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Ethics in Radiological Protection for Patients in Diagnosis and Treatment

Editor-in-Chief
C.H. CLEMENT

Associate Editor
H. YU, T. YASUMUNE

Authors on behalf of ICRP
F. Bochud, M-C. Cantone, K. Applegate, M. Coffey, J. Damilakis,
F. Fahey, C. Kurihara-Saio, B. Le Guen, J. Malone, L. Reid,
M. del Rosario Perez, F. Zölzer

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Editorial

PRACTICAL ADVICE ON ETHICS IN RADIOLOGICAL PROTECTION IN MEDICINE

Publication 138 (ICRP, 2018a) was the first ICRP publication dedicated to describing the ethical foundation of the System of Radiological Protection. It identified several core ethical values and procedural values already built into the System, but which had not been examined in depth previously. Importantly, it also established a common language to enhance understanding, discussion, and refinement of the role of ethics in radiological protection.

However, as mentioned in the Editorial to *Publication 138* (ICRP, 2018b), ‘while this publication is a major step forward in describing one of the three pillars of the System of Radiological Protection (scientific knowledge, ethical values, and practical experience), it is much more a beginning than an end’.

The present publication builds on this largely conceptual foundation to present how it may be applied in the practical application of radiological protection in medicine. This is a good starting point, especially given the maturity of ethics in medical practice, and the strong connection between biomedical ethics and the ethical values identified in *Publication 138* (ICRP, 2018b). The practical examples provided may even help in appreciating the ethical values in other settings. Nonetheless, it is likely that ICRP will develop additional publications on practical ethics in other sectors of radiological protection.

The structure of the present publication is also practical, beginning with an introduction in Section 1, followed by an overview of ethics in radiological protection, outlining practicalities of biomedical ethics, and describing the link between effects of exposure to ionising radiation and ethics in medicine in Sections 2–4. Section 5 is a bridge from the first sections to the case-based examples, describing a method used to evaluate ethical values in various case-based examples. The 21 case-based examples, 11 in Section 6 on imaging and 10 in Section 7 on therapy, form a large part of the present publication, representing approximately one-third of the main text. They draw on actual clinical practice, but do not necessarily reflect actual events. They are designed to present a wide range of plausible situations that help demonstrate varying degrees of compliance with ethical values. Section 8 concludes the publication by

addressing education and training in medical ethics. Also practical are the 30 key messages identified throughout the publication and gathered in Annex A for ease of reference. They might serve as triggers to recall the lessons behind them.

Answering questions of ethics (what should we do?) can be as challenging as answering questions in science (what do we know?) – sometimes even more so. Nonetheless, both are essential to good practice of radiological protection in all domains, as the application of ‘common sense’ and practicality through experience.

Ethical dilemmas generally arise when there are different cultural values, misunderstandings, or competing interests such as advantages and disadvantages affecting different individuals. Just as difficult is the balancing of ethical values (or principles); for instance, the core ethical values of beneficence and non-maleficence, prudence, justice, and dignity. At a conceptual level, all are essential, none are absolute, and there is no a-priori ranking among them. However, when faced with a practical problem, it is often necessary to decide which are most important, and the weight that should be given to each. We hope this publication, especially through its practical case-based examples, will guide both radiological professionals and medical practitioners in navigating challenging ethical decisions.

CHRISTOPHER CLEMENT
ICRP SCIENTIFIC SECRETARY & CEO
EDITOR-IN-CHIEF

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ETHICS IN RADIOLOGICAL PROTECTION FOR MEDICAL DIAGNOSIS AND TREATMENT

