

(174) For whole body irradiation, a significant part of the difference between males and females comes from breast cancer, which is almost exclusively associated to females. For single organ irradiations, the situation is more subtle. In general, females tend to be more radiosensitive – in particular for the lungs (+100 %) and the thyroid gland (+300 %) – but they are for instance less radiosensitive for the colon (−55%) and the liver (−55%) (*Publication 103* – Table A.4.18).

(175) As reported in the *Publication* 152 (ICRP, 2022) the calculation of radiation detriment needs to be updated to better reflect changes in reference population data and cancer severity parameters, variation of cancer risk with sex and age and between different populations, improvement in cancer risk models, and advances in risk estimation for hereditary effects.

4.1.3.3. Embryo and foetus

(176) Radiation effects in the embryo and foetus have been reviewed in *Publication 90* (ICRP, 2003). During embryogenesis, most cells are in the process of replication and differentiation so the organs and tissues have a high risk of radiation-induced detriment. The cancer risk to the foetus is considered the same throughout gestation as that of early childhood (ICRP, 2003). There is no threshold for cancer risk which have been suggested at doses as low as 10 mGy in epidemiological studies (Wakeford and Bithell, 2021).

(177) Most of the time, the need for medical exposure arises from the need of the mother. This presents an ethical dilemma that must be resolved by balancing the needs of the unborn baby and those of the mother.

(178) For tissue reactions, the risk in the embryo is generally higher than that in children, but it strongly depends on the dose level and gestational age (Vock, 2017). In the pre-implantation period, the threshold for embryonic death (known as the ‘all or none phenomenon’) is 1.0 Gy of low-LET radiation.

(179) During the major organogenesis period (weeks 3–8 post conception), the radiosensitivity to malformation is maximum and the Commission judges that there is a dose threshold at around 0.1 Gy. Risks of malformation after in-utero exposure to doses well below 0.1 Gy are therefore not expected. Doses to the uterus of the order 0.1 Gy or higher can be reached with multiple CT examinations, interventional radiology procedures, or radiotherapy of the maternal trunk region. Indeed, it is not rare to discover that a woman is pregnant during these or other procedures if care is not taken to ensure pregnancy status before radiation exposures. Therefore, professionals may face an ethical dilemma in respecting the values of beneficence, non-maleficence, dignity and autonomy considering both the patient and the foetus.

(180) In the next gestational period of minor organogenesis (weeks 8–15 post conception) severe mental retardation after irradiation may occur at a dose threshold of about 0.2 Gy. The possibility of a non-threshold dose response for lower IQ loss cannot be excluded but any effects on IQ following in-utero doses under 0.1 Gy would be too small to be of practical significance.

4.1.3.4. Elderly

(181) The lifetime risk of cancer from radiation exposure continuously decreases with age. For instance, the lifetime attributable risks of total cancer incidence per absorbed dose from

uniform external exposure to gamma rays for the female Euro-American composite population is approximately 10 times lower for adults in the 70–79 age-group compared to children in the 0–9 age-group (ICRP, 2021). For adults in the 90–99 age-group, the risk is another factor 20 lower. This is largely due to the fact that due to the short remaining life expectancy, there is not enough time for cancer to develop. Radiation dose is less of an issue for the elderly compared to the level for younger ones, yet radiographers/technologists must optimise imaging for all patients. And given the widely varying health status of elderly patients it is crucial to tailor medical care individually and thus to not deny an examination because of advanced age (Gossner, 2022).

(182) One of the largest differences in radiation sensitivity between younger and elder populations is observed for thyroid cancer. According to the World Health Organisation the groups most likely to benefit from iodine thyroid blocking following a nuclear accident are children, adolescents, pregnant and breastfeeding women, whereas individuals over 40 years of age are less likely to benefit from it. (WHO, 2017b). This approach is justified by the ethical value of beneficence, but also by the value of non-maleficence because the risk of side effects from stable iodine increases with increasing age as the incidence of thyroid diseases is higher. These ethical values could also be invoked in dental radiology for a differentiated approach of the use of contact-shielding of the thyroid between young and older patients.

4.1.3.5. Individual radiosensitivity

(183) People with certain monogenetic genetic diseases such as ataxia telangiectasia, are more sensitive to radiation but these are rare (Taylor et al., 1975). Individual radiosensitivity also depends on the life style. For instance an interaction has been observed between radon and smoking for the risk of lung cancer (Darby et al., 2005).

(184) Currently, there is no possibility to identify radiosensitive patients, except those with a monogenetic disorder. But if this changes in the future, radiological protection may face the same ethical considerations as those already present with genetic susceptibility in general. In that case, it is to be expected that a solid ethical culture will be needed to answer such questions as who should benefit from such tests, how the patient should be involved, or what one should do with the results.

4.1.4. Uncertainty

4.1.4.1. Doubt and uncertainty

(185) According to UNSCEAR, there is a "high degree of consensus on how radiation induces tissue [reactions and] some understanding of repair mechanisms with time" (UNSCEAR, 2012). In contrast, our knowledge is much less certain for stochastic effects. While there is a good degree of consensus on the role of DNA mutation, the same is not true for cancer development, which is believed to proceed in a multistep fashion modified by other factors, such as adaptive response, impact of the immune system, genomic instability, and bystander effects. The role of these factors at low and very low doses are the subject of scientific debate, with some authors doubting that any effect at all may be present (Tubiana, 2009). On the basis of the reported experimental studies on biological mechanisms relevant for the inference of cancer risks from low-dose radiation the UNSCEAR Report 2021, Annex C on Biological Mechanism of Cancer, provide the basic evidence on radiation effects (UNSCEAR, 2021). The document provides the guidance on assessing the quality of individual studies and of the synthesis of evidence from several studies, and the approach to radiation experimental study quality assessment and to synthesis of findings across studies. The approach provides for increased methodological rigour, which could enhance the degree of coherence,

transparency and objectivity in assessments. For hereditary effects in humans, the scientific consensus is that they are plausible, but at a much lower frequency than the induction of cancer.

(186) In practice, this incomplete knowledge of the effects of ionising radiation on human health falls within the general framework of uncertainties. Uncertainty is precisely codified in the field of metrology, where measuring instruments are used to estimate the true value of a physical quantity. However, this notion cannot be confined to the laboratory, as uncertainty can have different meanings for different actors and is often associated with doubt in general. For instance, many patients and their relatives do not understand uncertainty as being a lack of knowledge of the experts. Some patients consider uncertainty as a defect or weakness that may affect their trust on the professionals. For the authorities and decision-makers uncertainty is often related to the likely consequences of decision options and public reactions (Hoti et al., 2020). Each of these understandings of uncertainty may imply the need to consider different ethical values when risk is communicated. In particular, the notions of fairness and trust are critical in devising approaches to the uncertainties in risk, its communication, and governance (Malone et al., 2019, Chapter 7; Malone, 2020)

4.1.4.2. Uncertainty of measurement of the dose and the estimation of risk

(187) The "Guide to the expression of uncertainty in measurement (GUM)" provides an explicit and pragmatic definition of the uncertainty (JCGM, 2008): a "parameter, associated with the result of a measurement that characterises the dispersion of the values that could reasonably be attributed to the [quantity subject to measurement]". The UNSCEAR (UNSCEAR, 2015, 2019) and numerous reports of the NCRP review what is known and not known about dose and risk, and clinical outcomes, and how to describe their uncertainties (NCRP, 1997, 2007, 2009, 2012, 2018b, 2020).

(188) Typically, patient dose at the point of interest cannot be directly measured. Instead, it is usually measured or calculated on a phantom in a reference condition. In radiation therapy, the dose delivered to the patient is estimated individually. The general uncertainty associated with the delivered dose to the tumour and the organs at risk can be kept down to a few percent thanks to traceable calibration of the absorbed dose, careful positioning and patient immobilisation at time of simulation, treatment planning and accurate treatment delivery, etc. In diagnostic radiology, the dose is usually estimated using phantoms and the uncertainty is much larger. For example, the maximum tolerance for the calculation of the CT Dose Index (CTDI) by a CT scanner is set at ±20 % (IEC, 2019). In nuclear medicine, the dose is often computed by assuming a standard pharmacokinetic model of human physiology, which can be based on human or animal studies. This is an approximation associated with an uncertainty that can be easily reach a factor of two or more. In radiopharmaceutical therapy, it is becoming more common to perform dedicated measurements (theranostics). But the uncertainties are significantly larger than external radiotherapy (ICRU, 2022).

(189) The lowest uncertainty associated with stochastic risk has been shown in epidemiological and radiation biology studies for low-LET and high dose-rate external radiations at dose levels above 100 mGy (UNSCEAR, 2015). Below 100 mGy, the non-zero value of the risk is not proved but there is increasing epidemiologic evidence of cancer risk from low doses and low dose rates of exposure in patients and workers and some vulnerable populations (NCRP, 2018a; Shore et al., 2018; JNCI Monograph, 2020, Wakeford and Bithell, 2021). The Commission justifies the application of LNT model based on the precautionary principle. The associated uncertainty remains large.

(190) The definition of the radiation risk itself is also sometimes vague or ambiguous. For example as mentioned above, the detriment is often not fully understood by professionals, who may be taught it in a simplified way (i.e. a probability to induce fatal cancer). Even when it is

well understood, the estimation of the detriment in other populations than Asians and Euro-Americans, which have been chosen to define the baseline mortality rates, may also add some uncertainty and raise ethical concerns about health equity. The value of DDREF has been set equal to two, but other choices could have been made under other assumptions (NRC, 2006).

4.1.4.3. Communicating about uncertainty

(191) For the radiological protection professionals, the uncertainty associated with the risks (and the benefits) when applied at the individual patient level, using medical imaging and radiation therapies is one of the main motivations to apply a prudent approach. For health-care workers, a clear knowledge about uncertainty is essential when they communicate with patients and their relatives.

(192) Indeed, uncertainty is an important aspect of the risk and benefit information that is part of the communication with patients and their relatives. The strict application of the ethical values of autonomy, as well as transparency and honesty require the professionals to be open about what is known, what is not known, and what may be uncertain or considered controversial. However, discussing uncertainty needs to be filtered by the value of empathy, since some patients may not want to know, or may be afraid to learn the level of uncertainty. Furthermore, patients and their families also have the right NOT to know when making shared decisions about their care (Andorno, 2004).

(193) When faced with a patient who wants to know, the application of the "Powell principle" can help to address the value of honesty when communicating about uncertainty (Powell, 2004). This principle requires the professionals describing the benefit and risk of a radiological procedure to state clearly what they know, what they do not know, and what they personally think. Crucially they need to distinguish clearly between the three. Finally, shared decision-making communication may reveal questions that patients and their family raise that the professional may not have immediate answers for. It is important for the radiological protection professional to be transparent in stating what they may not know but what they can and will find out for the patient/family.

(194) Key Message 24: Health-care professionals need to inform patients not only about the benefit and risk but also about the uncertainty in benefit/risk and its precise magnitude. This is based on the ethical values of transparency and honesty. The value of empathy must also be considered, since some patients may not want to know, or are afraid to learn about the level of uncertainty.

(195) The main difficulty in communicating the uncertainty associated with radiological risk is that there is no consensus on its magnitude at low dose and low dose rate. There is also variation in the individual patient response that is not known. The calculated estimates for an imaging procedure typically provided to patients, on websites and information brochures are for an average adult and based on epidemiological evidence. In addition, quantitative numerical values are either too scary for patients and the public or often difficult to understand even by clinicians. One solution could be to communicate qualitatively, for instance by mentioning the degree of consensus among radiological protection organisations and experts. For example, most patients that are considering a screening CT scan – whether or not they are familiar with physical sciences – would probably find it more informative to hear a statement like: "The majority of radiological protection and scientific organisations believe that the risk from one CT scan to develop cancer is very low" (see Table 4.1).

(196) A common alternative to the broad description of uncertainty is to compare with situations people are familiar with. For instance, natural background radiation or exposure to

cosmic radiation during aeroplane flights are often used to communicate the stochastic risk to patients. The assumption is that this will help the patient to put the radiation risk associated with medical exposure into perspective and relate it to a situation that they may understand and be comfortable with (Image Gently, 2022).

(197) Recently, the Commission proposed to use the effective dose as an approximate indicator of possible risk to communicate about stochastic risk in medicine (ICRP, 2021). The advantage of such a formulation is that it allows to give an idea about the uncertainty associated with risk estimates. In the same publication, the Commission proposed a scale linked to effective dose in the context of risks and benefits from medical imaging, with general terms to describe the dose linked to possible levels of risk and examples of procedures within different dose ranges. Table 4.1 presents this semi-qualitative scale reproduced from *Publication 147* (ICRP, 2021). The second column also provides a numerical estimate of the risk of cancer and on which evidence it is based on. This latter point is important for discussing the uncertainty with the patient.

(198) Furthermore, the risk of developing cancer within, say 10–30 years, has different implications for different persons, depending on their personal values, their situation, their age and the benefits of the medical procedure. The uncertainty about benefit and harm should therefore be factored into the whole process of communication. The level of risk avidity or aversion of the patient, family, and the clinicians treating them also influence these communications and shared decisions. Again, ethics, and empathy in particular, can help. In the process of shared decision-making, the clinician can be active in eliciting information about patient desires, context and values that influence the relevance of the degree of communication about risk and benefit.

Table 4.1. Effective dose ranges and terminology for describing risks from different medical diagnostic procedures for adult patients of average age (30–39 years) based on UK data (ICRP. 2021). The Risk bands of column 2 are lifetime detriment adjusted cancer incidence to nearest order of magnitude.

Effective dose (mSv)	**Risk of cancer**	**Proposed term for dose level**	**Examples of medical radiation procedures within different dose categories**
< 0.1	Inferred < 10^{-5} on LNT model	Negligible	Radiographs of chest, femur, shoulder limbs, neck, and teeth, ^{99m}Tc sentinel node imaging, radionuclide labelling for in vitro counting with ^{14}C and ^{57}Co.
0.1–1	Inferred 10^{-5} – 10^{-4} on LNT model	Minimal	Radiographs of spine, abdomen, pelvis, head and cervical spine. ^{99m}Tc for imaging lung ventilation and renal imaging.
1–10	Inferred 10^{-4} – 10^{-3} on LNT model	Very low	Barium meals, CT scans of the head and combinations of chest, abdomen, and pelvis, barium enemas, cardiac angiography, interventional radiology; ^{99m}Tc myocardial imaging, lung perfusion ^{99m}Tc for imaging lung perfusion, ^{99m}Tc imaging of bone lesions, cardiac stress tests and ^{99m}Tc SPECT imaging; imaging with ^{18}F, ^{123}I, and ^{111}In.

