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Guidelines on Professional Ethics for Medical Physicists

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GUIDELINES ON PROFESSIONAL ETHICS FOR MEDICAL PHYSICISTS

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TRAINING COURSE SERIES No. 78

GUIDELINES ON PROFESSIONAL ETHICS FOR MEDICAL PHYSICISTS

INTERNATIONAL ATOMIC ENERGY AGENCY
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Dosimetry and Medical Radiation Physics Section
International Atomic Energy Agency
Vienna International Centre
PO Box 100
1400 Vienna, Austria
email: Official.Mail@iaea.org

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FOREWORD

Medical physicists work in a clinical environment and contribute to ensuring safe, quality and effective medical uses of radiation for the benefit of patients. They work as part of a team in fields using radiation for diagnosis and treatment, such as diagnostic radiology, nuclear medicine and radiotherapy. Despite the important roles and responsibilities of medical physicists, recognition of medical physics as a healthcare profession is uncommon. This has several consequences, including the lack of access to comprehensive academic education and clinical training programmes to acquire the competencies needed to practise at the highest standards. These competencies include the knowledge, skills and attitudes pertaining to professional ethics.

In March 2021 the IAEA fielded a targeted survey globally to explore the access to and understanding of professional ethics by medical physicists in diverse settings and with diverse experience, specializations and backgrounds. The results were presented at the 63rd Annual Meeting of the American Association of Physicists in Medicine, within the framework of a symposium dedicated to professional ethics in practice for medical physicists. The survey revealed a lack of understanding of professional ethics and a need for training, educational resources and continuous professional development activities on this topic in most settings. The IAEA subsequently conducted consultancy meetings to draft the present publication, which is intended to complement other IAEA publications on professional matters and the education of medical physicists, including Roles and Responsibilities, and Education and Training Requirements for Clinically Qualified Medical Physicists (IAEA Human Health Series No. 25), the medical physics educational series (IAEA Training Course Series Nos 37, 47, 50 and 56 (Rev. 1)) and Guidelines for the Certification of Clinically Qualified Medical Physicists (IAEA Training Course Series No. 71). This publication aims at providing medical physicists with an overview of the basic principles and applications of professional ethics, examples of medical physics related scenarios in which ethical principles are applied and providing information on educational resources.

The IAEA officers responsible for this publication were G. Loreti and D. van der Merwe of the Division of Human Health.

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1. INTRODUCTION

1.1. BACKGROUND

The International Basic Safety Standards (IAEA Safety Standards Series No. GSR Part 3) [1] requires that ethical guidelines and recommendations of the International Commission on Radiological Protection (ICRP) [2] are taken into account, particularly in biomedical research programmes. More recently, the ICRP has reported on how ethical values are incorporated into the system and principles of radiation protection [3]. Professional ethics, however, not only apply to research, but are also integrated into the practice of all health professionals. As independent practitioners, medical physicists are confronted with decisions that directly impact on patient care. Therefore, when performing research or practicing in a clinical environment, medical physicists can expect to be confronted with a variety of situations that entail engagement with ethical principles.

A code of ethics for Clinically Qualified Medical Physicists (CQMPs) was published in Appendix 1 of the IAEA Human Health Series No. 25 as it applies to professional conduct, research and education [4]. It was based on the American Association of Physicists in Medicine and United Kingdom publications that were current at the time. An updated, more universal code of ethics for CQMP has not been developed. The need for educational resources and guidance in professional ethics for medical physicists was identified through an IAEA survey that was conducted in 2021, the results of which were presented and deliberated at a joint IAEA/American Association of Physicists in Medicine (AAPM) symposium [5].

1.2. OBJECTIVE

This publication aims to provide clinically qualified medical physicists (CQMPs) working in all specialties of medical physics in Member States, with information on professional ethics and, in so doing, contribute to their practice in the healthcare environment. This publication complements other IAEA publications related to the medical physics profession [4, 6-10] and goes beyond the role of ethical principles as applied to research conducted in a clinical environment.

1.3. SCOPE

This publication provides an overview of the basic principles of ethics as applied to the medical physics profession and portrays practical examples of dealing with ethical dilemmas in practice. The document also includes guidelines on the content of professional ethics modules that may be incorporated into medical physics academic programmes, and structured and supervised medical physics clinical training programmes. A list of core educational resources completes the publication.

1.4. STRUCTURE

Section 2 describes how the roles and responsibilities of medical physicists are influenced by ethical principles and conduct. Section 3 provides an overview of the key ethical principles that impact on the practice of medical physics. Section 4 discusses elements of ethics as they pertain to the workplace in general, scientific integrity, the pursuit of research and direct interactions with patients. Scenarios that constitute ethical dilemmas in medical physics are presented in Section 5 and in each case, a description is provided that demonstrates how ethical principles can be used to respond to the dilemma. Section 6 provides guidelines on the academic and

clinical training that is needed for medical physicists to achieve competence in professional ethics and lists some suggested core reference texts.