ICRP PUBLICATION 157

Approved by the Commission in March 2023

Abstract—*Publication 138* defines the ethical foundations of the ICRP System of Radiological Protection based on core values (beneficence and non-maleficence, dignity, justice, and prudence) and procedural values (accountability, transparency, and inclusiveness). The purpose of the present publication is to propose a practical application of values for medical radiological protection professions. As medicine has a long history and strong culture of ethics, this publication 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 publication 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 publication proposes to combine them: dignity and autonomy; beneficence and non-maleficence; prudence and precaution; justice and solidarity; transparency, accountability, and honesty; and inclusiveness and empathy. This allows a structured review of practical situations from an ethical perspective. For the sake of both example and education, this publication proposes 21 realistic scenarios (11 in imaging procedures and 10 in radiation therapies). 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 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 be easily understood. Although primarily aimed at medical radiological protection professionals, this publication 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 prerequisite 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* (ICRP, 2018a) 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 the code of ethics of their regulatory and professional bodies, and to that of their employer, which may include values of accountability, transparency, safety, and patient-centredness.
- Everyone in the diverse groups of relevant stakeholders in health care is responsible for assuring strong shared 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 the 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 depend on the needs and cultural background of each patient and family, which are explored in shared decision-making.
- Risks should be defined explicitly as those that are known with certainty, those that are potential, and those where there is uncertainty in the scientific community (or that are not yet fully understood).
- 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 publication 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 ICRP 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 publication 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 publication 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* (ICRP, 2018a) clarifies the ethical basis of the ICRP System of Radiological Protection, and highlights the core ethical values of the system (beneficence and non-maleficence, prudence, justice, and dignity), along with the 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 of 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 first seeks 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 (WHO) 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). In the same year, the World Medical Association (WMA) defined the ethical obligations of physicians in the Declaration of Geneva (WMA, 2017), which was followed in 1949 by the International Code of Medical Ethics, revised multiple times (WMA, 2022c).

(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 theories 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 also 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 are known, those that are potential (or probabilistic), and those where there is uncertainty in the scientific literature (or that are not yet fully understood). 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 paternalism¹ of the medical profession, 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 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 transnational 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 impacts on available resources: special interest groups may divert resources to benefit themselves; health professionals may be under 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; and 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 overutilisation 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 publication examines how the ethical values adopted by the Commission can be applied in solving dilemmas in 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 publication promotes always acting on core ethical values when faced with some dilemma or conflict in daily practice.

¹Medical 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 interests. These principles are still at the heart of contemporary medical ethics, where beneficence and non-maleficence are core values.

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 have had 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 such as forced sterilisation, tissue irradiation, 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 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 purposes. In the treatment of non-cancer conditions, such as intractable pain (Smith and Doll, 1982), skin conditions (Widder, 2014), infections (Salomaa et al., 2020), and 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 kept a legal framework to support forced sterilisation or abortion reflecting unscientific eugenics² 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 surgery, x ray was one of the options of authorised procedures for involuntary sterilisation (The Mainichi, 2018). In the preamble of the 'Law concerning lump sum payment to those who have undergone eugenic surgery based on the former Eugenic

²Eugenics is a set of beliefs and practices (unscientific and unethical) aimed at 'improving' the genetic make-up of a group. Eugenics programmes included positive measures, such as encouraging individuals deemed to be 'particularly fit' to reproduce, and negative measures, such as marriage prohibition and forced sterilisation of people deemed to be 'unfit for reproduction'.

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 (The Mainichi, 2019). Actual situations regarding how radiation technology was used for voluntary and involuntary sterilisations have not been systematically analysed to date. 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) Judgement on whether 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 from 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 to for help). These will not always favour the consensus of a profession above the 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). Healthcare systems, like every system, involve people to do the work, and people invariably make mistakes. Healthcare systems are increasingly complex, and require systems engineering, continuous review and improvement of care, and lifelong education of the healthcare 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. 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 computed tomography (CT) scans. This harbours echoes of behaviour to standards not shared with its main stakeholders, as will be seen later in this publication (Sections 6 and 7). Both radiation dose and risk – as we understand them – have not always been disclosed to patients; this must change. Imaging is overutilised and not justified in many circumstances (Shrank et al., 2019). The consequences include both the significant consumption of resources with little return in individual patient or societal outcomes, and 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, 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 the practices to be unacceptable.