(continued on next page)

Table 4.1. *(continued)*

Effective dose (mSv)	Risk of cancer	Proposed term for dose level	Examples of medical radiation procedures within different dose categories
10–100	Risk 10^{-3} – 10^{-2} based on LNT model and epidemiology	Low	CT scans of chest, abdomen, and pelvis, double CT scans for contrast enhancement, interventional radiology; ^{67}Ga tumour, and ^{201}Tl myocardial imaging; multiple procedures to give doses of 10s mSv, endovascular aneurysm repair. (10–35 mSv). Renal/visceral angioplasty, Iliac angioplasty, follow-up of endovascular aneurysm repair. (35–100 mSv).
100s	$>10^{-2}$ based on epidemiology	Moderate	Multiple procedures and follow-up studies.

4.2. Ethical values particularly present in medical radiological protection

(199) This section is particularly dedicated to people with knowledge in radiological protection who wish to know the ethical specificities of the use of ionising radiation in medicine. It begins by describing what distinguishes patient exposures from those of the public or workers. Then, the application of the principles of radiological protection in medicine and their relationship with ethical values are reviewed.

4.2.1. Special aspects of medical use of radiation

(200) In *Publication 105* (ICRP, 2007b), the Commission discusses the unique aspects that distinguish medical patient exposures from other exposures. The first one is that the exposure is deliberate. In radiation therapy, the primary aim is to treat cancer by delivering a given dose to a target, whereas in the other medical exposures the aim is to provide diagnostic information or to conduct an interventional procedure in which ionising radiation is not adventitious. In both situations, a deliberate exposure is acceptable when and because there is a direct individual medical benefit that is larger than the potential harm. In other words, the ethical values of beneficence and non-maleficence are correctly applied through the principle of justification. In addition, prudence suggests the application of doses as low as reasonable, i.e. as low as compatible with achieving the diagnostic or therapeutic goal.

(201) Another important aspect is that they are voluntary in nature. Such voluntary exposures are associated with varying degrees of informed consent, which is a consequence of the application of the ethical values of dignity and autonomy. To request informed consent requires that professionals spontaneously deliver the appropriate information about benefit, harm and uncertainties to the patient. This follows from the application of the procedural ethical values of transparency, accountability and inclusiveness. Of course, the need to inform and involve the patient in decision-making has to be balanced by what the patient needs, what the patient is able to understand, and what the patient is willing to know. Therefore, the fine-tuning of what should actually be communicated must be selected with the help of the ethical value of empathy in accordance with shared decision-making.

(202) Finally, the demographics of the patient population are also an important aspect because they tend to be different from the usual populations addressed in non-medical radiological protection, that is, workers and members of the public at large. In medical

irradiations, specific sub-populations, like children, women (in particular in the childbearing age), and elderly patients are of special concern, because they are either more sensitive or less sensitive to ionising radiations. Here, the ethical values of justice and equity in medicine are put into practice by advocating for a specific patient, rather than the more general radiological protection perspective, which is more focused on populations. This can be implemented by applying the principle of optimisation, which is discussed in more details in the following section.

4.2.2. Biomedical ethics and application of the principles of radiological protection

(203) Among the three principles of radiological protection, only justification and optimisation are applied to patient exposures. To date, these two principles are almost entirely based on the ethical values of beneficence and non-maleficence through risk-benefit considerations, which themselves may be problematic (Malone, 2020). The uneven application of values like dignity/autonomy, prudence/precaution, justice/solidarity, accountability/honesty or inclusiveness/empathy inevitably has consequences for the implementation of justification and optimisation.

4.2.2.1. Justification

(204) As for any medical procedure, all radiological procedures, either diagnostic or therapeutic are expected to benefit those referred. The first principle of radiological protection, justification, is a means of ensuring this. The Commission identifies three levels of justification for all medical exposures. Level 1 is very general and states that the use of ionising radiation in medicine is accepted as doing more good than harm. Its justification is taken for granted. Justification of level 2 concerns particular procedures with specified objectives (e.g. the use of 4D CT for planning specific radiation treatments). The aim is to ensure that the procedure normally improves the management of the patient group. It is a matter for national professional bodies, health and regulatory authorities for evaluating such evidence-based, and indication-based protocols. Level 3 justification concerns the application of the procedure to an individual patient, which should be judged to do more good than harm to the individual in his/her circumstances.

(205) For many years, the Commission has suggested that such questions can be addressed with the help of economic analyses, where all advantages and disadvantages caused by a certain course of action could be expressed in monetary values and the final decision could be made on the basis of cost. Medical decision-making is not so simple, with innumerable scenarios and individual variation; the cultural norms, changing societal and patient-centred values have become ever more important in directing healthcare system management. The problem is that radiation benefit and harm are often not able to be measured by the same standard or at the same time, even when both are narrowly defined. If the choice is between a CT scan versus no CT scan and therefore the risk of a wrong diagnosis (no pulmonary embolism), a missed cancer, or a delayed diagnosis (e.g. perforated appendicitis) which would lead to a wrong therapeutic decision and potential patient harm or even death, then the comparison with a small, future cancer risk from one CT scan now may be reasonable (e.g. Doria et al., 2006). However, in most practical cases, the balance between uncertain benefit against very small, probable harm is complex, because the available evidence for both seldom allows direct comparison of like with like and because the range of harms considered is generally too narrow (Malone, 2020).

(206) Progressively, the Commission has moved away from the use of cost-benefit analysis especially for medical radiological protection where cost-effectiveness analysis is preferred (Hunick, 1996). It should be complemented with qualitative methods (ICRP 1973, 2006a, 2006b; Zölzer and Stuck 2019), with a direct link to patient health outcomes. The NCRP

(NCRP, 1995) provides an explanation of cost-effectiveness analysis, meta-analyses, and systematic reviews that can assess justification. Initiatives from the IAEA, WHO, EC, and other bodies emphasise the need to address this question urgently to manage overuse and inappropriate use of resources. This is implicitly reiterated in the Bonn Call for Action, which identified improvement in justification and education around this principle as a priority (IAEA/WHO, 2014).

(207) Real evidence of benefits, at the level of improved health outcomes for individuals or society, is harder to obtain in imaging than in therapy. However, Fryback and Thornbury (Fryback and Thornbury, 1991) proposed a six-level hierarchical scale of a parameter linked to the benefit(s) of the imaging procedure, which they call "efficacy" and which is also related to the concept of image quality. Efficacy is defined as the benefit of a test under *ideal conditions* such as a randomised controlled trial. This means that it is not necessarily going to work as well under the normal day to day working conditions of a clinic or hospital. This latter condition is defined as 'effectiveness', or how an imaging procedure or any test would perform in such an unstructured, working environment. An example scale of clinical efficacy of diagnostic imaging is presented in Table 4.2. For many decades, medical physicists concentrated their efforts to provide measurements of technical efficacy (Level 1). More recently, the diagnostic accuracy efficacy (Level 2) has been made available. Algorithms called mathematical model observer (based on the measurements of image parameters obtained with phantoms) have been proposed to automate the process and estimate the efficacy of a radiologist that would have been asked to perform a given task under ideal conditions (Barrett et al., 2015). Although this is an improvement, such a quantification is still closer to proving the "non-toxicity" of the procedure than really assessing the benefit of the imaging system. Note that achieving each lower level is necessary but not sufficient to achieve the next level of efficacy.

Table 4.2. Six level scale of the clinical efficacy of diagnostic imaging [adapted from Fryback and Thornbury (1991)].

Level	**Typical measures of analyses**
1. Technical efficacy	Physical measurements of image quality (e.g. MTF, SNR)
2. Diagnostic accuracy efficacy	Percentage correct diagnoses in case series; sensitivity and specificity
3. Diagnostic thinking efficacy	Number of cases in a series in which image judged "helpful" to making the diagnosis
4. Therapeutic efficacy	Number of times image judged helpful in planning management of patient in a case series
5. Outcome efficacy	Percentage of patients improved with test compared with/without test
6. Societal efficacy	Cost-effectiveness analysis from societal viewpoint

(208) Summarising the principle of "doing more good than harm" justification amounts to considering only the ethical values of beneficence/non-maleficence at the expense of others. An ethical application of this principle obliges the stakeholders to consider the values of dignity/autonomy in connection with the free and informed consent of the patient, as well as the values of justice/solidarity when it comes to making good use of limited resources.

4.2.2.2. Optimisation

(209) Some of the observations just made concerning justification also apply to the second principle of radiological protection, optimisation. The purpose of keeping exposures ALARA

is of course to maximise good and minimise harm, which again relates to beneficence and non-maleficence. In the context of medical patient exposures, this principle is implemented by managing the radiation dose commensurate with the clinical purpose. This raises similar questions as to how benefits and risks can be quantified and may be even more important for optimisation than for justification (Malone et al., 2019; Malone, 2020).

(210) The need of other values than beneficence and non-maleficence to practically apply the principle of optimisation becomes evident when it is expressed in full as keeping exposures ALARA "taking into account economic and societal factors". In the discussion on the interpretation of ethical values in Section 2.2, prudence is the value most tightly linked to optimisation. In other words, the application of ALARA is a matter of careful judgment and mixes quantitative and qualitative values. The reference to economic and societal factors suggests that the values of justice and solidarity are important for optimisation.

(211) Key Message 25: When an individual is exposed to ionising radiation, it is important to take into consideration the characteristics of that person. The ethical values of justice and solidarity and the principle of optimisation need to be put into practice when, for example, pregnant patients and children need a CT or interventional procedures.

(212) There is ethical guidance in the European basic safety standards, for example, on when to perform some interventional procedures if the imaging equipment is not appropriate or if the interventionists are not trained in radiological protection (European Directive of the Basic Safety Standards, 2013). This training includes staff protection for the justification and optimisation of medical exposures which may require high staff exposures for patient optimisation (See Chapter VII on Medical Exposures, art. 55 to art. 64. Art.19 Justification of practices). In other special situations, optimisation may require personalised care in pregnant patients who may have difficulties with normal positioning in lifesaving, urgent interventional procedures or in young children who have difficulty with motion, sometimes requiring sedation/anaesthesia.

5. REVIEWING PRACTICE FROM AN ETHICAL PERSPECTIVE

(213) This section proposes an evaluation method to analyse specific situations from an ethical point of view. This method allows the stakeholders to review clinical situations and assess how they comply with the ethical values fundamental to practice. The goal is to use this approach to help with decision-making. In the first part of this section (Section 5.1), an evaluation method for rating the compliance and non-compliance with the ethical values is presented.

(214) In the second part of this section (Section 5.2), examples of questions are provided to serve as prompts for reflection and discussion, which are called "sensitising questions". This table of sensitising questions provides an additional tool to help in learning and using the method.

(215) This evaluation method is then put into practice through case-based examples dedicated to diagnostic imaging (Section 6) and radiotherapy (Section 7).

5.1. Evaluation method of ethical values of scenarios

(216) In day-to-day practice health care providers work within their professional codes of ethics. When situations arise that are outside of routine practice or when disagreements arise, then a more in-depth study of relevant ethical literature and rigorous discussion are necessitated.

(217) The paired ethical values that have been defined in Sections 2 and 3, and the background in radiological protection given in Section 4, assist health professionals and stakeholders in identifying ethical issues, finding relevant literature, and working together towards decisions.

(218) In this report, an evaluation method is presented that challenges the user to assess scenarios for their compliance or non-compliance with the values outlined in Sections 2 and 3 (Table 2.4). These paired values are presented in a table form (Table 5.1), and users of the method indicate compliance and non-compliance with the paired values in the given scenario. All the values are not addressed in all the scenarios; rather, those with greatest impact are emphasised.

(219) Compliance is indicated as being strong (☺☺), weak (☺) or neutral (-). Likewise, non-compliance is indicated as strong (☹☹), weak (☹) or neutral (-). Some scenarios demonstrate compliance with a value when considered from one perspective, and non-compliance when considered from another. Thus, it is possible to score both (☺☺ or ☺) and (☹☹ or ☹) for the same value. The method has been presented to numerous professional groups during the last five years and published in paper and book forms (Malone and Zölzer, 2016; Malone et al., 2019).

Table 5.1. Table for the evaluation of scenarios.

	dignity/ autonomy	beneficence/ non-maleficence	prudence/ precaution	justice/ solidarity	transparency/ accountability/ honesty	inclusiveness/ empathy
Compliance						
Non-compliance						

(220) The scenarios that follow are taken from many aspects of diagnostic imaging (Section 6) and radiotherapy (Section 7) practice and were drawn from the authors' experience. As new technologies and practices emerge, new scenarios will arise. The presented scenarios are simplified in order to illustrate underlying ethical challenges. All names and institutions named

in each of the scenarios are fictional. What is important is the process of analysing the ethical values in practical situations in team discussion.

(221) The authors of this report provide assessments of the scenarios, but do not claim that there is always a unique solution to each scenario. In individual cases, readers might come to different conclusions, or might want to consider values that have not been discussed here.

5.2. Sensitising questions

(222) In working through the scenarios, readers should have the definitions of core and procedural values in Table 2.4 above at hand. Table 5.2 provides sensitising questions that will serve as prompts for reflection and conversation on the compliance or non-compliance of the scenarios with the values. The listed questions are not intended to limit but rather to open discussion.

Table 5.2. Sensitising questions for the paired values.