2. ROLES AND RESPONSIBILITIES OF CLINICALLY QUALIFIED MEDICAL PHYSICISTS

Medical physicists working in the clinical environment are highly specialized health professionals [1, 9, 11] who typically apply principles of physics to contribute to quality, safe and effective medical uses of radiation (e.g. diagnostic radiology, nuclear medicine or radiotherapy). The detailed roles and responsibilities of CQMPs in all specialties were published by the IAEA [4], in accordance with the requirements of the International Basic Safety Standards (IAEA Safety Standards Series No. GSR Part 3) [1].

2.1. MEDICAL PHYSICISTS AS INDEPENDENT PRACTITIONERS IN HEALTHCARE

Due to the nature of work in a clinical environment, CQMPs can expect to be confronted with ethical issues and it is therefore important that they are prepared to deliberate and engage in ethical matters in accordance with established ethics principles. CQMPs work as part of a team of other healthcare professionals, but they are professionally independent as individual practitioners, and therefore are expected to conduct their work in alignment with the professional standards defined by their national certification body (where existing). This implies that CQMPs exercise independent judgements and decisions pertaining not only to scientific and technical matters, but also to the ethical dynamics in the environment in which they practice. CQMPs therefore need to be alert, aware, and equipped to seek out the ethical aspects relevant to their work activities and situations.

3. FUNDAMENTAL PRINCIPLES OF ETHICS IN HEALTHCARE

Healthcare and medical science professions (including medical physicists), engage in so called “frontier activities”, as they act within an environment where suffering, distress, vulnerability and death are frequent. These situations may create or amplify conflicts of values. In a pluralistic (e.g. diverse, multicultural) society, different people may not agree because they have different values, and their priorities are not the same when values are in conflict [12]. The most well-known ethical approach taught to healthcare and medical science professions is known as principlism, i.e. principle-based ethics [13]. While agreement may be reached on a set of principles, subsequent agreement on the best way to apply principles and values in a given situation is not necessarily easily achievable, because it is subject to interpretation. High stakes challenges in healthcare increase the visibility of value conflicts. Decisions in healthcare have important consequences for individuals and society. Medical physicists, like other professionals working in healthcare settings, are expected to be aware of the currently most agreed on fundamental principles and support transparent decision making based on ethical arguments, and the autonomy and best interest of the patient [13].

3.1. VALUE SYSTEMS IN MEDICAL ETHICS AND GUIDING PRINCIPLES

In medical ethics, it is generally considered insufficient to rely on one’s own conscience or feelings, as they are too subjective and shaped by one's personal, cultural and societal influences to be considered as universal indicators of what is ethically appropriate; additionally, they are influenced by different types of experience and education. Ethical theories tend to either refer to a moral code or duty (e.g. rules or commandments as part of religion or professional ethics, also called a deontological approach [14]), or refer to values and principles (principlism). Other

ethical approaches refer to motivations of people and the virtue of an action (virtue ethics) or focus predominantly on good or bad consequences of an action (consequentialism). The most commonly found approach in medical ethics combines a consequentialist with a deontological approach and results in the definition of the four main principles of biomedical ethics: beneficence, non-maleficence, respect for autonomy and justice [13].

The ICRP has recommended five "core values" (beneficence, non-maleficence, prudence, justice and dignity) and three "procedural values" (accountability, transparency and inclusiveness) as the ethical principles that underly and inform practical implementation, respectively in radiation protection [3]. Malone, *et. al.* [15] suggested a redesignation to "core, correlated and procedural principles" based on a broader review of radiological protection, which included the related fields of public and environmental health, and proposed the addition of honesty, solidarity, sustainability and empathy. Given that CQMPs routinely apply several radiation protection principles professionally, these approaches may also be considered useful when formulating national guidelines.

The seven subsections below define and describe key guiding principles considered to be the most pertinent to medical physicists that are conducting research or practicing in a healthcare setting or residents who are undergoing clinical training in medical physics.

3.1.1. Beneficence and non-maleficence

Beneficence and non-maleficence are examples of an approach based on consequences of an action. In medicine the aim is to promote patient well-being and avoid harm to the patient. The challenge lies in defining what is good or bad. Healthcare professions and patients might disagree about what constitutes good or bad consequences. Some might consider it best to prolong the length of life to the maximum time, while others might give priority to quality of life over length of life. Thus, it becomes important to discuss perceptions of what is good or bad among all people involved in decision making. To understand and accurately predict consequences, it is also of utmost importance to provide the best available and most relevant information to the decision makers [16].