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

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

(24) When asked, patients have repeatedly reported a desire to know both dose and risk (Larson et al., 2007; Merck et al., 2015), and this patient/family knowledge 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 that a majority favour informed consent for patients that undergo imaging with ionising radiation (Karsli et al., 2009).

1.2. Scope and purpose of this publication

(25) Ethics has a long history in medicine, and it is important that the ICRP System of Radiological Protection is applied consistently in practice. As such, this publication 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 are not the primary target audience for this publication, but their point of view has been taken into account in its preparation, thanks to the presence of a patient advocate during a seminar organised by WHO, and the critical review of a preliminary version of the publication prior to public consultation.

(26) This publication starts with a review of historical development of the ICRP System of Radiological Protection and its evolving ethical foundation, along with additional key concepts of ethics (Sections 2–4). Based on this background, this publication 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, while it is important that education and training in radiological protection provides a sound understanding of the hazard of ionising radiation and how to apply the principles of radiological protection, it is equally essential to ensure sound competences in ethics, both in theory and in practice (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* (ICRP, 2018a), 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, patients by the International X-Ray and Radium Protection Committee (the precursor of ICRP). The focus of policy at this time was on avoiding what is now called ‘tissue reactions’ (deterministic effects), and the goal was to keep doses below thresholds to avoid those harms.

(28) Key Message 4: This publication builds on *Publication 138* (ICRP, 2018a) 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’) arise 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 patient, professional, and societal concerns into account were required in an ethical system of radiological protection.

(30) In 1966, the Commission 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 Commission 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 Commission 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* (ICRP, 2007a), published *Publication 105* (2007b) which interpreted the principles for a clinical context. The interpretation of the principles for patient care is outlined in Table 2.1, although this is not without criticism (Malone, 2020).

Table 2.1. Key principles of the ICRP System of Radiological Protection (ICRPædia Glossary) interpreted for the medical context [*Publications 73 and 105* (ICRP, 1996, 2007b)].

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
Optimisation	The process of determining what level of protection and safety makes exposures, and the risk of potential exposures, as low as reasonably achievable, taking into account economic, societal, and environmental factors	Optimisation applies to (1) equipment and facilities, and (2) working processes/protocols (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 avoid unacceptable risk	No dose limits for patients. Emphasis is on justification and optimisation

(32) *Publication 138* (ICRP, 2018a) identifies dignity, beneficence and non-maleficence, prudence and 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 ICRP 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 ICRP System of Radiological Protection (ICRP, 2018a).

Core ethical values	Definition	Example in <i>Publication 138</i> (ICRP, 2018a)
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

(continued on next page)

Table 2.2. (continued)

Core ethical values	Definition	Example in <i>Publication 138</i> (ICRP, 2018a)
Beneficence and non-maleficence	Promoting or doing good, and avoiding doing harm	The primary aim of the ICRP 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
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 practical implementation of the core values of the ICRP System of Radiological Protection (ICRP, 2018a).

Procedural ethical values	Definition	Example in <i>Publication 138</i> (ICRP, 2018a) (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 publication builds on *Publication 138* (ICRP, 2018a) 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, 1979/2019; 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 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* (ICRP, 2018a), the Commission considers it necessary to provide additional interpretations to this set of values, clarifying some particularly important notions that have been well discussed in the field of biomedical ethics, and with which health professionals are familiar.

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

(37) Interpretations of the core and procedural values that are particularly 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 used in the scenario evaluation procedure introduced in Section 5, and carried out in Sections 6 and 7 (Table 5.1). 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* (ICRP, 2018a), this publication presents dignity and autonomy first, following the order well established in biomedical ethics (Beauchamp and Childress, 1979/2019; Malone et al., 2019, Chapter 2).