Core Ethical Values and additional values with definition (See Table 2.4)	**Examples of sensitising questions**
Dignity/autonomy The value and respect that every person has and deserves regardless of her/his age, sex, health, social condition, ethnic origin, religion, etc., protected by the Universal Declaration of Human Rights The capacity of individuals [or groups] to act freely, decide for themselves, and pursue a course of action in their lives	• Have we discussed the role the patient wishes to take in decision-making? • Have we respected patient confidentiality? • Has the patient's health information been shared only as necessary for their care? Within the scope of the purposes for which it was collected? • Have we understood and addressed barriers to the patient making the right choice for them? • Have we disclosed the information the patient would want for their medical decisions? • What are the patient's goals of care? • Is the benefit of the procedure consistent with the patient's own goals of care? • Is there stigma or biases about patients, families, or colleagues influencing our reactions or choices in the scenario? • Has the patient's privacy been respected? (e.g. shielding, physical location of exam/treatment, and of sensitive discussions)

(continued on next page)

1980 Table 5.2. *(continued)*

Core Ethical Values and additional values with definition (See Table 2.4)	**Examples of sensitising questions**
Beneficence and non-maleficence/harm-benefit balance The duty to promote or do good, and to avoid harm. The requirement to balance benefits and risks	• Does the procedure provide a medical benefit? Have we considered the psychological benefit after an imaging procedure? (And even when it is not clearly indicated in an imaging guideline if a patient is really worried?) • Have risks of harms been minimised? • Does the risk outweigh expected benefit? Are risks and benefits well-balanced? • Is the procedure aimed at prevention, cure, palliation, rehabilitation, or improvement in quality of life? Does it address psychosocial concerns? • Is it consistent with clinical guidelines? Are there particularities of the patient that the guidelines don't take into account? • Is there a risk of medicalising, over-diagnosing, or over-treating the patient? • Will the additional information provided by the test change the treatment approach? • Have the potential harms of too much diagnostic scrutiny been taken into account? • Is there a conflict between what the medical team thinks is the best course of action and what the patient would like? Is there conflict among the medical team? Between the patient and their family/caregivers? • Are we ordering tests to avoid conflict, manage perceived legal risk, or to persuade patients to accept treatment recommendations? • Are we educating the patient or caregivers about the limitations of testing?
Prudence/precaution Making informed and carefully considered choices without the full knowledge of the scope and consequences of an action Preventing or reducing risk in the absence of scientific certainty	• Are we ready to make a decision or do we need more information? To take other dimensions into account? • Do we have enough knowledge about uncertainty and the level of evidence that we have? (For example, inferring risk of internal dose from evidence of external dose.) • Is the decision proposed sensitive to the many dimensions of the dilemma? • Have we accepted appropriate standards of evidence for risks of serious harm where evidence is incomplete? • Have we excluded concerns just because we have no high-quality evidence for them? • Are we discussing uncertainty with the patient or family? • Have we considered the unintended consequences of our choices, in medical and non-medical domains?

1981 *(continued on next page)*

1982 Table 5.2. *(continued)*

Core Ethical Values and additional values with definition (See Table 2.4)	**Examples of sensitising questions**
Justice/solidarity Upholding what is right, equitable, and fair Distributive justice: fairness in the distribution of limited medical resources Restorative justice: repairing harms done Social justice: recognition of human rights to equitable treatment and assuring equal access to opportunities Solidarity: consideration of the common good and the societal structures that ensure it and interpersonal relations of recognition, reciprocity and support	• If resources are limited, are we following a justified allocation rule (equality, priority, need, potential to benefit)? • Is our process for allocating resources procedurally fair? • Are clinical loyalties, personal relationships, the patient's status and influence, or social judgments and biases swaying our distribution of resources? • Is some group or person receiving an unfair share of benefits? Of harms? • Are there environmental costs to our practices and how should they be addressed? • Are our practices and technologies environmentally sustainable? • Are our practices and technologies financially sustainable for patients, for the health care system, and for society? • What are the opportunity costs of our resource use? • Have steps been taken to level the power relation between health professionals and patients, so the patient can communicate their concerns? • Are there social determinants of health affecting the patient? • Is there a historical mistrust between health professionals and this specific patient populations? What can we do to be worthy of and restore trust? • Are there aspects of the patient's context that are barriers to their receiving and benefiting from care? How can we address them?

1983 *(continued on next page)*

1984 Table 5.2. *(continued)*

Core Ethical Values and additional values with definition (See Table 2.4)	**Examples of sensitising questions**
Accountability & transparency/honesty Obligation to answer for decisions and actions to those who are affected, and to accept the consequences. Accessibility of information about the deliberations and decisions, and the honesty with which this information is shared. Honesty is the professional and personal commitment to candid and truthful sharing of information.	• Have the effects of ionising radiation been shared with the patient? • Have we discussed additional information that would help the patient for their personal care and life decisions? For their self-understanding? • Is there information we are reluctant to disclose? Why? If we disclosed this information, do we think the patient might make a different decision than the one we think is best? • Have we provided patients with information about relevant alternatives outside our scope of practice? Have we facilitated necessary referrals for patients to understand alternative approaches? • In cases of adverse events and near misses, has the patient and/or family been informed of the event? Of the steps taken to address the event for the patient and future patients? • What steps can we take to re-establish trust? To manage the residue of mistrust? • Are we making an honest attempt to help the patient understanding their prognosis, or are we delaying an uncomfortable conversation? • Do we have a conflict of interest, such as financial interests or health system pressures, that are influencing professional judgment?
Inclusiveness/empathy Giving people the opportunity to participate in discussions, deliberations, and decision-making concerning situations that affect them. Sharing another's emotional response and/or understanding their feelings and perspectives.	• Was the patient included in the initial discussion on treatment options? • Have we taken steps to understand the patient's perspective and concerns? • Have we expressed empathy in concrete ways? Allowed the patient time to experience emotions? Helped ensure their needs are met? • Have we listened to patients' concerns (e.g. about radiation exposure) without judgment? • Have we paid attention to how differences in viewpoints affect us? How they might limit our ability to provide appropriate care? • Has the health care professional involved the whole medical team and the family/carers in the discussion?

1985

6. CASE BASED EXAMPLES IN IMAGING PROCEDURES

(223) Sections 6 and 7 present a range of scenarios involving day-to-day application of radiation in diagnostic settings. The scenarios draw on experience but are not necessarily literally true. Their purpose is not to demonstrate good practice or compelling good ethical behaviour. Rather it is to construct plausible (if necessarily dramatic) situations, and to be an intuitively convincing illustrations of both compliance and non-compliance with the ethics values already identified in Sections 2, 4, and 5.

(224) Evaluation methodology has already been outlined in Section 5 and includes useful sensitising questions that will allow an inexperienced reader approach ethical evaluation of even complex situations. However, in the scenarios that follow, evaluation is not always comprehensive, and they have been constructed so that they are relatively easy to assess intuitively. Hence, it is not expected that even those new to ethics will need to use the sensitising question table in detail during an initial reading of the following text. However, it is expected that Table 5.2 will prove useful to a more intense and rigorous reading and/or to evaluating new situations.

6.1. Richard Grey: Determination of best care

(225) Richard Grey was referred by his general practitioner (GP) for an ultrasound examination to explore the cause of ongoing upper abdominal pain. The GP had reason to suspect gallstones but did not include this in his referral note. Mr Grey was chairman of the hospital board, and the staff in the imaging department greeted him on arrival. They decided to add an abdominal-pelvic multiphase contrast CT examination to the ultrasound scan to provide their chairman with the most discerning service they could offer. Although this was not advised by clinical guidelines, the staff felt it would move them more quickly to diagnosis and staging if cancer was involved. They might not have taken this approach had the referral note been more complete mentioning the GP's suspicions. The radiation and other risks of this high-dose CT procedure were explained to Mr Grey, and he consented to it (Malone et al., 2016, Malone et al., 2019).

Table 6.1. Ethical compliance evaluation of Richard Grey's scenario

	dignity/ autonomy	beneficence/ non-maleficence	prudence/ precaution	justice/ solidarity	transparency/ accountability/ honesty	inclusiveness/ empathy
Compliance	☺	—	—	—	☺	☺☺
Non-compliance	—	☹☹	☹☹	☹☹	☹	☹

(226) The dose to Mr Grey is in the upper end of the range for CT examinations. This is not warranted, as the simpler ultrasound procedure, performed first, could have identified gallstones as the source of the problem. Both examinations were performed, and the CT confirmed the ultrasound diagnosis. There are issues in this case regarding failures of both justification and optimisation. They arise from several sources including the inadequate GP referral. Had his suspicion about gallstones been mentioned, the more elaborate CT scan might not have been undertaken. The department protocols for identifying the correct examination in radiology were consistent with national guidelines and, if followed, would have directed Mr Grey first to ultrasound. But, the staff were anxious to offer their chairman the most sophisticated examination that might help with his diagnosis. Ultimately, it proved to be unnecessary. In getting Mr Grey's consent, the explanation offered to him referred primarily to dose and risk. It did not refer to the fact that the examination would not be appropriate, based on available guidelines.

(227) Under non-maleficence and prudence, (☹☹) given because of unnecessary exposures and the associated potential risk of harm. Respect for the dignity/autonomy of Mr Grey is recognised through obtaining his consent to the procedure but receives only (☺) as the information provided was incomplete. The more complex CT would only have been necessary if cancer was suspected or had been established and was being staged. The consequences were inadequately recognised by the staff in their anxiety to do well for their chairman and gave rise to the issues noted. These include failures under the headings of justice (☹☹) as the complex CT is a poor use of resources. In addition, (☺) under transparency is scored for presenting accurate information on risk, but also (☹) for honesty as the staff was not being totally truthful regarding the information about the appropriateness of the CT examination. The staff did not seek joint decision-making, so receive (☹) for inclusiveness, but they were clearly working out of empathy with their chairman and score (☺☺), in this category.

6.2. Augustus Browne: Surgeon acting independently

(228) Professor Augustus Browne, an orthopaedic surgeon, held a weekly outpatient clinic in a public hospital where he saw both new patients and patients attending for follow-up. His clinic was well resourced and a model of efficiency, keeping to time with little waiting by his patients. Professor Browne insisted all his patients had a relevant, up-to-date, radiology examination before seeing them. The director of radiology and the imaging medical physicist advised against this practice. His response was dismissive, pointing out that the radiology service had considerable waiting times for responses whereas he ran an efficient patient-friendly service (Malone and Zölzer, 2016; Malone et al., 2019).

(229) He required that patients brought copies of their medical images with them to the clinic, stating it took too long to get a radiology report which, when received, may not have addressed his concerns. So, he read the images himself. Pre-signed forms or authorised referrals on the information system were provided for patients, and they were sent to radiology for the required examinations. The Radiology Department was concerned that Professor Browne might bypass the department entirely and take his referrals elsewhere, and thus reluctantly accepted the situation. Prof. Browne did not share any of these concerns with his patients. Likewise, he did not discuss potential benefits or harms with them which he dismissed as largely speculative. He felt that as a doctor, he was an advocate for his patients, and acted accordingly.

Table 6.2. Ethical compliance evaluation of Augustus Browne's scenario

	dignity/ autonomy	beneficence/ non-maleficence	prudence/ precaution	justice/ solidarity	transparency/ accountability/ honesty	inclusiveness/ empathy
Compliance	—	—	—	☺	☺	—
Non-compliance	☹☹	☹☹	☹☹	☹☹	☹☹	☹☹

(230) In seeking to run a tight, efficient clinic, Professor Browne does disservice to his patients and oversteps important boundaries in a variety of ways. He does not individualise his patients' image requisitions. In some instances, he may request unnecessary examinations as similar studies may already have been acquired recently. He does not discuss with his patients the reasons for the tests or the potential benefits or harms, nor does he seek their consent. He reads the examinations himself rather than relying on the interpretation of properly trained radiologists. He thinks he understands the findings on the studies in which he is interested but he is not an expert radiologist and may be missing incidental findings that might benefit his patients.

(231) Professor Browne's practice fails all five ethical values on significant grounds, and so he scores (☹☹) for each (Table 6.2). With regard to dignity/autonomy, this is not respected in the way the decision to conduct examinations is taken, especially as individual conditions are not taken into account. His practice exposes many patients to unnecessary radiation risk with no benefit, under non-maleficence and prudence. He reads the images himself which possibly harms some patients whose studies may be inadequately interpreted. He scores (☺) under justice/solidarity for providing a service for all his patients that is timely and uses the clinic's resources efficiently. He scores (☹☹) under justice as either the patient, insurance company or society are paying for many unnecessary and possibly useless examinations. He does not consider on the possibility of risk and offers practically no information to the patient in this regard, so scores a clear (☹☹) for prudence and transparency and accountability. He scores (☺) for accountability, as he works hard to ensure a good quality service for his patients. However, on the final value, he scores an unqualified (☹☹) under inclusiveness/empathy.

6.3. Dr John Cinnamon: Resumption of practice after equipment failure

(232) The hospital interventional radiology suite had a recent breakdown requiring replacement of the x-ray tube. The supplier sourced the new part, arranged to have it delivered and installed three days later. After installation the medical physicist, Dr Russet, was contacted to acceptance test of the equipment and certify it as safe for clinical use. Dr Russet was working elsewhere. As it did not appear to be urgent, Dr Cinnamon, head of interventional radiology, had left calling Dr Russet until the last minute, Dr Russet advised that he would be available in four days. (Malone et al., 2019).

(233) Given these circumstances, Dr Cinnamon was reassured by the company engineer that it would be all right to accept patients once the tube was replaced. Procedures were started immediately. Thirty-five patients were imaged prior to the arrival of Dr Russet. He tested the machine outside normal working hours so that it would be available for use during the day. He found a filter missing and the automatic exposure controls gave patient doses in the range of 2–10 times higher than those prevailing before the tube was changed; 35 patients therefore receive significantly higher doses. Dr Cinnamon was upset, but decided the patients should not be told, as the information might worry them. Dr Russet advised that there is an obligation to let the patients know, and a duty to inform both the hospital and the regulator. Dr Cinnamon decided to do neither, and referred the matter to the radiological protection committee, scheduled to meet three months later. It came to light that the engineer was inexperienced and was assigned in response to Dr Cinnamon's insistence on immediate tube replacement.

Table 6.3. Ethical compliance evaluation of John Cinnamon's scenario

	dignity/ autonomy	beneficence/ non-maleficence	prudence/ precaution	justice/ solidarity	transparency/ accountability/ honesty	inclusiveness/ empathy
Compliance	☺	—	—	—	—	☺
Non-compliance	☹☹	☹☹	☹☹	☹☹	☹☹	☹☹

(234) This scenario is not uncommon since urgent, major repairs are often required, and the medical physicist may not always be immediately available. In this case, the medical physicist could have been advised, once the tube failed, that he will be required at short notice sometime in the coming days. This would allow work to be rescheduled, or assistance sought. The dose increase after a major service is not common but occurs frequently enough for rigorous testing to be advised when equipment upgrades, major servicing or component replacement takes place. Lesser failures, for example in image quality and other aspects of equipment performance, can and do occur and may also be unacceptable in equipment used on patients. Inappropriate advice from an inexperienced engineer is an important factor in this situation.

(235) In Table 6.3 there is (☺) under dignity and autonomy as Dr Cinnamon recognises the urgency of the examination but two (☹☹) as the increased dose imposes a larger burden of risk and fails to respect the dignity and autonomy of the patients. Using equipment that has not been verified safe may lead to increased harm or risk, without sufficient additional benefit so (☹☹) under beneficence and non-maleficence. It is imprudent to act without checking for changes in the equipment's performance giving (☹☹). It was dishonest to not explain the situation to the patient so (☹☹) for transparency and honesty. Since this is bad practice and can potentially impact on a great number of patients, (☹☹) are given for justice and solidarity as well. For inclusiveness, (☹☹) are given due to failure to advise the patients of the use of untested equipment, and (☺) as some empathy with the patients is demonstrated.