3.1.2. Autonomy and dignity

Respect for patient autonomy is the centre piece of modern medical ethics and enshrined in most jurisdictions and guidelines on medical ethics [17]. Modern societies are pluralistic. This means that they are composed of people from different and diverse backgrounds. People hold different religious or philosophical beliefs and have different views and values. Members of a pluralistic society accept such diversity [18]. The mutual acceptance of distinct views about how to lead a good life necessitates respect for the autonomy of each person [12]. Consequently, in a pluralistic society, each person is allowed to make independent choices pertaining to their healthcare, as long as no other individuals are harmed. Healthcare professionals are expected to respect - in the framework of their profession - the choices and the integrity of patients.

Any treatment or diagnostic intervention is only allowed after a fully informed and free consent of a patient has been provided. Healthcare professionals also have to respect the informational autonomy of patients. This means that they need the consent of a patient before information can be transferred to other people, including the patient's designated next of kin. Patients therefore have the right to decide whether their next of kin is informed or not [19], unless the patient has a legally mandated custodian (e.g. minors). Exceptions to this approach are usually defined by the laws of a country to inform others (without patient consent) in specific situations where an

overriding public health interest exists, e.g. in the case of some dangerous infectious diseases, or if there is a significant risk to the life or bodily integrity of the third person that could be avoided if the information is disclosed.

Respect for autonomy requires a patient to be capable of decision making. This capacity is to be evaluated and re-evaluated for each situation and decision to be made. Respect for autonomy is often mentioned together with human dignity. According to the philosopher Kant[1], human beings should always be treated as an end and never as a means [20]. As the concept of dignity has a variety of meanings [21], the four main principles of biomedical ethics (beneficence, non-maleficence, respect for autonomy and justice) [13] usually only refer to patient autonomy, wherein all persons with decision making capacity are entitled to autonomous decision making concerning their own bodies.

3.1.3. Justice

The principle of justice is used to make decisions in settings where resources are not sufficient to respect autonomous decision making of all patients [22, 23]. For instance, in most countries the number of organs available for transplantation is lower than the number of patients in need of such organs. Considerations of just distribution help to define which patient should receive an organ and which patient will remain on the waiting list or may even die because of a lack of sufficient number of organs for transplantation. Similarly, other types of care such as intensive care beds or ventilators may not be available in sufficient quantity following a catastrophe or mass accident, for instance. It is widely agreed that patients should not be discriminated against, based on characteristics such as race, gender, or other social characteristics. It is also expected that the right to health is not influenced by the legal status of a person but considered a human right inherent to any human being.

3.1.4. Prudence and precaution

Prudence is a so-called precautionary principle [24] and implies that where there is not adequately proven evidence about the consequences of an action, including implementing a new technology, or administering a new pharmaceutical, all possible precautions are expected to be taken before using it. In healthcare, this means that new treatments, procedures and techniques usually have successfully been tested in clinical trials first, in order to evaluate the consequences, before they can be widely used. All treatments and diagnostic procedures imply risks to patients and in the case of radiation, there can also be risks to healthcare personnel. In order to make an informed choice and to decide on the acceptable balance between risks and benefits, it is important to obtain sufficient data about benefits and risks, and to continue to monitor risks and benefits closely for all patients.

3.1.5. Honesty and transparency

Honesty and transparency are sub-principles that follow from the respect for patient autonomy [25]. In order to make autonomous decisions, the patient and all involved healthcare personnel are expected to have received honest information. This is a reciprocal duty: healthcare professionals have the obligation to tell the truth to their patients and vice versa. Transparency may include the right of patients to have access to their medical records, or that hospitals and

[1] "Act in such a way that you treat humanity, whether in your own person or in the person of another, always at the same time as an end and never simply as a means." [20]

other health institutions are expected to regularly publish transparent data on their treatment outcomes.

3.1.6. Accountability and liability

Healthcare professionals and healthcare institutions are responsible for the care they provide to patients, for how they minimize risks of treatments or diagnostic procedures, and for how they maximize safety and benefits [26]. The standards respected are defined in professional guidelines and often also in the law, especially with respect to risks of radiation, which may go beyond the risks to single patients and therefore concern the larger society. Accountability implies that actions and their consequences are monitored transparently and that actors can be held responsible for any errors or substandard behaviour. In medicine, many treatments have risks that cannot be fully excluded. Thus, healthcare personnel do not have an obligation to provide a certain result. In medicine, healthcare professionals have the mandate to exercise their profession with diligence with respect to its rules. Where lack of diligence demonstrated, healthcare professionals are liable for the harmful consequences resulting from it.