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

Drawn from <i>Publication 138</i> (ICRP, 2018a), except where marked by an asterisk (*)	Clinical interpretations
<i>Core value: dignity</i> 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 <i>Additional interpretation: autonomy</i> 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
<i>Core value: beneficence and non-maleficence</i> Beneficence and non-maleficence refer to the duty to promote or do good, and to avoid harm <i>Additional interpretation: balancing benefits and risks</i> 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 healthcare 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
<i>Core value: prudence</i> To be prudent is to make informed and carefully considered choices without the full knowledge of the scope and consequences of an action <i>Additional interpretation: precaution</i> 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 types 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
<i>Core value: justice</i> 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 <i>Additional interpretation: solidarity</i> Solidarity refers to consideration of the common good and the societal structures that ensure it, as well as interpersonal	Where healthcare resources are scarce, priority setting and resource allocation procedures balance maximising benefits and ensuring fairness in access to these resources Social justice requires healthcare 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 healthcare system for all, and also to social relations of mutual recognition and support, including support for the most vulnerable

(continued on next page)

Table 2.4. (*continued*)

Drawn from *Publication 138* (ICRP, 2018a),
except where marked by an asterisk (*)

Clinical interpretations

relations of recognition, reciprocity, and support*	
<i>Procedural value: accountability and transparency</i>	
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	The patient is often the one most affected by the decisions and actions of the healthcare professional, but families, caregivers, and the healthcare 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
<i>Additional interpretation: honesty</i>	
Honesty is the professional and personal commitment to candid and truthful sharing of information*	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
<i>Procedural value: inclusiveness</i>	
Ensuring that all those concerned are given the opportunity to participate in discussions, deliberations, and decision-making concerning situations that affect them	Inclusiveness means that the patient feels valued as a decision-maker about his or her health care, and involving family and carers. Not all people start from the same point, and understanding the gap is key to addressing any inequality
<i>Additional interpretation: empathy</i>	
Empathy can take emotive and cognitive forms: sharing another's emotional response and/or understanding their feelings and perspectives*	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

LNT, linear-non-threshold.

*Additional interpretation defined in this publication (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 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 5–7 (Tables 2.4, 5.1, and 5.2). Defined by the Commission in *Publication 138* (ICRP, 2018a), ‘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 and Hayashi, 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’ (UN General Assembly, 2007, Article 9).

(42) Historically, respect for human dignity has been reflected in calls for informed consent in *Publication 62* (ICRP, 1992) on biomedical research. Subsequently, in *Publication 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 fetus, additional protection, both in terms of consent and strict benefit/risk assessment, is 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, 2017) 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 the purpose of any test or treatment, what the results would imply, and 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, 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 (Vañó, 2021 and, for an example, see Section 6.8 below).

(45) Key Message 6: Healthcare 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 was not fully discussed in *Publication 138* (ICRP, 2018a), but it is particularly 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. US HIPAA, 1996), balancing patients’ fundamental privacy rights and the need of society to analyse patient data for improvement of health care and research. The healthcare 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* (ICRP, 2018a) states that respect for dignity and autonomy relies closely on the procedural values of accountability and transparency. In the present publication, the procedural values are interpreted below (Section 2.2.5) in the context of informed consent to medical interventions.

2.2.2. Beneficence and non-maleficence: benefit and risk

(48) *Publication 138* (ICRP, 2018a) highlights that beneficence and non-maleficence are central to the ICRP System of Radiological Protection, although these technical terms from biomedical ethics had not been used previously by the Commission (ICRP, 2018a, Para. 37). While workers, carers and comforters, and the public may also experience exposure in 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, such as 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 risk 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 benefit 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 (although 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 refers to the primary commitment or loyalty of the healthcare provider to the patient’s health and well-being (Bloche, 1999; WMA, 2017; 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 recognises 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 healthcare provider’s responsibilities include obligations to equity and sustainability in health systems. Thus, healthcare providers often face ethical dilemmas between what is ‘best’ for individual patients and what is sustainable and equitable in a healthcare 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, 2017). Keeping this premise, social trade-offs are sometimes necessary in medical ethics. This is discussed in greater 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-positive results and overdiagnosis (i.e. 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). Healthcare professionals often make decisions in conditions of uncertainty (i.e. in the face of risks and benefits that cannot be quantified reliably at that moment). It 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, Paras 47–48). Precaution requires first that credible risks for which there is no direct scientific evidence should be considered, such as the risks estimated with the help of the LNT model for doses <100 mSv [UNESCO, 2005b; ICRP, 2007a, 2018a, Paras 45–46; also see Shore et al. (2018) for the most recent review of the National Council on Radiological Protection and Measurement (NCRP) on the matter]. In addition, prudence also requires one 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, societal, and environmental factors’ (ICRP, 2020).