6.4. Norbert Coral: Baseline CT-scan

(236) Norbert Coral, a 63-year-old male who had just retired, moved with his wife to a new home near the sea. Apart from aches and pains common in an active individual of his age, he was well, but wanted to establish a care network within his new community. His new doctor performed a thorough physical exam and confirmed that Mr Coral was fit and healthy. However, he wished to establish baselines against which future evaluations could be compared and ordered a CT scan of the chest, abdomen, and pelvis. He noted that Mr Coral's previous radiological examinations were over ten years old and, given the advances in technology, that these would be of limited value for future comparisons. Mr Coral tried to inquire about the value of the CT, but he was quickly interrupted and told that it was routine in his new doctor's practice. Mr Coral agreed to have the CT scan, albeit somewhat reluctantly.

Table 6.4. Ethical compliance evaluation of Norbert Coral's scenario

	dignity/ autonomy	beneficence/ non-maleficence	prudence/ precaution	justice/ solidarity	transparency/ accountability/ honesty	inclusiveness/ empathy
Compliance	—	☺	—	—	—	☺
Non-compliance	☹	☹☹	☹☹	☹	☹☹	☹

(237) Although the patient may develop a health issue in the future where this baseline study may be useful, the CT scan for Mr Coral is of no direct benefit in this context. It is not included in appropriateness guidelines and is not well justified. When Mr Coral inquires as to the value of the procedure, he is rebuffed. Thus, the caregiver is not transparent regarding the choice and rationale for the imaging undertaken. Even if the procedure is justified, the patient could decide not to have it, or for example, to consider its financial implications for him/her. Healthcare professionals must fully explain what is involved and provide the patient with an opportunity to discuss it. A patient should not undergo a treatment or procedure without the opportunity for him/her (or their legal proxy) to fully understand its impact on medical management and potential side effects.

(238) Because the patient's reluctance to undergo the procedure was not taken seriously, (☹) is assigned for dignity/autonomy (Table 6.4). With regards to beneficence/non-maleficence, (☺) is given for the doctor's concern to provide a baseline for the future; however, this is offset by (☹☹) for the exposure of the patient to the risk of ionising radiation without clear evidence of benefit. In addition, the staff are scored (☹☹) for prudence, as they do not adequately consider the risk from radiation to the patient. Under justice, (☹) is scored as the situation involves a poor use of resources. Mr Coral's requests for information are rebuffed leading to (☹☹) for transparency. A (☺) is received for being compliant with respect to inclusiveness, but (☹☹) is also scored for not being empathetic and respectful of Mr Coral's concerns.

6.5. Julie Magenta: CT scan in woman trying to become pregnant

(239) Julie Magenta (40 years old) contacted her local hospital to schedule an appointment for an elective abdominal CT scan following a referral by her gastroenterologist. She requested the scan be performed prior to her going on holiday and was given an early appointment. On arrival, she was asked at reception, if she was pregnant and replied "No". On questioning, she stated her periods were irregular, and had been so for many years. The staff decided to proceed with the examination based on her sense of urgency, her history, and her denial of pregnancy (Malone et al., 2019).

(240) Ms Magenta had been having difficulty with conception, so was undergoing in vitro fertilisation (IVF) treatment, and fertilised eggs had been implanted a few weeks before the CT scan. She had not mentioned this at reception as she wasn't asked and was sensitive about the subject. She assumed, based on her prior experience, that the attempt would be unsuccessful. Less than a week after the CT scan, she is informed by her obstetrician that she was pregnant.

(241) She was delighted with the news until a friend told her that, if pregnant at the time, the CT scan could have harmed her embryo. Distraught, she arranged an appointment with Dr Beaver, the radiologist, to advise that she might have been pregnant at the time of the scan but did not mention she had been undergoing IVF treatment. Dr Beaver indicated that she should not be concerned. Even if the embryo had been damaged, it was likely it would not implant and would be lost, thereby ensuring no prospect of a harmed child. Ms Magenta was so distressed by this that she left before the interview was finished. Later the loss of the embryo is confirmed. She consulted the internet and is further distressed to find the radiologist's assessment echoed on several websites.

Table 6.5. Ethical compliance evaluation of Julie Magenta's scenario

	dignity/ autonomy	beneficence/ non-maleficence	prudence/ precaution	justice/ solidarity	transparency/ accountability/ honesty	inclusiveness/ empathy
Compliance	☺	—	—	—	—	☺
Non-compliance	☹☹	☹☹	☹☹	—	☹☹	☹☹

(242) Ms Magenta's case could be better handled. It is appropriate and normal practice to ask if the patient is pregnant. In addition, the potential risk to the embryo from radiation exposure could be explained and this would give the patient the opportunity to inform the staff of her IVF status. Her pregnancy status could then be established before proceeding with the CT. An alternative examination not involving radiation could be considered. When Ms Magenta returns and meets with Dr Beaver, her fertility issues are again not discussed, and she is told not to worry since she will likely lose the pregnancy if the embryo is damaged which distresses her even more.

(243) Table 6.5 awards (☹☹) under dignity/autonomy and inclusiveness/empathy based on the inadequacy of the radiologist's interview after the event. However, the hospital also scores (☺) for these values given its policy to ask about pregnancy status, consistent with practice throughout the world. However, more explicit information on potential damage to an embryo could elicit further information that would influence decisions, so (☹☹) is scored for non-maleficence, prudence/precaution and transparency particularly with regard to the adequacy of protocols for protection of the embryo/foetus. Ms Magenta's lack of full disclosure regarding IVF also contributed to the problems. However, within the culture of radiological protection, the emotional issues encountered here are often not recognised, appreciated, or prudently acted upon in practice or in protocol development. A (☺) is given for inclusiveness but (☹☹) is scored with respect to empathy.

6.6. Mary Jade: Breastfeeding following a nuclear medicine scan

(244) Mrs Mary Jade, (39 years old) was the proud mother of Jack, her 1.5-month-old baby. A single mother, she planned to carefully search, in the next months, for a babysitter to care for Jack. A ^{18}F-FDG PET study for suspected vertebral osteomyelitis was prescribed for Mary. The radiopharmaceutical was known to have a low concentration in breast milk and thus an interruption of breastfeeding was not required. Mary was very happy to receive this information. However, after completing the scan, she received a leaflet with instructions to limit close contact with infants for 12 h. The suggested approach was to express the milk, and to let another person feed the baby via a bottle. She was surprised and concerned, since she had not been informed of the need to do this and did not have someone to take care of Jack. Had she been aware of these instructions prior to the exam, she would probably have refused the procedure and asked for a postponement until breastfeeding was finished.

Table 6.6. Ethical compliance evaluation of Mary Jade's scenario

	dignity/ autonomy	beneficence/ non-maleficence	prudence/ precaution	justice/ solidarity	transparency/ accountability/ honesty	inclusiveness/ empathy
Compliance	—	☺☺	☺☺	—	☺	☺
Non-compliance	☹☹	☹	—	—	☹☹	☹☹

(245) Family arrangements can differ and attention to possible diversity and equity should be part of the information process. The example shows the importance of addressing the practicalities of patients' personal situations, concerns, and perspectives in a timely manner. Good timing is important in giving information and allows patients to make properly informed decisions. The instructions on the need for a carer and limitation of contact, when given after the procedure, create anxiety, concern, and practical difficulties. Good communication should be well structured and respect the dignity of the patient and her living arrangements. A leaflet given after the scan is unacceptably perfunctory.

(246) Table 6.6 demonstrates that dignity and the possibility of maintaining autonomy is inadequately addressed in this scenario (☹☹). The compliance level with respect to beneficence/non-maleficence is good (☺☺), while some non-compliance arises (☹) from the late information on contact limitation and the need for a carer. Nevertheless, there is good compliance (☺☺) with prudence/precaution in limiting unnecessary exposure to the child. Partial compliance is recognised (☺) for transparency/accountability/honesty in relation to the exam itself, and for inclusiveness/empathy, as the presence of the baby was considered. However, the fact that complete information was not given before the exam, can be viewed as strong non-compliance (☹☹) in transparency, and in inclusiveness and empathy. Important information was untimely and only given in leaflet form.

6.7. Suzy Rainbow: Multiple paediatric procedures

(247) Suzy Rainbow was a happy and active 4-year-old girl. Her parents had noticed that she started to limp, favouring her right leg, and took her to the paediatrician. Upon examination, it was revealed that Suzy also had a slight fever. The paediatrician suspected that she might have osteomyelitis and referred her to a nearby community hospital for imaging. The hospital's radiology department did not have a radiologist or radiographer with specific experience of imaging children, and they decided to use their young adult protocols. Suzy was unable to give her doctors a good sense of what part of her leg was hurting and so radiographs from the pelvis to the foot were acquired. Following several visits and multiple imaging sessions, staff determined that she had neuroblastoma. Her treatment extended over several years with periodic imaging to monitor progress. Since Suzy was a child who already had several radiographs and CTs, it was decided that MR would be used for follow-up imaging. Because of her age, it was necessary to sedate or anaesthetize her during MR imaging sessions.

Table 6.7. Ethical compliance evaluation of Suzy Rainbow's scenario

	dignity/ autonomy	beneficence/ non-maleficence	prudence/ precaution	justice/ solidarity	transparency/ accountability/ honesty	inclusiveness/ empathy
Compliance	—	☺☺	☺☺	☺	—	☺
Non-compliance	☹☹	☹	☹	☹☹	☹	☹☹

(248) In the initial work-up, the radiologic service tries to address Suzy's health concerns appropriately and with empathy, but they are not well prepared to image a child. Nevertheless, Suzy deserves quality healthcare just like her adult counterparts. MR may be the best choice for follow-up imaging but relying on it just because it does not involve ionising radiation may not be the only reasonable choice. Repeated use of MR with sedation or anaesthesia may also have immediate and long-term adverse effects such as cognitive effects from some medications used for sedation and gadolinium deposition with MR contrast use.

(249) The right procedure for the patient should be chosen and, in this case, it could involve the use of ^{123}I meta iodobenzylguanidine (MIBG). With either ^{123}I MIBG or MR, the risk of adverse effects is quite low. The decision should be shared with the child's proxies, normally the parents, who are not included in this case (non-compliance ☹☹ rating for dignity/autonomy and also for inclusiveness). The staff should consider all risks, and the family perspectives (non-compliant), not just those associated with radiation. They should have ensured paediatric radiography protocols were employed or, if not, they could send her to a facility such as a children's hospital. In Suzy's case, initially performing a radiographic survey to localise the site of pain and potential infection, or a ^{99m}Tc labelled MDP bone scan, could have been helpful in determining the site and extent of her disease and helped reach a quicker diagnosis.

(250) The staff tried to make the right decisions regarding Suzy's care and thus receive (☺☺) for beneficence/non-maleficence (Table 6.7). They also received (☹) for repeated use of anaesthesia or sedation. They receive (☺☺) for compliance and (☹) for non-compliance with respect to prudence/precaution but (☹) with transparency since the facility did not disclose some limitations in their protocols and did not seem to provide the family in shared decision-making.as well as both (☺) for compliance and (☹☹) for non-compliance with respect to the values of justice/solidarity in ensuring the patient was cared for but may not have provided the most appropriate, sustainable imaging resources for the community.

6.8. Janice Blue: Late-stage lung cancer

(251) Janice Blue (45 years old) had recently been diagnosed with advanced lung cancer. She was a married mother of two children, a 13-year-old boy and a 17-year-old girl. She was a very successful professional and her children were preparing to embark on their high school and college education. Thus, she wanted to take an aggressive approach to her treatment. The prognosis was not good. Her oncology physician decided not to order an FDG PET/CT scan as it was expensive, and it was unclear that it would lead to a change in the patient's management. He felt that advanced imaging resources would be better directed to patients more likely to benefit from them. He advised Ms Blue of the gravity of her situation. She was not a candidate for surgery, and he did not alert her to the possibility of advanced imaging. She found the news devastating and did not understand how her clinical situation could be so serious. The clinical staff moved forward with the prescribed plan although some of the members expressed the opinion that advanced medical imaging in Ms Blue's case might have provided her with a better understanding of the seriousness of her illness.

Table 6.8. Ethical compliance evaluation of Janice Blue's scenario

	dignity/ autonomy	beneficence/ non-maleficence	prudence/ precaution	justice/ solidarity	transparency/ accountability/ honesty	inclusiveness/ empathy
Compliance	—	☺☺	☺☺	☺	—	☺☺
Non-compliance	☹☹	—	—	☹	—	☹

(252) The staff follows local best practice for imaging in patients with advanced lung cancer. Thus, the patient and her family do not receive information on advanced medical imaging that might help her better understand the extent of her disease. The fact that the patient is at the end of her life is seen as important and creates a reluctance, among the professionals, to utilise these technologies for her case. It is assumed that a patient with a better prognosis would benefit more from such resources. However, even patients at the end of life can benefit from advanced medical care when it creates an opportunity for them to live a dignified life. The staff is empathetic to Janice's situation, but they avoid sharing information with her that would improve her capacity to make good decisions.

(253) In Table 6.8, (☹☹) are scored for dignity/autonomy due to inadequate discussion and disclosure around Janice's treatment and imaging options. For both beneficence/non-maleficence and prudence/precaution, (☺☺) are awarded, based on good compliance with the agreed local approach to imaging options. An empathetic approach is recognised with two (☺☺) but the situation notably lacks inclusiveness for which it receives (☹). The staff receives both a (☺) and a (☹) for justice as their approach may, in general, be a good use of resources, even if this is not so for Janice.

6.9. Eleni Tsakaris: Whole-body CT check-up for asymptomatic patient

(254) Mrs Eleni Tsakaris (41 years old), an entrepreneur, was travelling for vacation and picked up a free magasine at the airport of arrival. She found an advertisement from a private clinic offering "combined check-ups" that did not require a physician referral. However, this check-up did include a whole-body CT scan. Eleni contacted the clinic to enquire about the value and risk of the CT scan as she had previously read that CT was associated with a much higher radiation exposure than a radiograph. The physician representing the clinic provided detailed information about the value of included medical and lab tests. He informed her that the CT scan was an integral part of their assessment, and that the associated cancer risks were negligible. Mrs Tsakaris booked an appointment, and all check-up tests were performed promptly, and all yielded negative results. She was impressed with the efficiency and quality of the service. Later, her friend, who happened to be a medical physicist, explained to her that whole-body CT scans were not generally recommended for people without symptoms and carried a lifetime risk of radiation-induced cancer. Mrs Tsakiris was disappointed that this important information was not given to her by the clinic.