3.1.7. Inclusiveness

Inclusiveness is a sub-principle related to the principle of justice that states that all human beings should have equal access to opportunities and resources in healthcare. This might require special efforts to include vulnerable populations and people of certain characteristics who might be excluded or who could be easily marginalized, if mitigation measures are not applied. For instance, typically, special attention is directed to groups and individuals that are vulnerable due to poverty, to physical or mental disabilities, or because they belong to minorities or are dependent in a way that limits their decisional autonomy [27].

4. ETHICS IN MEDICAL PHYSICS PRACTICE

4.1. GENERAL WORKPLACE ETHICS

Workplace ethics is a set of principles and values to be respected by employees and employers. In the healthcare system, all persons present in a given space have to respect these rules, including patients, carers and visitors. There are widely agreed on ethical rules, often enshrined in a country's laws, to govern these workplace relationships. They cover a wide range of behaviour, which can be roughly summarised as rules of behavioural integrity and mutual respect. In medical physics, several professional organizations and certification bodies have promulgated statements related to ethical behaviour of members or registered practitioners respectively, that may be useful to readers of this publication [28-34].

4.1.1. Professional relationships

The work of a CQMP has, in common with other healthcare related work, a number of characteristics that lead to an imperative for a high level of professional behaviour. Hallmarks of professional behaviour include:

- Academic education in a defined area of knowledge;
- Commitment to apply this knowledge in a way that benefits others;
- Autonomy in course of action or expression of professional duties;
- Adherence to ethical and quality standards determined by peers;
- Formal qualification standard such as professional certification and registration.

In facing the challenges of their profession, CQMPs are expected to interact with their colleagues in the workplace in a way that recognizes a professional mutuality. Respect for the knowledge of others is essential, and the medical physicist is called to implement this respect by integrating the expertise of co-workers into decision making and practice patterns when exercising professional judgement. CQMPs are expected to always place the welfare of patients first. In decision making and clinical practice, CQMPs are called to carry out independent judgement, based on their competencies and experience, with the aim of achieving quality outcomes. Their professional autonomy and competence in their area of specialization is expected to be recognised by colleagues and co-workers. In situations where differences of opinion or potential conflicts arise, they are best resolved in a collegial fashion, attempting to engage and educate the other party, where necessary. The CQMP participates in appropriate certification body processes (and licensure, where applicable) and expects peers to do so as well.

4.1.2. Practice audits

Practice audits or peer reviews are an important part of a profession [35]. CQMPs are expected to engage with their colleagues in practice audit processes [4], since medical physics requires specialized knowledge and experience unique to the CQMP. Such audits assess the adherence of the CQMP work to best practices and promote continuous quality improvement with a focus on the quality of care provided to patients. Recommendations guiding toward improvement and professional growth typically come from other CQMPs. In a practice with multiple CQMPs, audits are typically conducted by external, independent medical physicists who have no conflict of interest, and the audit methodology follows pre-existing standard procedures. The procedures and processes are specifically described, executed as planned and lead to a documented review result. The audit typically includes a review of the processes in place for the practice, relevant patient care techniques and records, compliance with various professional and regulatory standards, and the findings compared to contemporary standards of care. The independent CQMPs selected to perform the audit are expected to have certification and practice qualifications similar or senior to those whose practice is audited. These audits are normally scheduled on a recurring basis (e.g. biennially) and also include creation of metrics to ensure and document improvement, which can be assessed in the period between the scheduled practice audits.

4.1.3. Code of conduct

CQMPs are to conduct themselves in such a way as to enhance the general effectiveness of the workplace operation. Furthermore, their behaviour is expected to reflect their independent professional role within the department and embody their public role (e.g. public servant, healthcare worker etc.). They are expected to lead by example and exercise consistent alignment with professional standards. Actions are to be based on optimizing outcomes for patients, furthering the legitimate goals of the organization, maintaining a safe and welcoming workplace, and displaying a stewardship of resources.

4.1.4. Maintenance of competence

Consistent with the definition of professional conduct, CQMPs acquire the basic knowledge and competencies (a combination of knowledge, skills, and attitudes) to properly function in their position. Their qualifications in all work-related matters are expected to be transparent and appropriate; additionally, CQMPs do not engage in activities beyond their abilities, competencies or scope of practice. Since the scientific and clinical knowledge base of medical

physics is rapidly evolving; it is important for those in the field to engage in a continuous learning process relevant to their specialty, even if not required to do so by employers or certification bodies. CQMPs are expected to act in accordance with the codes of conduct of their certification body, academic institutions (e.g., faculty appointments where applicable), and professional societies and where applicable, in alignment with international guidelines pertaining to professional standards.