(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 publication, 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, policy makers should take preventive action, and that they should do so even in the face of uncertain evidence (Munthe, 2020).

(59) 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). An interpretation of precaution is that one 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, such as by weighing lifetime cancer risk against the clinical benefit of CT (Doria et al., 2006). In radiological and nuclear medicine imaging, for example, it is proposed that alternative non-ionising radiation imaging should be used where practical, especially in children, to reduce radiation exposure for follow-up examinations, especially CT scans; to promote weight-based nuclear medicine dosing; and in addition to a number of relevant steps to participate in quality assurance and dose registries. In radiotherapy, for example, the use of magnetic resonance imaging (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, this 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 the context of a clinical goal in medicine. In radiation therapy, ALARA applies primarily to normal tissue. The use of ALARA outwith this context may be misleading (ICRP, 2013).

(63) Precaution in the clinical context means taking an elevated lifetime risk of cancer of one 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 [i.e. 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 practicable 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) In *Publication 138* (ICRP, 2018a), the Commission recognises 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 (e.g. in the distribution of limited resources). In resource allocation, different values may govern a just distribution (e.g. maximising aggregate outcomes, improving the situation of the worst-off, or achieving equality in opportunity or outcomes). 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 paired 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 healthcare 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, healthcare workers and other workers, and the general public, to ensure the efficiency and even sustainability of the healthcare 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 healthcare professional and the 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 roles. This has implications for the relationship between health professionals and patients. ‘Healthcare 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, p. 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 should 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 (i.e. differences in health that are unnecessary, avoidable, unfair, and unjust) (Whitehead, 1991). The responsibility of the professionals is to take steps to enable disadvantaged groups to access and benefit from care (e.g. 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 Glossary in *Publication 138* (ICRP, 2018a), 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 the 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* (ICRP, 2018a), 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* (ICRP, 2018a), 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 appeared explicitly in the 1990 General Recommendations of ICRP (ICRP, 1991), and was reaffirmed in the 2007 General Recommendations (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* (ICRP, 2018a) 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 publication 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. *Publication 60* (ICRP, 1991) 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’.

(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 healthcare system, including access to imaging and radiation therapy, as a matter of justice and solidarity.

(79) *Publication 138* (ICRP, 2018a) 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, 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 and Childress (1979/2019, pp. 327–328), 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, 1979/2019, pp. 327–328; Malone et al., 2019, Sections 2 and 6).

(82) In this publication, 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 discussed extensively 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 healthcare 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 enquire 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 the information and is ready to make decisions (Beauchamp and Childress, 1979/2019). Devoting sufficient time to patient interaction is an aspect that is all too often neglected in a context where resources are often lacking.

(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 are 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 (recorded in electronic medical records in developed nations) as 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. Patients should have access to doses they receive and have the dose explained, just as they have access to medications, procedures, and healthcare information in their health record.

2.2.5.2. *Inclusiveness and empathy*

(89) *Publication 138* (ICRP, 2018a) 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 marginalisation.

(91) Empathy is introduced in this publication 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 emphasised with the paired core values of dignity and autonomy. Empathy for the patient’s 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 a 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, 2019). An institutional commitment to empathy in clinical care is important to allow radiological professionals the time and flexibility to respond to patients’ emotions and perspectives.