Table 6.9. Ethical compliance evaluation of Eleni Tsakaris's scenario

	dignity/ autonomy	beneficence/ non-maleficence	prudence/ precaution	justice/ solidarity	transparency/ accountability/ honesty	inclusiveness/ empathy
Compliance	—	—	—	—	☺	☺
Non-compliance	☹	☹☹	☹☹	☹	☹☹	☹

(255) The evidence indicates that whole-body CT has no value for an asymptomatic individual like Mrs Tsakaris. These scans are costly, they can lead to potentially risky follow-up exams, there is a risk of radiation-induced cancer, and they consume a costly scarce resource. Most national and international guidelines advise against whole-body CT for asymptomatic persons for these reasons. The scan is performed without a referral from an independent medical practitioner which leaves much to be desired. The service is quick, and the healthcare personnel are polite and efficient. On the other hand, the individual's worry about radiation-induced risks is not taken into consideration. Information is shared through a free magazine which clearly mentions that whole-body CT is included in the 'combined check-ups'.

(256) The clinic's physician provides no more than brief information to reassure Mrs Tsakaris that the risks are negligible, thus giving (☹) for dignity/autonomy (Table 6.9). Also, (☹☹) are scored for beneficence/non-maleficence and for prudence/precaution. Performance of inappropriate examinations is a poor use of scarce resources giving (☹) for justice. The quality of the information about risk provided to Mrs Tsakiris also give (☹☹) for transparency and honesty. However, the clinic is transparent in describing the scope of its service in the leaflet, giving a further (☺) for transparency. The physician provides detailed information about the value of tests performed by the clinic giving (☺) for inclusiveness, but his overall attitude was not empathetic to Mrs Tsakaris's concerns regarding risk leading to (☹).

6.10. Alpa Pennia: Abdominal lead shielding used due to pregnancy

(257) Alpa Pennia (26 years old) was admitted to the emergency room of her hospital with a persistent headache following a bad fall. The doctor referred her for a brain CT examination and asked if she was pregnant. She responded positively and that she was in her first trimester. The information she received about the radiation risk made her question the need for this examination. After careful consideration, she consented to the procedure. Although it was not standard practice for this clinic, the technicians offered her lead contact shielding to cover her abdomen given her concerns.

(258) Six months later, she gives birth to a baby boy with a malformation of his forearm. She can't help but think that her CT caused this malformation and returned to Radiology for advice. The radiologist told her that such an induced radiation effect was not possible. A year later, she still had doubts and so her son's paediatrician arranged a meeting with a medical physicist from another hospital for an independent opinion. Far from blaming the radiologists, Ms Pennia blamed herself for consenting to the CT scan. She was convinced that the radiation received by her baby was considerable. Why else would they have used lead protection? The medical physicist explained to her that the dose to her foetus was very low as he was not directly in the x-ray beam at any time. The lead shielding was unnecessary and only used to reassure her that precautions were being taken. Such malformations can arise even with no radiation and the chances it was related to the CT scan were minuscule. He stated that if she had been his spouse, he certainly would have recommended that she accept the CT exam. Only then did she take the first step towards accepting the situation.

Table 6.10. Ethical compliance evaluation of Alpa Pennia's scenario

	dignity/ autonomy	beneficence/ non-maleficence	prudence/ precaution	justice/ solidarity	transparency/ accountability/ honesty	inclusiveness/ empathy
Compliance	☺☺	☺☺	☺	—	—	☺☺
Non-compliance	☹	☹	☹	—	☹	—

(259) In their attempt to reassure Ms Pennia, the radiology staff provide her with contact lead shielding. As a result, she concludes that the radiation received by her unborn baby must be substantial. So, when the child is born with a malformation, she could not help but question her decision to consent to the CT scan. Her interaction with the radiologist does not allay her guilt. The medical physicist explains the situation in a more accessible manner which helps her better comprehend her situation.

(260) The medical staff were transparent about the radiation risks and respected the patient's dignity and autonomy without pressuring her to accept the CT exam. Faced with a worried patient, they showed empathy by offering lead shielding that was not recommended by their institutional guidelines. For this, (☺☺) are awarded for beneficence, autonomy and empathy. The staff acted with caution, and thus receive (☺) under prudence/precaution.

(261) In this case, offering unnecessary protection reinforced Ms Pennia in her belief that the radiation delivered to her child was considerable. This gives (☹) for autonomy because the clinic's actions resulted the patient's feeling of being alone to bear the weight of the decision. In addition (☹) is proposed for non-maleficence, as well as for prudence/precaution because the staff might have anticipated such a reaction. Finally, (☹) is scored for the transparency and honesty of the staff who chose not to tell Ms Pennia, even after she gave birth, that the lead shield was only used to mitigate her fear of radiation although it seemed to have had the opposite effect.

6.11 Andrew Plum: Recurrent coronary interventional procedure for chest pain

(262) Andrew Plum (50 years old, BMI 31 kg/m^2) had stable angina. His cardiologist and the patient and family decided to investigate by performing a diagnostic catheterisation which showed a complete block of the right coronary artery. After discussing these results, they decided at a later date, to proceed with a fluoroscopically-guided intervention to attempt to unblock this vessel. The patient and family were informed about the benefits and risks of these procedures and consented to them. They were also informed about the process for dose estimation if the procedure(s) exceeded a trigger level so that the patient might need follow up with a dermatology clinic.

(263) Mr Plum's interventional procedure was complex but successful, and had an estimated dose area product of 800 Gy cm^2 and 19 Gy peak skin dose, which exceeded the trigger level recommended by multiple national and international professional organisations (SIR/CIRSE) of 500 Gy cm^2 dose area product and 5 Gy peak skin dose. The dose and potential for skin injury were disclosed to the patient and the patient was referred to the dermatology clinic for skin checks. The cardiologist and the medical physicist discussed the case and the data were reviewed for more detailed dosimetry calculations, including the cumulative dose for both procedures. The peak skin dose was estimated to be 13.0 Gy ±15% and this information was entered into the patient's medical record along with all dosimetry information.

(264) At 50 days after the procedure, the patient noted well-defined skin redness on his subscapular right back. The dermatologist diagnosed acute radiodermatitis without necrosis and treated it with topical steroids. At 4 months, the skin had healed but there was a hyperpigmentation area.

Table 6.11. Ethical compliance evaluation of Andrew Plum's scenario

	dignity/ autonomy	beneficence/ non-maleficence	prudence/ precaution	justice/ solidarity	transparency/ accountability/ honesty	inclusiveness/ empathy
Compliance	☺☺	☺☺	☺	☺	☺☺	☺☺
Non compliance	—	—	—	—	—	—

(265) The medical staff were transparent and honest (☺☺) who chose to disclose both dose and risks to Mr Plum and family in a shared decision-making manner. Therefore, they respected the patient's dignity and autonomy. With a well-developed dose management and quality assurance programme, they showed teamwork, inclusiveness, and empathy (☺☺) by offering up to date guidance for skin injury risk and follow up. This is also the basis for the (☺) value for solidarity.

(266) In this case, offering both written and oral instructions before the procedure and immediately afterward and patient follow up to ensure safety, are critical parts of radiological protection that reinforced the patient/family's belief that the staff cared for them; in addition (☺☺) is proposed for non-maleficence, and (☺) for prudence/precaution because the staff anticipated risks and patient needs.

(267) Although the 11 scenarios presented above illustrate a wide range of imaging and ethics topics, they are by no means comprehensive. Rather, they are a collection of examples in which it is possible to illustrate application of an accessible method of evaluating and judging situations from an ethics perspective. In addition, the gradings in the tables do not necessarily provide uniquely correct answers. However, they are a starting point for discussion and further review by the reader. Readers may also find the scenarios provide a useful starting point/template to help generate new examples based on their own experience.

7. CASE BASED EXAMPLES IN THERAPY

(268) Section 7 presents a range of scenarios involving day-to-day application of radiation in therapeutic settings. The scenarios draw on experience but are not necessarily literally true. Their purpose is not to demonstrate good practice or compelling good ethical behaviour. Rather it is to construct plausible (if necessarily dramatic) situations, and to be an intuitively convincing illustrations of both compliance and noncompliance with the ethics values already identified in Sections 2, 4, and 5.

(269) Evaluation methodology has already been outlined in Section 5 and includes useful sensitising questions that will allow an inexperienced reader approach ethical evaluation of even complex situations. However, in the scenarios that follow, evaluation is not always comprehensive, and they have been constructed so that they are relatively easy to assess intuitively. Hence, it is not expected that even those new to ethics will need to use the sensitising question table in detail during an initial reading of the following text. However, it is expected that Table 5.2 will prove useful to a more intense and rigorous reading and/or to evaluating new situations.

(270) The aim of the scenarios in Section 7 is to illustrate issues that arise in radiotherapy, i.e. to deliver a high dose to the tumour with minimum dose to nearby normal tissues and sensitive organs. Issues raised in the scenarios include the appropriateness of the initial decision to use radiotherapy, the radiotherapy modality, the fractionation regime, and practices within treatment preparation and delivery. The influence of national and institutional policies is also considered, as are the relationships within the multidisciplinary team responsible for the preparation and delivery of radiotherapy.

7.1. Anna Fortune: Referral for recurrent malignant melanoma

(271) Anna Fortune (70 years old), had undergone a third resection for a recurrent malignant melanoma on her ankle. She was an inpatient in a private hospital. She was a well-educated, articulate woman and despite chronic arthritis, was actively involved in a wide range of activities. There was no evidence of spread beyond the surgical site, but it had failed to heal and presented as an open wound. Anna was slim and her ankle had little tissue mass overlying the bone. With this third recurrence, there was a real possibility that the disease may already have disseminated. Further surgery was not an option and, given Anna's overall condition and the limited evidence of its effectiveness, chemotherapy was also not considered a viable option. Anna was referred to a radiation oncologist for consultation. The possibility of immunotherapy might be considered at a later stage. Anna was extremely nervous, frightened for her future, anxious about the status of her disease, possible treatment options, and overall prognosis. She was not prepared to accept the possibility of no treatment or death. Given Anna's psychological status the radiation oncologist decided not to stress the poor prognosis and potential problems with wound healing, and to offer local radiotherapy. Treatment preparation was carried out and Anna was advised by the radiation therapists (RTTs) on side effects, which may include fatigue. They did not advise on skin care. Ultimately, radiotherapy did not proceed as Anna rapidly progressed to widely disseminated disease and died.

Table 7.1. Ethical compliance evaluation of Anna Fortune's scenario

	dignity/ autonomy	beneficence/ non-maleficence	prudence/ precaution	justice/ solidarity	transparency/ accountability/ honesty	inclusiveness/ empathy
Compliance	☺	☺	-	-	☺	☺
Non-compliance	☹	☹☹	☹☹	-	☹	☹

(272) Radiotherapy in malignant melanoma has benefits primarily in cases of lymphatic spread or brain metastases, with some evidence of benefit to the primary tumour in a palliative setting. Treatment, in a case like Anna's, could be considered, but not over an open wound that was failing to heal. The severe acute side effects associated with treating an open wound on fragile skin with little or no underlying tissue is unacceptable.

(273) The acceptance of Anna's wish to receive some treatment is based on respect for her dignity (☺), as shown in Table 7.1, but the failure to give advice on skin care also shows some disrespect in this regard (☹). Given Anna's strong desire for a treatment, there is weak compliance with beneficence (☺). However, the professional advice of staff on the best treatment option should be evidence based, regardless of the patient's eagerness to try almost anything. Evidence based practice does not indicate radiotherapy and (☹☹) are given for non-maleficence and prudence. Anna is not open to receiving evidence-based information, and while the oncologist's approach could be regarded as paternalistic, patients have a right to choose not to be given information. Thus, for transparency/ accountability both a (☺) and (☹) are awarded. The status and treatment of her disease and the lack of evidence for radiotherapy in her situation is not discussed with Anna and for inclusiveness one (☹) is given although staff were empathetic with her distress (☺).

7.2. John Conway: Incorrect use of No-Action-Level (NAL) Protocol

(274) John Conway (40 years old) had early prostate cancer and started treatment in the radiotherapy department. Given his age and the stage of disease Mr Conway was prescribed high-dose radiotherapy to the minimum volume of tissue necessary to encompass the tumour and to minimise dose to surrounding normal tissue. Mr Conway was simulated for treatment with a full bladder, which he found extremely uncomfortable. Staff sensitively explained that to ensure localisation of his tumour was correct and consistent, he would be required to drink 6 glasses of water each day before treatment. He was distressed but reluctantly consented. Rectal emptying was also advised. Consistent with the department's protocol, verification images were taken on the first three days of treatment with modifications made based on the findings and images acquired and checked weekly thereafter. In Mr Conway's case, treatments were modified during the first three days, based on the image findings, but no further images were taken throughout the remaining course. Mr Conway suffered acute, anticipated, side effects and had difficulty following the drinking protocol. His bowel habits also changed over this period resulting in looser stools and more frequency. It was likely that these side effects resulted in a change of prostate position relative to other organs.

Table 7.2. Ethical compliance evaluation of John Conway's scenario

	dignity/ autonomy	beneficence/ non-maleficence	prudence/ precaution	justice/ solidarity	transparency/ accountability/ honesty	inclusiveness/ empathy
Compliance	☺	☺	-	☺	-	☺
Non-compliance	☹☹	☹☹	☹☹	☹☹	☹☹	

(275) The evidence base for this approach requires reduction of the risk of systematic positioning errors using images acquired on the first three treatments followed by later review, analysis, and adjustment if necessary. Imaging at defined intervals to identify subsequent changes due to tumour shrinkage or the patient's physical condition was also required. The staff comply with the first part of the department protocol at that time, modify the treatment parameters on the first three days but do not take any further images during the treatment due to time and resource constraints. As a result, subsequent treatments are not optimised. The staff did not comply with the protocol, demonstrating a lack of understanding of the implications of not following it. There is also a management failure in not ensuring that staff are fully educated and trained on the scientific basis for the protocol.

(276) John's dignity/autonomy is given (☺) as shown in Table 7.2. Staff explain the reasons for drinking water as part of the procedure sensitively but there is non-compliance in failing to check for changes that could occur over the course of treatment (☹☹). The procedure is applied in principle to benefit the patient (☺) but is performed incorrectly and thus compromises beneficence and non-maleficence (☹☹). There is non-compliance with prudence failing to take possible consequences of incorrect application of the protocol into consideration. (☹☹). The approach is generally compliant with justice as Mr Conway's treatment is the same as that of other patients at the centre (☺), but there is also a lack of justice in the failure to correctly apply the protocol (☹☹). As the imaging is a routine part of the treatment process, the information given to Mr Conway on the procedure lacks transparency (☹☹). Empathy was shown in explaining the reasons for drinking large quantities of water as part of the procedure (☺). High-level equipment cannot deliver safe effective treatment without appropriate education for the staff using it, so this is a serious failure of accountability (☹☹) on the part of the management and those with responsibility for training.