4.1.5. Resources

In fulfilling their obligations to patients, CQMPs utilize and optimize appropriate resources to provide clinical services within their setting, in line with the principle of justice. It is considered part of the work of a CQMP to assess and identify – in collaboration with the medical team – what the optimal diagnostic or therapeutic radiological intervention is for the individual patient and to advocate that services to patients are provided using sufficient resources to ensure delivery of safe and effective care. Resource deficiencies are to be brought to the attention of both institutional administrators and clinical colleagues, along with remediation proposals. Ethical principles and documented deviations from professional standards, as a result of a lack of resources, may be used to justify the decision of a CQMP to refrain from participating in suboptimal delivery of patient care.

4.1.6. Communicating medical errors and incidents and the need for prevention mechanisms

The approach to medical errors may not only be to determine the best strategic response to rising legal costs for institutions and healthcare personnel, but also to consider the beneficial implications of delivering an appropriately ethical practice that would enhance patient trust and meet patients' needs and expectations after a medical error or any incident has occurred. Adequate individual and institutional approaches to medical errors are crucial, not only to alleviate patient distress, but also to prevent negative health consequences in healthcare personnel. Healthcare professionals involved in medical errors have been called "secondary victims" of medical errors as they can experience significant distress [36].

Following from the principle of respect for autonomy and the derived principle of honesty, patients have a right to be truthfully informed about any medical error. It is generally agreed that patients do not need to be informed in the case of "near misses", where the error was detected and corrected before any harm could arise, e.g. the wrong dose of a treatment (due to an error in the prescription or an error in the preparation) which was noticed before it was delivered to the patient. However, there is an important ethical and practical obligation to disclose near misses in the framework of a preventive institutional approach (e.g. through an incident reporting and learning system) [37]. Only if types of possible errors are identified thanks to a "near miss" can this type of error be prevented in the future.

Current approaches to medical errors are based on the empirical findings that "errors are human", i.e. they are likely to occur. However, most errors are not the consequence of inappropriate behaviour of individuals, as their causes are usually system or process related [38]. When accounting for human errors, it is important to implement procedures and systems to favour reducing the likelihood of their occurrence. Examples may include: increased redundancy in controlling practice (e.g. more than one CQMP checking a procedure or part of it)), more secure labelling (e.g. devising procedures to ensure the correct anatomic area is imaged or treated).). Additionally, it is important to foster a transparent healthcare culture, where personnel at all hierarchy levels are taken seriously and repeatedly asked to contribute

any observation about possible errors, without having to fear negative consequences. Institutions, but also all individual healthcare professionals, would benefit from being trained to implement up-to-date preventive approaches. This includes training on how to report, investigate and review incidents that could have resulted in medical errors to patients, and implement preventive measures to the occurrence of incidents [37, 39].

4.1.7. Whistle-blower protection

Healthcare professionals support appropriate reporting mechanisms and remedial actions when an event has occurred that is inconsistent with institutional or regulatory requirements, or ethical obligations, or when patient care is suboptimal or compromised. It is the duty of the CQMPs to cooperate fully with the analyses and investigations of these events, to provide truthful reports and additional input to their colleagues' reports when requested. Consistent with the obligations described above in Section 4.1.6, internal or external reviews, including investigations of processes and incidents, may be initiated. Patient related information is protected by medical confidentiality requirements. The rules of medical confidentiality required by the national authorities is to be respected and CQMPs are to align their practice to institutional and national directives pertaining to confidentiality. It may be necessary to obtain permission from patients and/or the relevant authorities to pass on relevant information to external reviewers or investigators. After having followed these procedures, CQMPs are expected to respect the ethical principle of honesty: it is unethical to withhold information or encourage others to do so.

4.1.8. Professional conflict of interest

CQMPs may encounter situations in which a conflict of interest, or a potential conflict of interest arises. The parties among whom the conflict exists may include the CQMPs, patient(s), the institution at which the CQMP is employed and/or an outside entity such as a vendor, a competing institution, or another employer of the CQMP. In all such situations, it is important to place the interests of the patient as primary. That said, conflicts of interest may be managed, through disclosure of the conflict or potential conflict, recusal from activities that might give rise to a conflict, or termination of contact/relationship with one of the entities associated with the conflict. The presumed or suspected existence of conflicts of interest may be just as problematic as an actual conflict of interest, so great care and full transparency should be exercised in all situations that may give rise to such conflicts.

4.2. GENERAL SCIENTIFIC INTEGRITY

"Research misconduct is traditionally defined as fabrication, falsification, or plagiarism (the so-called FFP categorisation)" [40] and toolkits exist to help with the implementation of scientific integrity (e.g. [41]).

