ETHICS AND MEDICAL RADIOLOGICAL IMAGING

A POLICY BRIEF FOR HEALTH-CARE PROVIDERS
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Acknowledgements

WHO convened an International Workshop on Ethical Aspects of Radiation Protection in Health Care in September 2019. This meeting, organized in cooperation with the International Commission on Radiological Protection Task Group 109,\(^1\) was held at WHO headquarters in Geneva, Switzerland. The workshop gathered 44 participants from 28 countries from all regions of the world\(^1\) representing key stakeholders,\(^2\) professional societies and international organizations\(^3\). WHO appreciates the ICRP colleagues who collaborated in the preparation of the event and the workshop participants for their valuable contributions, which informed the development of this document.

This policy brief was prepared by a WHO working group. The drafting was performed with input from the following working group members (ordered alphabetically by surname): François Bochud (Radiology Department, Lausanne University Hospital, Switzerland), Claire-Louise Chapple (Newcastle Upon Tyne Hospitals NHS Foundation Trust, the United Kingdom of Great Britain and Northern Ireland), Steve Ebdon-Jackson (Medical Physics consultant, the United Kingdom), Calvin Ho (Faculty of Law, University of Hong Kong, Special Administrative Region, China), Dina Hussein Salama (AFRA; Egyptian Atomic Energy; Misr University for Science & Technology/MUST, Egypt), Hussain Jafri (World Patients Alliance and Global Network for Science & Technology/MUST, Egypt), Hussain Jafri (World Patients Alliance and Global Network for Patient for Patient Safety, Pakistan), Min-Jeong Kim (National Evidence-based Healthcare Collaborating Agency, Republic of Korea), Valerie Luyckx (Institute of Biomedical Ethics and History of Medicine, University Children’s Hospital, Zurich, Switzerland) and Jim Malone (Medical School, Trinity College Dublin, Dublin, Ireland). The instrumental assistance of this working group is gratefully acknowledged. Special thanks are due to Steve Ebdon-Jackson who chaired the working group meetings and to Jim Malone who acted as lead writer.

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Declarations of interest

All members of the working group declared their interests according to WHO standard procedures. None of the interests declared were found to be significant.

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\(^1\) The Task Group 109 is focused on Ethics in Radiological Protection for Medical Diagnosis and Treatment, under Committee 3 and Committee 4 of the International Commission on Radiological Protection (ICRP TG 109; see composition (\(\_\_\_\_\)).

\(^2\) Stakeholders from the following 28 countries attended this workshop: Algeria, Australia, Austria, Brazil, Canada, Chile, Denmark, Egypt, France, Germany, Greece, India, Ireland, Italy, Japan, Lebanon, Malaysia, Pakistan, Portugal, Republic of Korea, Spain, Switzerland, Thailand, Tunisia, Uganda, the United Kingdom, Uruguay and the USA.

\(^3\) The workshop gathered clinicians, radiologists, nuclear medicine physicians, interventional cardiologists, endoscopists, radiographers, radiotherapists, medical physicists, medical students, patient champions, biomedical ethics experts, radiation protection experts and regulators.


\(^5\) WHO organized a symposium to present this document at the 16th International Conference on Clinical Ethics & Consultation held in Stellenbosch, South Africa between 30 November and 3 December 2021 as a hybrid event (virtual and in person) (\(\_\_\_\_\)).
Ethics is an essential component of radiation protection in medicine, but this has not always been recognized by the various stakeholders involved. Medical imaging is universally accepted as an essential tool in health care. Yet, unlike most of medicine, its patient safety practices draw on the system of radiation protection, as opposed to that provided by medical ethics. For this brief, the radiation protection framework can be viewed as relying on three components – professional development; regulation/governance; and safety culture. The radiation protection system was originally developed to ensure the safety of workers and the public, rather than to protect patients (IAEA, 2001). Over the past 25 to 30 years, the use of ionizing radiation in medicine has greatly increased and a lack of explicit reference to ethics has been recognized (Bochud et al., 2020; Malone et al., 2019; Malone, 2020). Over the same period, stakeholders in health care have been placing greater emphasis on patient-centred care (Gluyas, 2015). Within this context, the radiation protection framework is being gradually reformulated, and it is essential to identify how ethics will be integrated into its future.