7.3. Mary Indigo: Radiotherapy for painful bony metastases

(277) Ms Mary Indigo (80 years old) presented with widespread metastases from a primary breast cancer. When she developed severe back pain, she was prescribed radiotherapy of 20 Gy in ten fractions for a metastatic deposit in a thoracic vertebrae. Single fraction radiotherapy with an associated lower dose (8 Gy) has been shown to be equally beneficial for the management of bone pain. The option of a single fraction was not discussed with her, as it was routine practice within the hospital to give fractionated radiotherapy. The reimbursement system paid per fraction, not per patient. Mary was brought to the radiotherapy department in her hospital bed, was disoriented, in obvious pain, and it was clear that her cancer was at a very advanced stage. To treat Mary, it was necessary to transfer her from the bed to the treatment table, inevitably causing more pain. The treatment staff and hospital porters were involved in this process, as Mary was unable to move herself. Despite efforts to do this with as little trauma to Mary as possible, her pain was clear and in addition, her nightdress had ridden up leaving her lower body uncovered. Mary was positioned on the table, immobilised to prevent her falling, and eventually treated. Mary completed her course of treatment with significant distress and discomfort and lived for a further two months.

Table 7.3. Ethical compliance evaluation of Mary Indigo's scenario

	dignity/ autonomy	beneficence/ non-maleficence	prudence/ precaution	justice/ solidarity	transparency/ accountability/ honesty	inclusiveness/ empathy
Compliance	-	☺	-	☺	-	☺
Non-compliance	☹☹	☹☹	☹	☹☹	☹☹	☹☹

(278) The benefits of radiotherapy in reducing pain from bony metastases are well documented and evidence based. However, the evidence also clearly demonstrates that a single fraction can be as effective in reducing pain as a fractionated course delivered over a longer period. A single fraction would have been at least as effective in reducing the patient's pain and alleviating the distress and discomfort Mary suffers as she approaches the end of her life.

(279) Mary's dignity and autonomy is not adequately protected (non compliant ☹☹) as indicated in Table 7.3; she is not offered the option of a single fraction, and the procedure occasioned embarrassment. Mary's treatment is acceptable to the extent that radiotherapy is beneficial in reducing pain from bony metastases (compliant with beneficence ☺). What is not justified and not compliant with beneficence is the choice of a fractionated course (☹☹). There is also a level of non-compliance with prudence because of the foreseeable distress of the patient (☹) and with justice/solidarity because of the poor use of resources (☹☹), which may be partly due to the reimbursement policy linking payment to fractions delivered and not with patients treated. Consideration and appropriate attention by the staff regarding the patient's weak and painful condition showed some compliance with justice (☺). There is some empathy in that treatment was intended to reduce Mary's pain (☺). However, the procedure is lacking in other ways; the treatment options are not fully disclosed so that there is not an inclusive or transparent process (☹☹).

7.4. Emma Chestnut: Paediatric referral for proton therapy

(280) Emma Chestnut (6 years old), the oldest of three children, was referred for radiotherapy of a diffuse glioma of the brain. She had symptoms for some months and had undergone diagnostic tests, including a biopsy, prior to a definitive diagnosis. Some of the procedures caused considerable discomfort. Her parents were distressed by the diagnosis, concerned not least about the effect on her siblings, and the disruption to family life. They were of modest means with limited health insurance. Following partial tumour resection, they were referred to radiation oncologist, Dr Cherrytree, as radiotherapy was the most appropriate treatment option. There were two radiotherapy centres in their region, and one (private) offered proton treatment. The treatment options were explained together with their probable outcomes. Emma's prognosis was not good, and her tumour was likely to recur. Treatment with high-energy radiotherapy in a public department, which could start immediately and was covered by the family health insurance plan, was one option. The oncologist felt it was necessary to discuss the option for proton therapy, which is known to result in less radiation damage to normal brain tissue. Not informing the parents could have created future problems. However, the proton therapy was not covered by their insurance plan and the centre was some distance from their home. Emma's parents did not have the resources to pay for private treatment, but possibly felt they had failed Emma in not opting for proton therapy. Given Emma's diagnosis and prognosis and the family circumstances, Dr Cherrytree recommended treatment with high energy radiotherapy in the public department.

Table 7.4. Ethical compliance evaluation of Emma Chestnut's scenario

	dignity/ autonomy	beneficence/ non-maleficence	prudence/ precaution	justice/ solidarity	transparency/ accountability/ honesty	inclusiveness/ empathy
Compliance	-	☺☺	-	☺	☺☺	☺☺
Non-compliance	-	☹	☹	-	-	-

(281) Evidence shows that response to radiotherapy for Emma's tumour is good but usually short lived. Although proton treatment is preferable for many childhood tumours because of fewer long-term side effects, there is no evidence in Emma's case that proton treatment is more successful than conventional radiotherapy. While full information is given to the parents, with respect to outcome and treatment options, they face an emotional decision about which option to follow. Dr Cherrytree worked to involve the parents in the treatment decision for their daughter not withstanding its difficulties.

(282) Dr Cherrytree explained the two treatment options both of which would have had a benefit and was therefore compliant with beneficence and non-maleficence resulting in (☺☺) (Table 7.4), but also a (☹) is scored for neglecting the possibly more severe side effects from conventional radiation therapy. For this reason, a (☹) is also given for prudence/precaution. From a societal perspective excessive use of high-cost procedures such as proton therapy add significantly to costs so Dr Cherrytree was therefore compliant with justice in her advice (☺). Dr Cherrytree is compliant with transparency in outlining the possible treatment options Emma's parents might consider (☺☺), even if this may result in mental and physical distress for the family. Recognising the rights of the patient and her family to take an active part in the decision-making process is key and (☺☺) is given for inclusiveness/empathy.

7.5. Paul Trenton: Incorrect radiotherapy field placement

(283) Paul Trenton (50 years old) was in poor general health with an advanced tumour in his left lung. He was unfit for surgery and was referred for palliative radiotherapy. The busy clinic he attended had limited equipment and full treatment planning was not carried out for palliation patients. Paul was prescribed 20 Gy in ten treatments, using anterior and posterior opposing fields, with the option to consider further treatment later. The clinic was exceptionally hierarchical, teamwork was poor, and questioning was discouraged. The simulator staff noted the posterior field was marked incorrectly for the right side. They raised their concerns but were dismissed by the consultant.

(284) At the treatment unit, Paul was the last patient of the day, and no medical staff were on duty. The Radiation Therapists (RTTs) noted that the posterior field was drawn on the incorrect side, contacted the patient's doctor by phone and were instructed to treat the patient as marked. They were thus confronted with a serious dilemma. Treating as instructed would have given an unnecessary dose to the right lung and deprived the left one of a necessary dose. They considered giving the anterior field only but recording this would have contradicted the explicit instruction given. They were not prepared to mistreat the patient as he was in considerable respiratory distress and decided to treat the anterior field as marked, and to reposition the posterior field on the left side as per the prescription. The following day they approached a junior doctor on the team with whom they had a good working relationship, and the fields were corrected.

Table 7.5. Ethical compliance evaluation of Paul Trenton's scenario

	dignity/ autonomy	beneficence/ non-maleficence	prudence/ precaution	justice/ solidarity	transparency/ accountability/ honesty	inclusiveness/ empathy
Compliance	-	☺☺	☺☺	-	-	☺
Non-compliance	☹	☹☹	☹☹	-	☹☹	☹☹

(285) This is a clear example of a system failure where staff lack power to challenge effectively when it is essential to do so. As a result, the staff become the focus of the ethics discussion, but the physicians as well as the overall system must also be considered. Hierarchical structures still exist in many places, particularly where education is insufficient and employment opportunities are poor. Junior doctors and RTTs, are often vulnerable and at risk of reprimand or dismissal. Patients can receive poor care in such situations. It is important to note that professionals are ethically accountable to the patient as well as to their professions and colleagues.

(286) Table 7.5 notes non-compliance with dignity/autonomy (☹) by the doctor in his treatment of the RTTs, who were not encouraged to question aspects of treatment. Beneficence and non-maleficence for the patient are not respected by the doctor, who would have allowed him to be treated incorrectly rather than acknowledge the error (☹☹). But, the RTTs try to correct this, and deliver a correct treatment (☺☺). The staff avoid delivering an unnecessary radiation to the patient's right lung and in this way are prudent (☺☺) as well as empathetic (☺). The RTTs, in the context of their future at this clinic, might have considered not treating the left lung but, they put the patient benefit first and reposition the field correctly. The consultant's direction to proceed with an incorrect treatment must be considered non-compliant with prudence (☹☹). There is no transparency/ accountability and no inclusiveness or empathy in the system in this clinic (☹☹).

7.6. Mark Gentian: Non-reproducible position

(287) Mark Gentian (50 years old) was diagnosed with an early-stage prostate cancer and referred for radiotherapy. Treatment options were discussed with Mark. Given the stage of disease and his age, high dose intensity modulated radiotherapy (IMRT) was the preferred option. This was new to the department involved, and hence there was limited experience with it. To achieve the level of accuracy required the patient must be set up in exactly the same position every day. On Mark's attendance for his first treatment at the linear accelerator, he was positioned on the treatment table, with his trousers and underwear pulled down to the level of his upper thighs exposing the pelvic area. This was normal practice in the department and aspired to maximise the patient's comfort and to minimise his embarrassment. However, removal of the patient's lower clothing was essential to allow him to be repositioned accurately for every treatment.

Table 7.6. Ethical compliance evaluation of Mark Gentian's scenario

	dignity/ autonomy	beneficence/ non-maleficence	prudence/ precaution	justice/ solidarity	transparency/ accountability/ honesty	inclusiveness/ empathy
Compliance	☺	☺☺	☺	-	-	☺
Non-compliance	-	☹☹	☹☹	-	☹☹	-

(288) IMRT is the correct treatment for a person of Mark's age and disease profile. Precision and accuracy are integral to this approach to ensure the high dose area is confined to the tumour with minimal dose to the surrounding normal tissues. The staff, in attempting to maintain Mark's dignity do not understand its impact on the treatment outcome. There is a failure of management in not providing education and training on the introduction of new equipment or techniques. The staff fully inform Mark of his treatment options and the advantages and disadvantages of each approach prior to referral. The requirement to remove his lower clothing is not explained at the time of treatment preparation and the procedure is compromised. The consequence may be a failure to cure and/or overdosing the surrounding tissue.

(289) In Table 7.6 there is a (☺) under dignity and autonomy for the staff respect for the patient's privacy in trying to minimise his embarrassment. There is compliance with beneficence and non-maleficence (☺☺) in that IMRT is the correct option. But this is accompanied by non-compliance (☹☹) due to the suboptimal staff education/ training, leading to unsatisfactory execution of the treatment. Compliance with prudence and precaution (☺) is demonstrated as Mark has been informed of the options prior to the decision to proceed with radiotherapy. However, the failures regarding removal of his lower clothing are non-compliant with prudence and precaution (☹☹). There was non-compliance with accountability (☹☹) to Mark even though the staff demonstrated some empathy (☺) with him.

7.7. Jane Pink: Inappropriate use of new technology

(290) Jane Pink (70 years old), a frail lady, had a tumour of her larynx. Radiotherapy and surgery offered equal potential for cure but as Jane was considered unfit for surgery, she was referred for radiotherapy. The radiotherapy department equipment had recently been upgraded with the addition of two new linear accelerators with multileaf collimators. These allowed for shaping of the treatment volume to closely encompass the tumour and avoid more normal tissue. However, the tender process had not considered the accessory equipment required for the more accurate positioning and immobilisation essential to the new approaches. Staff had limited experience with these and had received no related training. A complex treatment plan using five fields was prepared for Jane. In the absence of immobilisation equipment, the patient was setup and treated using a simple headrest which was not fixed to the treatment table. Without fixation the patient was able to move her head during each treatment and it was likely that her head position was not consistent between treatments. The consequences could be a low tumour dose, or excessively high normal tissue doses.

Table 7.7. Ethical compliance evaluation of Jane Pink's scenario

	dignity/ autonomy	beneficence/ non-maleficence	prudence/ precaution	justice/ solidarity	transparency/ accountability/ honesty	inclusiveness/ empathy
Compliance	-	☺☺		-	-	-
Non-compliance	☹☹	☹☹	☹☹	-	☹☹	☹☹

(291) New equipment enables improved treatment and improved outcomes by offering a more tailored approach to patients' needs. When resources and experience are limited, tender specifications may not recognise the necessity for accessories which are essential to optimum application. Failures in education and training and the absence of a team approach to procurement may compound the situation and limit the potential of new equipment as well as create opportunities for unsatisfactory application. All these failures, which are present in this example, lead to inadequate treatment preparation, planning, and delivery as well as probable suboptimum outcomes.

(292) Table 7.7 indicates that there was non-compliance with dignity/autonomy as the patient was unaware of the implications of the lack of immobilisation arrangements and their importance (☹☹). The scenario complies with beneficence and non-maleficence (☺☺) as the new treatment was more tailored to minimising the dose to normal tissue but, there is also non-compliance with this value, (☹☹), due to the failure to effectively immobilise the patient with potential adverse consequences. There was non-compliance with prudence and precaution (☹☹) in the failure to include the necessary accessories and training. There was non-compliance with transparency and accountability (☹☹) and with inclusiveness and empathy in not including all members of the team in the equipment tender process (☹☹).

7.8. Aishling White: Failure of open disclosure

(293) Aishling White was appointed physicist at a Radiotherapy Clinic. She was asked, during the interview for her post, if she had experience in HDR brachytherapy and stated that she had attended lectures but had no practical experience. Shortly after her appointment, the physicist that normally planned HDR was off work due to illness. She was asked to plan an HDR treatment for an urgent case arising from pre-inserted catheters. She was reluctant to do so, but it was a small department with no alternative experienced staff member. So, she agreed, prepared the plan and it was delivered. Two days later, she realised that a basic mistake had been made leading to mistreatment. Her lack of experience, and the lack of a second check were likely contributory factors. Aishling was devastated and concerned about what her new colleagues might think of her. She further investigated the situation, decided that the error was not significant and that she did not need to report it (Malone et al., 2019).