4.2.1. Plagiarism and intellectual property

Plagiarism is "using other people's work and ideas without giving proper credit to the original source, thus violating the rights of the original author(s) to their intellectual outputs" [40]. Intellectual property is regulated by law in most countries. From an ethical point of view, the underlying principle is respect not only of copyright, but – more fundamentally – transparency and respect for the ideas of other people. Thus, from an ethical point of view, besides plagiarism of already published work of others, several related practices are also inappropriate. These are commonly referred to as "unacceptable practices" [40, 42] and include self-plagiarism, i.e. "re-publishing substantive parts of one's own earlier publications, including translations, without

duly acknowledging or citing the original" [40], take credit for or not acknowledge appropriately, the work or ideas of others.

4.2.2. Acknowledgements and citations

"Authors acknowledge important work and intellectual contributions of others, including collaborators, assistants, and funders, who have influenced the reported research in appropriate form, and cite related work correctly" [40]. Different ways exist to acknowledge or credit contributions of others in published and unpublished work. Substantial contributions to research merit co-authorship in publications. Extensive rules for authorship have been published in the past and are expected to be taught to all medical and research collaborators [43, 44]. All authors and those mentioned in the acknowledgement section of a publication should consent in written form before submission of a manuscript to a journal or editor. To avoid incompatible expectations, the types of involvement and crediting is typically agreed on before the collaboration starts and updated regularly, based on contributions of the different collaborators. Citations of own and others' work need to follow existing rules. "Expanding unnecessarily the bibliography of a study" in order to increase citation of the authors' work or work of others is also recognised as "unacceptable practice" [40].

4.2.3. Conflicts of interest in research

It is important to recognise the conflicts of interest, as they may lead to bias in medical and research practices and distort the medical evidence base. "Actual and perceived conflicts of interest undermine confidence in the generation and interpretation of scientific evidence. The financial relationship between industry and academics has come under particular scrutiny, although conflicts of interest can be financial and non-financial, direct and indirect" [45]. "All authors disclose any conflicts of interest and financial or other types of support for the research or for the publication of its results… Reviewers or editors with a conflict of interest withdraw from involvement in decisions on publication, funding, appointment, promotion or reward." [40]. However, it is also widely recognised that the simple act of declaring an interest is not sufficient. Declaration only may result in a false reassurance that all conflicts of interest have been managed appropriately [45]. Each healthcare professional is expected to declare any possible conflicts of interest openly and, in addition, examine critically whether conflicts of interests interfered with the knowledge generation, clinical and research practices employed, or generation of the findings.

4.3. RESEARCH

Research is commonly defined as "the quest for knowledge obtained through systematic study and thinking" [40]. Medical research is important to produce evidence-based knowledge pertaining to disease mechanisms and patient care and is needed to improve the health and outcome of patients. Medical physics-related research that contributes to improved methods of providing services, including the development of, or new applications of, radiation and health technology and agents, may also be pertinent here. All healthcare professionals involved in research have the responsibility to ensure that research produces unbiased results that undergo appropriate validation processes before considering clinical implementation. All research findings are to be employed in the best interest of the patient. Inappropriate applications of research findings may seriously endanger the health of patients or, in some cases, indicate an unjustified waste of resources [46, 47].

4.3.1. Integrity in dealing with healthcare data and patients

As in clinical care, all research activities are expected to be done in alignment with the four main principles of biomedical ethics (beneficence, non-maleficence, respect for autonomy and justice) [13, 47]. Patients need to be informed transparently whether research practices will require additional interventions, data, records, images or sample collection and storage that are not part of the usual clinical procedures. They need to be informed in detail as to whether the additional research practices will increase risks and/or benefits, in order to be able to provide informed consent. Respect for the autonomy of research participants – healthy volunteers or patients – implies that their wishes are respected concerning handling of any identifiable information related to them. Integrity in dealing with patients and healthcare data requires transparent information about which data are collected, to which degree they are anonymised, how, where and how long they are stored, and for which type of research they may be reused. Many jurisdictions allow patients to provide not only specific consent to an already defined research project, but also general consent for future use of their data for medical research that is not yet fully defined [48, 49]

4.3.2. The need for human research ethics committee clearance: approvals and waivers

Research that may impact clinical practice requires additional safeguards [50]. When performing research, it is not sufficient to have obtained the informed consent of a research participant to be authorised to carry out research. A requirement [1] for any medical research involving human beings, or identifiable data, records, images or samples derived from them, is approval by a competent research ethics committee, also called Institutional Review Boards [50]. Researchers have to describe the research methods, the justification of the research, as well as any possible benefits and harms, and submit all documents provided to research participants including information material and informed consent forms. Researchers also have the obligation to abide by the details of the research study as presented to the research ethics committee and inform them of any deviations or amendments during the course of the study.