To address this, the World Health Organization (WHO) convened a stakeholder workshop on ethics for radiation protection in health care. It explored the enhancements of medical imaging that might be achieved through a greater emphasis on and integration of ethics. The workshop noted that compelling individual advocates for an ethics approach are part of the history of radiation protection (ICRP, 1990; 2007; Bochud et al., 2020; Cho et al., 2018), and those involved in imaging generally believe they are acting morally. Nevertheless, medical ethics values such as dignity and autonomy, non-maleficence and beneficence, justice, prudence/precaution and honesty/transparency are not well known, understood or applied in practice in medical imaging (Bochud et al., 2020; Malone et al., 2019; Malone, 2020). These values, when applied in radiological services, would underwrite a shift from paternalism to patient-centred care and shared decision-making, and maximize benefits and reduce harms. They also would improve consideration of patients’ goals, values and obligations to others, as well as aspire to fair and equitable resource allocation throughout the health system. At the conclusion of the workshop, WHO undertook to address the issues identified. Building on the existing arrangements, this brief proposes a framework in which a range of initiatives can be developed to align patient radiation safety with WHO expectations and those of other international bodies including the International Atomic Energy Agency (IAEA) and the International Commission for Radiological Protection (ICRP). It is intended to be consistent with initiatives on global health ethics, patient safety, universal health coverage and radiation safety (WHO, 2015; 2021; IAEA, 2014; IAEA & WHO, 2014).
2. Scope, purpose and target audience

The brief highlights the need to further integrate ethics into the existing framework for radiation protection in medical imaging. In doing so, it adds a fourth component – ethics in medical imaging – to the framework and it is important that ethical values will become a central feature of imaging whether as part of patient-centred clinical pathways or in routine imaging practice. This framework may also be applied to investigations using non-ionizing radiations, such as those involved in ultrasound and magnetic resonance imaging. The approach is relevant to all imaging procedures.

The target audience is those involved in the operational delivery of health care, for example chief executive officers and managers of imaging facilities and the professionals who, on a daily basis, request and deliver medical imaging. It also includes professional organizations and those providing radiological and radiation protection education. Patients, their representatives, others who advocate for improvement in health care delivery, as well as higher level policy-makers, may also find this brief valuable, although they are not its primary focus. WHO also expects to address a broad spectrum of stakeholders’ needs by developing further comprehensive tools and guidance to facilitate implementation of the policy positions identified here.

3. Ethics in health care

Medicine is a vocation requiring commitment to scientifically sound practice and the law as well as to upholding the principles of medical ethics (WHO, 2020). The first codes of medical ethics go back thousands of years. Today, they are reinterpreted, and internationally agreed ethical standards for medicine, research and public health have been developed. An example is The Declaration of Geneva, produced by the World Medical Association (WMA, 2017). For many this “modern version” of the Hippocratic Oath spells out ethics obligations for medical doctors and other health-care providers.

As a fundamental part of its role, WHO is committed to promote the highest ethical standards. One of its core functions is “articulating ethical and evidence-based policy options” and WHO must “ensure that policy-makers and health implementers … keep ethics at the heart of their decision-making” (WHO, 2020).

An ethical perspective is essential whenever patient-centred services or public health initiatives are being planned or implemented. While not explicit, it should be a fundamental requirement for routine services as well as when unforeseen events occur. Examples include: practices where overdiagnosis/overtreatment is suspected or identified, or where the law and operating procedures lack maturity or are otherwise inadequate, and in crisis situations, for example during the coronavirus disease 2019 (COVID-19) pandemic (WHO, 2020; 2021). The medical imaging procedures under consideration here are essentially medical acts, and hence medical ethics applies to them.