Table 7.8. Ethical compliance evaluation of Aishling White's scenario

	dignity/ autonomy	beneficence/ non-maleficence	prudence/ precaution	justice/ solidarity	transparency/ accountability/ honesty	inclusiveness/ empathy
Compliance	☺	-				
Non-compliance	☹☹	☹	☹☹	☹☹	☹☹	☹

(294) This scenario stresses the importance of a second check and the value of honesty and open disclosure in radiotherapy. Unlike many other medications or procedures, there is no antidote or corrective action that can be taken once radiation has been administered. The aphorism "measure twice, cut once" is particularly apt for the situation. In this case the urgency superseded the importance of treatment verification. But, by hiding her mistake, Ms White undermines the appropriate evaluation of the impact of the error and prevents potential corrective action(s). As a physicist, she probably has the knowledge to assess the impact of a minor dose discrepancy, but by not consulting with the physician, she is acting outside her primary area of expertise.

(295) The behaviour Ms White and the treating radiation oncologist exhibit may not stem from bad intentions. Professionals acting off protocol can arise, for example, from changing practices or a desire to improve efficacy or efficiency in an individual case. But such should not be achieved at the cost of errors in treatment. Open disclosure of errors honours the autonomy and dignity of the patient and allows the experience to inform future actions. Aishling White's hesitation about disclosing her error can be attributed to not wishing to damage her own reputation. This behaviour is not limited to individuals but is present in whole systems. Transparency increases patients' confidence and demonstrates respect for them.

(296) Table 7.8 notes (☹☹) for dignity and autonomy as the error had not been disclosed to the patient but (☺) is given as the intention was to provide necessary treatment as quickly as possible. The violation of the value of non-maleficence (☹) is clear even if there was not great harm to the patient. The values of transparency/accountability are also not adhered to in the failure to disclose the error (☹☹). Prudence is clearly lacking adding another (☹☹). By hiding her mistake, the values of justice and solidarity are violated (☹☹) potentially leading to repetition of the error. There is lack of inclusiveness in Ms White's failure to report and her not consulting with the physician (☹).

7.9. Joyce Primrose: Choice of Treatment Technique

(297) Ms Primrose (82 years old) was a breast cancer survivor, an active painter, an avid book reader, and community participant. She presented with four intracranial metastases and was offered stereotactic radiosurgery (SRS) by Dr Greene, the radiation oncologist. He discussed with Ms Primrose the balance of treating local lesions as compared to whole brain therapy, and decided to undertake further imaging, which identified three additional lesions. At the time, this raised significant questions about the longer-term benefits of SRS which tended to be limited to those with five or fewer lesions. Nevertheless, Dr Greene offered her SRS over whole brain radiotherapy to protect her from potential damage to cognitive function (Malone et al. 2019). Dr Greene was balancing the scientific evidence with his own prior experience, the specific circumstances of Ms Primrose, and the fact that their clinic had ample availability of SRS.

Table 7.9. Ethical compliance evaluation of Joyce Primrose's scenario

	dignity/ autonomy	beneficence/ non-maleficence	prudence/ precaution	justice/ solidarity	transparency/ accountability/ honesty	inclusiveness/ empathy
Compliance	☺☺	☺	☺☺	-	☺☺	☺☺
Non-compliance	-	☹	-	-	-	-

(298) Choice between treatment methods is one of the ethical dilemmas radiation oncologists must face regularly. Available studies inform decisions at the time, for the patients that match the characteristics of the participating cohorts. However, the studies do not always address all the issues of importance to a particular patient and, in practice, it is sometimes necessary and ethical to make decisions that may be considered off protocol but are best suited to the situation being presented.

(299) Dr Greene shows respect for his patient's dignity and autonomy by protecting the functions that are important to her, and his ongoing engagement with the patient scores (☺☺) under these values as well as transparency (Table 7.9). He is also exercising prudence in undertaking further imaging and scores (☺☺). While SRS will treat the visible lesions resulting in a (☺) for beneficence, there is a chance that by not giving her whole brain radiotherapy, more lesions may appear in a short interval, and may negatively affect her survival giving a (☹) beneficence/non-maleficence. No score is given under justice, but in circumstances where SRS has limited availability (☹) would be warranted.

7.10. John Montgomery: Clinical trial recruitment

(300) John Montgomery (93 years old) a reasonably fit bachelor, lived with his elderly brother. He presented with significant pain and discomfort from a recurrent tumour of his inner ear. He had been treated with surgery and radiotherapy two years previously and had been disease free until two months ago. Further surgery was not possible, and he was referred for palliative radiotherapy for symptom control and possible reduction of the tumour size. The consultant suggested entering John into a clinical trial for immunotherapy in combination with radiotherapy. John was an intelligent man, but he was confused as to his prognosis. He did not understand the terminology used by the doctor and the extensive technical literature he was given which outlined the trial treatment, potential benefits, and anticipated side effects. He concluded that the trial had the potential for cure but as he wasn't clear he asked a medical friend to review the literature he had been given and to explain it in plain language for him. His friend pointed out that the literature was clear that the experimental treatment was not curative, and the immunotherapy was associated with severe side effects which would be exacerbated by the radiotherapy. If John were on the treatment arm this would cause him significant discomfort and distress. John chose not to enter the trial and to proceed with palliative radiotherapy.

Table 7.10. Ethical compliance evaluation of John Montgomery's scenario

	dignity/ autonomy	beneficence/ non-maleficence	prudence/ precaution	justice/ solidarity	transparency/ accountability/ honesty	inclusiveness/ empathy
Compliance	☺	-	-	-	☺	-
Non-compliance	☹☹	☹	☹	☹☹	☹	☹☹

(301) Clinical trials are a key component of evidence-based medicine and are usually conducted within a framework of research ethics. However, in this case we are assessing the situation from the perspective of the impact of the existence of the trial on the clinical experience of an individual patient, John Montgomery. Recruitment into trials is important and ultimately beneficial to patients. However, given the limited number of eligible patients, recruitment is often difficult and even eligible candidates may not always be suitable. In this instance, given his age and symptoms, the patient is clearly unsuitable and might suffer undue harm and distress as well as unacceptable side effects. The explanations offered are unintelligible to the patient and his physician and the investigators fail to make it clear that even the most optimistic trial outcome is not curative and significant side effects are possible.

(302) When a trial is undertaken, it is necessary that resources are in place to spend time with patients to explain it fully, including potential outcomes that can impact on quality of life. Failure in this regard, excludes John from the decision-making process.

(303) Table 7.10 notes that there is insufficient respect for John's dignity/autonomy (☹☹) in his selection. The information provided is poorly suited to him leading to (☹☹) for inclusiveness/empathy. The probability of serious side effects scores (☹) for non-maleficence. Transparency/accountability received a (☺) as detailed information was provided but also received a (☹) as the literature available was not comprehensible to a layperson. Recruitment onto trials without resourcing good patient communication, is a poor use of the trial facilities and the patients' time and goodwill. Hence it is non-compliant with justice/solidarity (☹☹). There was a lack of prudential thinking in risking exposing a person approaching the end of their life to side effects that could prove unacceptable to them (☹).

(304) Although the ten scenarios presented above illustrate a wide range of therapy and ethics topics, they by no means comprehensive. Rather, they are a collection of examples in which it is possible to illustrate application of an accessible method of evaluating and judging situations from an ethics perspective. In addition, the gradings in the tables do not necessarily provide uniquely correct answers. However, they are a starting point for discussion and further review by the reader. Readers may also find the scenarios provide a useful starting point/template to help generate new examples based on their own experience.

8. EDUCATION AND TRAINING IN ETHICS

8.1. Education and training of relevant stakeholders

(305) Key Message 26: Everyone in the diverse groups of relevant stakeholders is responsible for assuring strong radiological protection and ethical values in health care. Each target group needs to be empowered and educated to ensure that patients are imaged and treated correctly.

(306) Historically a paternalistic approach, where the health professionals knew best and the patient accepted what they were told without question, was adopted and the possibility of risk was rarely discussed. Modern medicine has moved to a paradigm of shared decision-making as far as is realistic. This is based on open honest communication with patients on the benefits and risks discussed before imaging or treatment commences. This shift requires an educational grounding in ethics as it underpins clinical practice in the use of radiation in imaging and treatment. Currently teaching in biomedical ethics education is not homogenous across health professional schools (Taylor 2009; Brown et al., 2014; WMA, 2015; UNESCO, 2018; AUR, 2017).

(307) All those involved in health care are responsible for assuring strong radiological protection and ethics. Each target group needs to be empowered and educated to ensure that patients are imaged and treated correctly. An education and training programme on ethics in radiological protection in medicine should consider the stakeholders' profile in order to tailor the contents accordingly. This applies not only to experts, but also to patients and families as well as to medical students and the broad spectrum of health professionals. Ethics is an essential component of an effective and balanced radiological protection education and training that enables informed decision-making and helps achieve the greatest possible benefit at the lowest possible risk (Demeter et al., 2016; ICRP, 2018a; Malone et al., 2019). It is essential to tailor the contents of the educational programme to the needs of the specific stakeholder group (IRPA, 2008).

(308) Key Message 27: Although it may be of value to integrate the ethics teaching into everyday practical education, it is necessary to provide specific, practical teaching on ethics.

(309) Education and training on ethics for all professionals dealing with medical uses of radiation both within their formal education (e.g. radiographer's and radiation therapists (RTTs) school, radiology and radiation oncology residency and medical physics graduate school) and as part of continuing medical education/professional development will be essential in order to establish ethical behaviour in the medical use of radiation as a key component of practice and to prepare health professionals to face the ethical issues that could potentially be encountered in the future. It is imperative that education in the ethics of radiological protection is built on a solid foundation specific to the area of radiation medicine where the health professional will be working. This foundation must provide the scientific and clinical knowledge and skills which underpin the individual discipline and prepares the graduate to work safely and effectively. The scientific foundation must also include radiological protection as it pertains to the specific discipline. In addition, there must be a component of continuing medical education/professional development programmes (CDP) spanning a career.

(310) An effective and balanced education and training programme in the ethical issues related to radiological protection enables health professionals to help patients, families and carers to understand the procedure, its importance and also its risk supporting informed

decision-making and helping to achieve the greatest possible benefit at the lowest possible risk. Health professionals requesting and/or performing radiological medical procedures have a shared responsibility to ensure that the procedure is appropriate and will be of benefit to the patient (Image Gently, 2022).

(311) The clinical value of the use of radiation technologies in medicine are clear; however, inappropriate or unskilled use of such radiation technologies or failure to provide appropriate equipment and/or education may increase risk and result in harm for patients and/or workers. Examples of inappropriate or unskilled use include inappropriate imaging requests, failure to optimise an imaging protocol or a calibration for a patient, use of suboptimal equipment or techniques or applying pressure to image or treat patients too quickly resulting in a failure to complete the full range of checks prior to exposure or to understand why they are necessary. (NPR, 2009; New York Times, 2010; Tamarat and Benderitter, 2019).

(312) As ethical issues arise regularly during practice, education and training in the ethical principles of radiation radiological protection in medicine requires a theoretical basis reflected in examples from clinical experience. This includes adhering to professional codes of ethics, institutional policies, and maintaining competencies through lifelong learning. However, there will be times where an ethical dilemma requires a formal, explicit response from a professional and graduates should be prepared to process these situations clearly and systematically while presenting their ethical reasons for their decisions to others.

(313) However, there will be times when an ethical dilemma requires a formal and explicit response from a professional. Therefore, graduates should be prepared to process these situations clearly and systematically when presenting the ethical reasons for their decisions to others. This underpins the need for continuing medical education/professional development in ethics of medical radiation practice.

(314) Students and graduates need to be able to integrate ethics into their daily practice. Historical and recent examples can be used to stimulate analysis and discussion on the systemic, cultural, and human factors that may have contributed to harm and how ethical principles can be applied to limit the potential for harm in future applications of radiation in medicine. In Section 5, sensitising questions are meant to serve as prompts for reflection and conversation on the compliance or non-compliance of the scenarios with the paired ethical values. This exercise is an example of how asking sensitising questions may elicit engagement of patients and empower them to share their needs and questions. Other material can be found in (Brenner et al., 2001; Paterson 2001; Goske et al., 2008; NPR, 2009).

(315) Additional teaching and learning approaches for complex ethical issues include the use of simulated patients and role play (PERCS, 2021). The goal should not be to attempt to present every possible clinical scenario but to provide the learner the confidence and critical thinking skills that will allow her or him to handle difficult ethical issues as they arise. Ethical issues related to radiation health technology and its uses will continue to evolve including integration of artificial intelligence (Geis et al., 2019). Education and training on ethical dimensions of radiological protection should also address the use, precautions, and biases of artificial intelligence and machine learning, and how this will require strong ethical foundations (Geis et al., 2019).

(316) Digital learning has provided the opportunity to extend education to a much wider audience and innovative approaches in e-learning are not restricted to didactic lectures. They provide an excellent platform for low- and middle-income countries and in situations where staff shortages do not permit health professionals to attend conferences or workshops.

8.1.1. Education for the engagement and empowerment of patients, families, and carers

(317) Rapid developments in medical technology applications have resulted in many new challenges for both health professionals and patients, families and carers. Health professionals have an ethical responsibility to ensure their knowledge is sufficient for appropriate use of new technology or treatment approaches and to inform patients, families and carers of the reasons behind their decisions. Patients, families and carers ethical rights must be respected but it must be remembered that they are partners in the shared decision process. They must respect the ethical issues associated with unnecessary or excessive demands for inappropriate imaging or treatment modalities and be prepared to take the advice offered in open/transparent communication (Brenner et al., 2001; Paterson et al., 2001; Goske et al., 2008; NPR, 2009).

(318) Volunteer radiological protection awareness and education campaigns in radiological protection around the world have provided success stories of advocacy and education that include patients, families, and carers. These campaigns are part of the culture shift to improve radiation health literacy that also integrate and embed ethical values (Image Gently, 2007; AfroSafe, 2018; ArabSafe, 2021; ESR, 2022). While ethics-based education is not explicit in these campaigns, the values are respected in the materials and integrated in the messaging in terms of beneficence/non-maleficence, prudence, justice, dignity, accountability, transparency and inclusiveness.

(319) Key Message 28: Radiological protection campaigns have improved radiation health literacy for the consumer and provided transparent ethical values for all stakeholders.

(320) For consumers of radiological medical procedures, the hospital environment, the technology and medical language all may be unfamiliar, frightening, and overwhelming. There are also many questions that arise in the navigation of medical care, decisions that must be made, and expectations of patients and family members. More and more facilities and patient support organisations provide written or web based educational materials for patient and public engagement to clarify patients' rights, including equal rights of access to health care, asking questions, consent, privacy, filing complaints, and how to request an ethical review of their care (IRPA, 2008).