The competent research ethics committees review and evaluate whether the harm-benefit balance is ethically appropriate, whether information to participants is appropriate and informed consent standards are fulfilled. Special procedures exist in different countries for research using truly anonymous or fully anonymised data. Based on specific regulations, the competent research ethics committees may provide waivers of consent in situations where data and samples have already been obtained without specific research consent. Conditions for waivers are usually that risks to research participants are minimal or very small that the research interest outweighs the autonomy rights of patients and the results cannot be practically obtained in an alternative way where patients are asked to provide active consent, and that there is no reasonable indication that research subjects would have refused to participate [48].

4.3.3. Intellectual property

In some settings, ownership of intellectual property can be problematic with respect to the medical physics profession. It is possible that the CQMP may find, in the course of their work, that they may acquire knowledge or learn techniques that an employer or vendor may consider proprietary intellectual property. In cases when the CQMP practice setting change, a conflict may arise between the obligation to respect confidentiality concerning the intellectual property-protected new techniques and the obligation to provide the best possible care to the patient. Care should be exercised when contractually agreeing to intellectual property restrictions

associated with medical physics work products, balancing the proprietary needs of the employer or funding source with the overall imperative to place patient benefit first. Medical physics residents are typically not exposed to proprietary techniques during their education process that cannot be disclosed or used in post-training practice. CQMPs however are expected to understand contractual and other legal obligations related to the intellectual property they create or encounter in their practice. Careful acknowledgement of the creators and owners is expected when discussing, presenting, or publishing material that may be subject to intellectual property use or disclosure restrictions, and legal restrictions must be observed.

4.4. GENERAL MEDICAL ETHICS

4.4.1. Interaction with patients

All interactions with patients is typically governed by respect for the principles of medical ethics, in particular patient autonomy (and related or derived principles such as honesty, transparency, informed consent, and dignity), justice (and the derived principle of inclusiveness), as well as the principles referring to duty of healthcare professionals to strive for the best possible consequences: beneficence, non-maleficence and related principles that refer to the needed diligence to deal with uncertainty of consequences (this requires prudence and precaution) or the principles that describe in more detail how healthcare professionals' will be held responsible for their actions and the resulting consequences (accountability and liability).

Respect for patient autonomy is an ongoing process which requires appropriate truthful information, so that patients are able to make informed decisions [51]. In many situations, there is no clearly defined "patient good", as this concept may vary according to the degree of risk an individual wants to accept for a given possible benefit. Medical guidelines exist that define decision making trees and medical indications, based on consensual medical evaluations of which treatments are considered of sufficient benefit and which treatments may be futile. While patients are not entitled to request futile treatments, e.g. antibiotic treatment for a viral infection where the antibiotic treatment is of no medical use, they have a quasi-absolute right to refuse treatment, even if this treatment is considered beneficial by healthcare professionals and relevant guidelines. Respect for patient refusal requires healthcare professionals to carefully evaluate whether the patient has decision making capacity and has understood all relevant information. An important ethical obligation is to find sufficient time to discuss with patients refusing treatments, in order to understand their reasons, to provide additional information if needed and to give the patient time to obtain a second opinion. Studies have shown that in many cases patient refusals are a way for patients to communicate their need for more information [52].

4.4.2. Interaction with the public

The work of CQMPs may include – where relevant – contact with the public. Interactions with the public require careful attention to the impact they may have with respect to public health and also to the perception of the public of the profession of medical physics and the institution with which they are affiliated. In addition to all of the principles described above, CQMPs are expected to exercise great care in making public pronouncements to avoid misunderstandings or misperceptions. Discussions with colleagues occur in the context of a mutual foundation of basic knowledge related to the subject, discussions in the public forum may not have that medical, technical, or scientific foundation and so will need to be undertaken with special care.

Interactions are expected to be scrupulously honest and objective, reflect accurate scientific, clinical, and professional consensus and be characterized by a professional demeanour.

5. EXAMPLES OF ETHICAL DILEMMAS AND APPLYING ETHICAL PRINCIPLES IN GENERAL

A process of "ethical reasoning" is invoked when confronted with an ethical dilemma in practice in which there is a clash, complexity or contradiction in ethical principles [53, 54]. This process has multiple steps in which the issue is first clearly identified to be an ethical one, all information is then collected, authoritative sources (e.g. guidelines, experts) are then consulted as needed so that different possible ethical solutions can be identified. A moral assessment is then made on each of these solutions. The most relevant values, duties and rights of all affected parties, and the pros and cons of each solution are weighed prior to concluding the best option. Only then is the way forward discussed with affected parties and/or action taken on the decision.

Ten scenarios that are considered to be typical in CQMP practice, are outlined below and suggestions are made of the professional response, as well as the ethical principles that were used to guide the reasoning process.