(94) In the context of radiological protection in medicine, empathy means that the concerns of those affected, and 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; also see Section 8), so that it is possible to frame it as something which should be expected of a health professional, and for which every professional should continuously strive. 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 strive continuously to achieve it.

(96) Empathy is also a corrective to a possible overemphasis on rights and obligations in traditional ethical theory, which has been emphasised in care ethics, arising from feminist bioethics (Gilligan, 1993; Beauchamp and Childress, 1979/2019). Care ethics highlights the perspectives of caregivers, 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, 1979/2019). It also highlights the concerns and needs of caregivers 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, healthcare 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 healthcare 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. Healthcare 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 that 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 WMA brings a modern perspective to the medical oath (WMA, 2017). It emphasises the humanitarian aspects of medicine, enjoins respect for the individual patient, and advises doctors to also look after their own health. The document was first adopted in 1948, and it has been amended several times over the years. The latest version, published in 2018, introduced well-being of both patients and physicians for the first time (WMA, 2017). 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 the code of ethics of their regulatory and professional bodies, as well as that of their employer, which may include values of accountability, transparency, safety, and patient-centredness.

(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 codes of ethics of ICRP (ICRP, 2014) and 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), the American Association of Physicists in Medicine (Skourou et al., 2019), and the International Radiation Protection Association (IRPA, 2004).

(103) Modern codes of ethics typically articulate the professional's responsibility to patients, society, colleagues, and 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 scope³, supporting sustainability of the healthcare 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 in the context of team care, appealing 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'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>).

3.2. Role of international, national, and institutional ethics committees

(105) International ethics committees have been established by some intergovernmental or non-governmental scientific and professional bodies, such as WMA (WMA, 2015, 2022b), the Council of Europe (Council of Europe, 2022), and the United Nations Educational, Scientific and Cultural Organisation (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 and 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 adopt legislation (UNESCO, 2010b).

(108) Healthcare 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 in order 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 the process. Next, 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 in order to address the risk of confirmation bias. These are 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 been considered previously 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 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 that comments 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 on the committee. This publication can serve as a resource for ethics committees and 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 should have access to radiological protection expertise in order to provide guidance and education on specific dilemmas in practice.

3.3. Clinical practice developments

(113) In the last decades, approaches to the practical implementation of ethical values in specific clinical practices 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* (ICRP, 2018a) to be derived from respect for dignity] has been specified in the requirement to seek and respect the patient’s informed consent or decline of medical interventions: that patients should 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 (e.g. physician-centred or patient-centred standards) and possibilities for considering consent to be ‘implied’ (e.g. 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). Furthermore, patients with the same level of knowledge may come to different decisions, all of which may be valid. There is discussion in radiology about the appropriate manner of achieving transparent understanding of benefit/risk for diagnostic examinations (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 Papon, 2016). The Image Wisely and Image 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 due to historical reports of severe side effects and poor outcomes. However, research reveals that, 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 evolve over that time period. It is important, therefore, that the healthcare 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. Healthcare 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 inpatient 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 fetus, 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 fetal doses <100 mGy should not be considered a reason for terminating pregnancy, and pose little risk to the fetus (ICRP, 2000). The question of involving the pregnant person's partner or the father of the fetus 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, 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 parental 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 healthcare team must judge the adolescent patient's maturity.

(121) The values of patient dignity and autonomy continue to inform medical decision-making when patients lose decision-making capacity either temporarily or permanently. 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 in decision-making. 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 healthcare 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' judgement 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 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 and waiting areas, and provide 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, and 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 is developing rapidly 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 and Lee, 2022). As technology and research practices evolve, with 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 the 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 to considerations of minimising patients' physical and psychological distress.

(129) Treatment that does not benefit the patient directly 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 understand that all treatment options have been exhausted. Efforts at supportive communication should be extensive before unilateral judgements 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 initially 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' 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 the patient's 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 four-vessel cerebral angiography) and alternative radionuclide or Doppler transcranial ultrasonography examinations 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 in 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, 2017; 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, 2019).

(136) In the 1990s, 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