(321) Patient's rights also carry with them responsibilities in how a patient and their family members should act in relation with the health care facility. For example, they have a duty to be considerate and respectful, and take responsibility for their care with a certain benefit/risk (thus to accept or to decline care). In addition, they should 'be aware that your right to be involved in your plan of care does not include receiving medically unnecessary treatment'. They may also 'voice concerns to hospital staff, medical staff, without fear of reprisal or discrimination; request assistance for concerns or file a formal grievance with patient & family advocacy and receive a written response; utilise the hospital's grievance process as well as or instead of filing a complaint with the regional department of health and/or The Joint Commission' (EC, 2002; Australian Charter, 2018; Emory, 2022).

(322) In order to implement these rights and responsibilities of patients and the public, improvement of health literacy is essential. Health literacy is "linked to literacy and entails people's knowledge, motivation and competencies to access, understand, appraise, and apply health information in order to make judgments and take decisions in everyday life concerning health care, disease prevention and health promotion to maintain or improve quality of life during the life course." (Sørensen et al., 2012; Bastiani et al., 2021).

8.1.2. Educating and involving other stakeholders

(323) Non-health care professionals in positions of authority with respect to medical uses of radiation must also have substantial knowledge and understanding of ethical considerations of radiological protection. This is because decision-making and actions according to legal obligations of administration officials have a great impact on large number of citizens. They should keep responsibilities to protect dignity and rights of each individual citizen and at the same time have to work for public health. Accountability, responsibility and inclusiveness is key of their everyday practice, however, it is prerequisite that such procedural aspects must be derived from core and fundamental ethical values which govern their decisions and actions, especially at conflicting situation between individual's rights and public interests. This involves ensuring equity of resources across the country and that health professionals involved in radiation use are educated and trained appropriately. They should also take responsibility for monitoring services and for public education programmes.

(324) Hospital managers must ensure that they provide the appropriate resources for the services they offer and that these services are maintained for optimum effectiveness. Managers must be confident that the staff employed to work in these areas are registered with the statutory body or professional society, have received the necessary education and are facilitated to maintain competency. All workers with radiation technologies must also understand the ethics of radiological protection because they sometimes confront ethical dilemmas and take responsibility in decision-making and/or communication with patients and the public. Medical clerks are often the person whom patients first contact in the health care facility and sometimes deal with patients' claims or problems when these patients cannot talk directly to their physicians or other health professionals. Many such staff do not receive ethics and communication education and training, which would allow them to understand patient and family well-being and respect.

(325) Vendors should understand their ethical responsibilities in ensuring software and equipment are appropriate and safe, with training in use (IAEA/WHO, 2014).

8.2. Elements of ethical education and training in radiological protection in medicine

(326) Key Message 29: An understanding of the basic principles of radiological protection is an absolute pre-requisite – this understanding is necessary but not sufficient without also including ethical training – for all health professionals working with radiation for the purpose of diagnosis or treatment.

(327) The core of safe and accurate practice is an understanding of both the principles of radiological protection and the ethical foundation for its application. However, in the clinical setting, situations arise where the health professional is required to make an ethical judgement with regard to their own practice or the practice of other health professionals with whom they interact. This can be both challenging and complex and requires a knowledge foundation providing the basis from which to evaluate a clinical situation and to then act appropriately.

(328) In this context, education and training in ethical principles as they apply to radiological protection should be based on Bloom's hierarchical taxonomy of learning. It has long been recognised that learning takes place at an increasing level of complexity from the simple recall of facts to the process of analysis and evaluation. This ascending order of complexity was first described by Benjamin Bloom, an American educationalist (1913–1999) (Bloom, 1956) and remains the most widely used taxonomy or classification of the levels of

thinking during the learning process (ACGME, 1999; European Parliament, 2008; UNESCO, 2018). Bloom and colleagues devised the hierarchical taxonomy to classify forms and levels of learning. It was based on the premise that you cannot apply or evaluate something until you understand it, learning at the higher level is dependent on having acquired the prerequisite knowledge and skills at lower levels. In 2001, it was revised by Anderson and Krathwohl (Anderson and Krathwohl, 2001) (Table 8.1) and currently used across a professional career.

Table 8.1. Taxonomy of Learning Definitions in Anderson and Krathwohl's updated Bloom Hierarchical Taxonomy (Anderson and Krathwohl, 2001).

Remembering	is retrieving information from long-term memory
Understanding	is constructing meaning from instructional messages including oral, written and graphic communication
Applying	is carrying out a procedure in a given situation
Analysing	is breaking the material into its constituent parts and determining how the parts relate to one another and to the overall structure or purpose
Evaluating	is making judgements based on criteria and standards
Creating	is putting elements together to form a coherent whole function: reorganising elements into new patterns of structure

(329) This model enables the educator to define the student learning outcomes based on the knowledge, skills and competencies that are necessary for health professionals to make carefully considered ethical decisions in the clinical setting when using radiation. The table below gives some examples as to how the knowledge, skills and competencies (KSCs) can be defined. This enables development of education and training modules as part of an education programme. Each of the key professional groups needs a specific set of KSCs essential for their effective participation in the optimisation process. Table 8.2 is an example of how to develop a learning matrix for radiological protection ethics in the medical environment. It is iterative and must be reinforced with repeated discussion and study, leadership modelling, and learning throughout one's career (ACGME, 1999; Frank et al., 2010, Frank et al., 2015).

(330) Key Message 30: The Bloom taxonomy model enables the educator to define learning outcomes based on the knowledge, skills and competencies that are necessary for health professionals to make carefully considered ethical decisions when using radiation in medicine.

8.3. Conclusion for education and training

(331) While available educational contents, learning strategies, and resources may differ locally, the current ICRP document and scenarios approach may provide a foundation for the ethics training in radiological protection in medicine. In contrast with the vertical integration of these subjects into the educational curriculum at a given point in time, the longitudinal approach by integrating ethics and radiological protection throughout the medical curriculum seems to be a more effective strategy. It would begin in the undergraduate schools of all health professionals, continue with post-graduate training, and continue through the arc of one's professional career, which would take into account changing societal values, learning strategies, and radiological protection science. Stakeholder education in ethical use of radiation should also include regulators, vendors, and managers. Finally, the improvement in health literacy by patients, their families, and carers is vital to ensure an informed decision-making process and improved patient outcomes.

Table 8.2. Example of a framework of knowledge, skills, and competencies (KSCs) for ethics learning by radiological protection students and health professionals. Refer to Section 5 for definitions of the ethical values, sensitising questions, and Sections 6 and 7 for the case scenarios. Please note that this table provides only a sample of possible KSCs, not a complete list.

Knowledge	Skills (ability to apply knowledge)	Competencies, (Attitudes/Behaviours)
Principles of radiological protection		
• Define the **health risks** associated with radiation exposure across the age spectrum • Define the principle of **justification** • Define the principle of **optimisation**	• Estimate the radiation dose to be delivered to the patient by different imaging and treatment options. • Compare and contrast the advantages and disadvantages of a range of imaging and treatment options (part of justification process) • Compare and contrast optimised protocols for different populations of patients • Consider also possible radiation risk for the involved workers in some processes such as interventional procedures	• Establish a system of DRLs (part of optimisation) at institution level, • Ensure that the process of justification is embedded in the department protocols and procedures • Audit and implement change as appropriate
Core and procedural values of ethics of radiological protection in medicine		
• Define the ethical values of **dignity/autonomy** • Identify the core components of dignity/autonomy • Define the core components of confidentiality • List the different areas where dignity/autonomy and privacy can be compromised • List the most commonly encountered cultural differences • Define the uncertainties associated with specific procedures	• Have awareness of fundamental human rights that dignity/autonomy and privacy must be respected • Review the patient notes to inform yourself appropriately • Plan your discussion with the patient tailored to their individual needs • Prepare an area for patient discussion that ensures autonomy and privacy/confidentiality • Consider capacity of some patients to accept additional radiation risk from imaging procedures to evaluate or confirm some pathologies	• Implement the informed consent decision process for all patients undergoing imaging and therapeutic procedures • Support the patient in making a decision • Act to respect privacy and not to breach confidentiality balancing with needs of information sharing with others • Create an environment that respects the religious and cultural perspectives of the patients • Manage confidentiality based on the patient's priorities and values

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Table 8.2. *(continued)*

Knowledge	Skills (ability to apply knowledge)	Competencies, (Attitudes/Behaviours)
• Define the ethical values of **beneficence/non-maleficence** • Identify the relevant evidence-based clinical referral guidelines. • List the benefits of performing a given procedure • Recognise radiation risks associated with the procedure • Recognise the potential harm from not performing the procedure. • Identify examples where public/patient information may differ from evidence-based medical opinion	• Determine how the value of beneficence/non-maleficence can be applied in the process of justification • Ensure that the procedure conforms to the clinical referral guidelines and the departmental protocols. • Explain the benefits and the potential harm associated with the procedure to the patient. • Ask the patients what they understand about the proposed procedure.	• Apply the value of beneficence when weighing benefit/risk in recommending radiological management • Validate the requested procedure's appropriateness • Ensure that the patient understands the options necessary to make an informed decision.
• Define the ethical values of **prudence/precaution** • Identify the purpose of the proposed procedure • List the consequences of an inappropriate procedure that uses ionising radiation • Define the known benefits of the procedure relative to the patient condition • Define the known risks associated with the procedure relative to the patient condition	• Identify sources of uncertainty about radiation risks associated with the procedure. • Explain the factors considered in selecting a procedure • Appraise any unintended consequences of the selected procedure in the medical and societal domains • Discuss any uncertainties associated with the proposed procedures with the patient	• Evaluate the information provided in deciding to proceed with an imaging procedure • Assess if the patient and family are comfortable with the decision (shared decision-making) • Analyse possible risks and benefits on the basis of the characteristics of a specific scenario set • Carefully consider all choices and take a prudent action acknowledging the uncertainty

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Table 8.2. *(continued)*

Knowledge	Skills (ability to apply knowledge)	Competencies, (Attitudes/Behaviours)
• Define the ethical values of **justice/solidarity** • Describe the values of equality and fairness· • Describe the resources available locally and in the wider region • Consider fairness in resource allocation • Consider how fairness is applied in the rules and procedures in the processes of decision-making	• Identify factors to keep equality and fairness in local and global health system • Prioritise the proposed procedure in the context of the available resources • Make priority order considering fair resource allocation • Discuss conflict of interest (actual or perceived) for individuals and/or institutions	• Provide care in a fair, equitable manner to all patients • Justify the proposed procedure in the context of effective use of resources • Manage any identified conflict of interest for individuals and institutions • Support choice/decision to contribute to fair resource allocation • Reject any monetary inducement that may support unfair resource allocation. • Ensure effective use of resources to maintain a sustainable health system.
• Define the ethical values of **accountability/transparency/(honesty)** • Explain your roles and responsibilities as an expert • List the radiological protection systems and policies • Identify the emergency contact person/s • List alternative imaging procedures that could be considered • Disclose necessary information open to public	• Explain any potential side effects associated with the proposed procedure • Evaluate the benefits associated with the procedure • Evaluate the risks associated with the procedure • Appraise alternatives procedures • Discuss the plan for managing a radiation incident • Discuss how to inform the patient and/or the family if something goes wrong as a consequence of an error or incident • Discuss how to manage the public disclosure of a radiation incident	• Defend the decision on a proposed procedure against possible alternative approaches • Create a written long term management plan with a complex patient • Evaluate the appropriateness of radiological protection for a patient or staff member • Implement a plan for procedures following a radiation incident • Disclose all relevant information about radiation risks and benefits to the patient

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Table 8.2. *(continued)*

Knowledge	Skills (ability to apply knowledge)	Competencies, (Attitudes/Behaviours)
• Define the ethical values of **inclusiveness/empathy** • List the components of effective listening • Define the principles of an 'empathic approach' in medicine • Give examples where patient and medical team opinions might differ	• Establish a rapport with the patient • Compare and contrast empathy and sympathy • Examine how inclusiveness can be achieved • Appraise effective listening skills • Interpret the proposed procedure in language the patient can understand • Respond to patient queries	• Facilitate the patient in making a decision with respect to the proposed procedure • Implement patient/ public involvement plan • Facilitate inclusiveness of patients and families

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GLOSSARY

Accountability (modified from *Publication 138*)

Obligation of professionals to answer for their decisions and actions to those who are affected, and to accept the consequences

Autonomy (modified from *Publication 138*)

The capacity of individuals [or groups] to act freely, decide for themselves, and pursue a course of action in their lives.

Beneficence (quoted from *Publication 138*)

The act of promoting or doing good. Beneficence is a key value of biomedical ethics. In radiological protection it is to increase the direct and indirect benefits for individuals, communities and the environment.

Dignity (modified from *Publication 138*)

The value and respect that every person has and deserves regardless of her/his age, sex, health, social condition, ethnic origin, religion, etc., protected by the Universal Declaration of Human Rights.

Empathy

Sharing another's emotional response and/or understanding their feelings and perspectives.

Empathy can take emotive and cognitive forms.

Honesty

The professional and personal commitment to candid and truthful sharing of information.

Inclusiveness (quoted from *Publication 138*)

Ensuring that all those concerned are given the opportunity to participate in discussions, deliberations, and decision-making concerning situations that affect them.

Justice (quoted from *Publication 138*)

The upholding of what is right, equitable and fair.

- Distributive justice: fairness in the distribution of advantages and disadvantages among members of a people community.

- Environmental justice: equitable distribution of environmental risks and benefits; fair and meaningful participation in environmental decision-making;

recognition of community ways of life, local knowledge, and cultural difference.

- Intergenerational justice: fairness towards everyone, with attention also to future generations.
- Procedural justice: fairness in the rules and procedures in the process of decision-making
- Restorative justice: giving priority to repairing the harm done to victims and communities.
- Social justice: promoting a just society, by recognition of human rights to equitable treatment and assuring equal access to opportunities.

Non-maleficence (quoted from *Publication 138*)

Act of avoiding harm. Non-maleficence is a key value of biomedical ethics. In radiological protection it is to reduce the direct and indirect harm and risk for individuals, communities and the environment.

Precaution

Measures taken to prevent or reduce risk in the absence of scientific certainty.

Prudence (quoted from *Publication 138*)

To make informed and carefully considered choices without the full knowledge of the scope and consequences of an action.

RTT

Professional with responsibility for the delivery of radiotherapy to cancer patients and, as part of the multidisciplinary team, for elements of treatment preparation and patient care. Currently there are over 20 different titles used internationally and RTT is an umbrella term.

Solidarity

Consideration of the common good and the societal structures that ensure it, as well as interpersonal relations of recognition, reciprocity and support.

Transparency (modified from *Publication 138*)

Refers to accessibility of information about the deliberations and decisions, and the honesty with which this information is shared.

Transparency is a necessary component of accountability.

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