Good medical practice is based on upholding the basic values of biomedical ethics (Beauchamp & Childress, 2013; WHO, 2010; 2015). However, it may also draw on the values of public health, which include transparency, accountability, inclusivity and solidarity. At times the values may appear to be in conflict, for example prioritizing the need of an individual over that of society, or vice versa. This can arise in many settings including triage in a clinical environment, or in creating policies that favour one course of action over another. The rationale and goals for such decisions must explicitly include ethical considerations in addition to the economic and resource issues, which are more frequently cited in support of decisions. Transparency and accountability are essential in such situations. Indeed, the values underlying the expectations of civil society, including solidarity, empathy and sustainability should reasonably be expected to be present in medical imaging practice.
Radiation protection in medical imaging: values and ethics

The current widely accepted approach to radiation protection throughout the world is supported by an international system based on advice from ICRP (ICRP, 1990; 2007). It relies on three principles – justification, optimization and dose limitation, which provide the basis for the components of the radiation protection framework mentioned above, that is professional development; regulation/governance; and safety culture. Though primarily designed with occupational and public exposures in mind, the system is being reviewed and adapted – not always successfully – to address medical exposures. This is particularly so since the mid to late 1990s (EC, 1997; IAEA, 2001).

Many health care workers assume that conformity with the fundamental principles of radiation protection in medicine (that is, justification and optimization) is sufficient to ensure ethical good practice in medical imaging. Such compliance is expected to address all the relevant important moral issues adequately, and thus negate the need for explicit involvement of medical ethics. However, this is not always so, and the current framework does not address the many dilemmas that can arise. This is well established in the literature (Malone et al., 2019; IAEA, 2011). See also the example in Box 1.

Practice varies worldwide and even where the radiation protection framework is well deployed, deficits remain regarding ethics compliance (Malone et al., 2016; Malone et al., 2019). Positive ethics outcomes are frequently not recognized and the impact of neglect of ethics is seldom addressed. As the shift away from paternalism continues, patient expectations and advocacy groups reinforce the need for a more explicit approach to ethics.

The components of the existing radiation protection framework, though distinct, share similar themes and goals with the ethics approach. Their effectiveness has been greatly enhanced by their concerted collective application over a long period. Similar considerations apply to the more explicit presence of ethics in medical imaging. On its own, this would be of benefit, but the potential impact is likely to be much greater when the values are embedded within the radiation protection framework as an additional component. Doing so would further optimize resource allocation in health care and aid the shift to patient-centred care.
Box 1. Importance of ethics in medical imaging: an example

The purpose of this example is not to demonstrate good practice or compelling good ethical behaviour. Rather it is to construct a plausible (if necessarily dramatic) scenario which is an intuitively convincing illustration of both compliance and noncompliance with ethical values. For convenience, the example is rated against the limited set of values discussed below (Malone et al., 2019).

Ms Anna Auburn, a successful entrepreneur in her early 40s, is referred by her general practitioner for an ultrasound examination to explore the cause of ongoing upper abdominal pain. The general practitioner has reason to suspect gallstones but omits to include this in his referral note. Ms Auburn is also chairman of the hospital board. The staff in the imaging department decide to add an abdomino-pelvic multiphase contrast CT examination to provide their most discerning service to her, even though it is not advised by national clinical guidelines. They might not have taken this approach had the referral note mentioned the general practitioner’s suspicions. The staff ask Ms Auburn if she could be pregnant. She responds emphatically that she is not and omits to tell the staff that she is receiving ongoing IVF treatment (about which she is sensitive). The radiation and other risks of the CT procedure are explained and are significant as the equipment, though functioning well, is not new. However, the staff do not mention that the scan could prove unnecessary, depending on the outcome of the ultrasound. Ms Auburn consents. Both scans are performed efficiently within 40 minutes of each other — first the CT and then the ultrasound when the specialist radiologist becomes available. Nothing is identified on the CT, while the ultrasound identifies the gallstones.

- **Dignity and autonomy**: Due to the requirement for consent, the performance is mixed in the example above. It was good regarding informed consent to the radiation risks, but unsatisfactory that the CT was performed without providing information on its possible inappropriateness, particularly in a patient with child-bearing potential.

- **Beneficence/non-maleficence**: Performance in this category is poor, as there was unnecessary potential harm from the inappropriate CT, and a risk of harm to an embryo or fetus, whose existence had not been excluded.

- **Justice**: Performance is poor. Top of the range CT examinations are a scarce and limited resource that was poorly deployed. A patient with greater medical need may have been displaced.

- **Prudence/precaution**: Performance was poor, giving insufficient weight to possible/probable harms, and the pregnancy status of the patient.

- **Honesty and transparency**: Performance was mixed; withholding the information on inappropriateness was poor while providing it on CT dose/risk was good. Failure to disclose IVF treatment cannot be excused based on sensitivities, but may be mitigated by being unexpectedly confronted with the question. The patient should be a partner in information sharing and decisions.

Other values, including **empathy**, **inclusivity** and **sustainability**, are also relevant but cannot be addressed here. However, this necessarily limited discussion provides examples of how informative the lens of ethics can be in assessing situations.
5. Strategies for culture change

It is to be expected that the culture change envisaged will prove challenging to some health professionals and their organizations, and this will need to be addressed in future actions. To ensure progress, consideration of ethics must become an integral component of radiation protection in health care. It must complement, highlight, and be highlighted by the key components that sustain its existing framework. The perspective of ethics will help focus radiation protection on the patient, as part of the shift towards patient-centred health care, and will not diminish the importance of traditional approaches.

All stakeholders share a collective responsibility for the current lack of explicit reference to medical ethics and should contribute constructively to integrating ethics seamlessly into radiation safety and clinical practices. As in many other areas, it will be important to avoid a blame culture. Rather, the emphasis should be on seeking acceptance that the scope of radiation protection must evolve towards more holistic and patient-centred approaches, and be guided by well-integrated values already widely applied in clinical medicine and/or public health.

Professionally mandated values and purpose-specific education/training tools are essential to raise awareness and commitment. These can empower stakeholders and result in quality improvements in health care, while enhancing both equity and safety. The values will need to attract a wide level of support and be clearly understood. The tools should include generic teaching materials and videos for undergraduate and continuing education; checklists for implementation; and generic documents and forms, such as patient charters and informed consent forms.

Implementation programmes will be required for health care workers, hospital managements, professional societies, governmental bodies, patients, their advocates and the public. Academics, journalists and social media influencers may facilitate engagement and raise awareness of radiation safety as part of the more general medical ethics discourse now in the public domain. This will need adoption/adaptation of radiation protection terminology so that it avails of the rich language, discourse, and heritage of biomedical ethics. In doing so, special attention will be required to the needs of patients, patient advocacy groups and the public.

Adoption of culture change by health care workers will require engagement, leadership, motivation, and support, from their local management and professional societies. Patients and families will be key partners as services move to the expectation that patients will be actively involved in informed decision-making about their care. Initiatives must be sensitive to the local context. The availability of human and financial resources, characteristics of particular settings and other considerations are relevant. A broad consultation is essential, particularly with health education specialists.

All this is possible. The COVID-19 pandemic has provided examples of success in bringing ethics into professional and public discourse about the appropriateness and the deficiencies of medical responses and public health actions. This experience of bringing values like prudence, solidarity, honesty, dignity and autonomy to the fore could aid development of a strategy to promote the integration of ethics into the radiation protection framework.
6. Summary and way forward

Medical ethics is foundational to good medical practice. A WHO workshop identified that radiology and medical imaging generally take place within the legal and good practice arrangements for radiation protection but with little reference to medical ethics. This lack of awareness of ethical standards, which has recently come to prominence, may have profound consequences for patients, and there is an urgent need for WHO to address it. This will be achieved by providing guidance and support materials for professional stakeholders, patient advocates, patients and the public. The intention is to help integrate ethics holistically with the other components of the framework for medical radiation protection. This will facilitate an essential cultural change in medical imaging, consistent with current more general approaches to patient-centred health care delivery and safety.
References