5.1. EXAMPLES IN DIAGNOSTIC RADIOLOGY

5.1.1. Scenario A

Situation: A CQMP performs a routine annual evaluation of a mammography system. As part of the process, reports are reviewed from several preceding years. The numerical results of most of the ionization chamber measurements are exactly the same from year to year, a nearly impossible physical possibility. The medical physicist carrying out the annual evaluation is concerned that actual measurements may not have been performed.

Response: In such a situation, the predecessor is contacted to review the data and discuss the concerns. In the absence of a convincing explanation for the anomalous data, the current medical physicist acts as a whistle-blower and informs the administrative and clinical management at the institution, as well as relevant regulatory authorities.

Principles applied: Honesty and transparency as well as accountability and liability guide the CQMP's response here, in addition to the obligation to report and investigate medical errors or situations that might have triggered them

5.1.2. Scenario B

Situation: A computed tomography (CT) technologist mentions to the CQMP that several physicians routinely request repeat CT scans on patients without reviewing the existing image data sets from recently acquired CT procedures.

Response: The CQMP engages with the radiologists and physicians. A decision support system based on appropriateness criteria is implemented to address the issue at the procedural level. The system is designed to recognize that, while there may be medical indications for repeat CT scans, unnecessary repeat scans can often be avoided by adherence to agreed appropriateness criteria. Furthermore, the CQMP may also create procedures that allow for dose reduction for medically warranted repeat CT scans performed to follow a specific medical condition.

The CQMP may request that training is organized to inform the physicians on the best practices with respect to repeat imaging with ionizing radiation techniques.

Principles applied: Beneficence and non-maleficence are relevant to this scenario and need to be respected, along with the imperative to place the benefit of the patient first.

5.2. EXAMPLES IN NUCLEAR MEDICINE

5.2.1. Scenario C

Situation: When reviewing quarterly dose calibrator linearly tests, the CQMP notices that the results have an unusual level of consistency from quarter to quarter. Upon further investigation the medical physicist discovers that the nuclear medicine technologist performing the test uses a calculation procedure that assures that the test exactly matches the expected decay values, regardless of the performance of the dose calibrator system.

Response: The CQMP repeats the linearity test and verifies that the function of the dose calibrator is appropriate, and that no actual deficiency has gone undetected. In a collegial fashion, they then review the erroneous calculations with the nuclear medicine technologist and explain the mathematical error. The CQMP creates a new procedure for properly performing the linearity test and trains the nuclear medicine technologist in the process. Appropriate documentation is created and, if required, regulatory reporting is completed. In case any harm resulted to patients from the errors, all patients who were affected by the errors are then fully informed about what happened (open disclosure) and any resulting harm is clinically mitigated or managed, as appropriate.

Principles applied: Honesty and transparency, as well as accountability and liability are again applied in this response. In addition, the CQMP applies the principles related to responsible professional relationships described in Section 4.1.1. and the duty to disclose medical errors in Section 4.1.6.

5.2.2. Scenario D

Situation: A CQMP is a co-primary investigator on a clinical trial to assess the efficacy of a particular combination of radiopharmaceutical therapy regime and tumour type. In setting the patient selection criteria, it becomes clear that the financial and political support for the expensive and limited availability treatment agents to be administered would be significantly enhanced by adjusting the criteria to admit a higher proportion of insured patients.

Potential response: CQMPs engage their co-investigators in a careful review of the purposes of a clinical trial, in particular ensuring that the prioritization/selection is based on clinical need and the investigational goals of the study. Admission to the study is expected to be based on these characteristics and cannot be modified by attempts to improperly influence access to limited resources based on factors other than clinical and scientific imperatives. All research needs prior approval by a research ethics commission, which would ordinarily reject inclusion criteria based on the resources of research subjects.

Principles applied: In this example, the principles of justice and inclusiveness as described above are paramount. Further, the principles associated with scientific integrity and honesty require patient selection criteria that are relevant and transparent.

5.3. EXAMPLES IN RADIATION THERAPY

5.3.1. Scenario E

Situation: A new multi-energy linear accelerator has been installed. The administrators and radiation oncologists are anxious to begin using it for patient treatments and exercise considerable pressure on the CQMP to release the system for clinical use.

Response: In this situation, the ethical imperative for the CQMP started at a time much earlier than the requests described above. It is the duty of the CQMP team to anticipate this predictable situation. CQMPs are expected to devise an action plan before the linear accelerator has been delivered. At the outset of the project, it is important that the CQMP defines a timeline for the installation, acceptance testing, commissioning and licensing of the linear accelerator and associated systems (radiation therapy planning, oncology information system, etc.). The timeline and necessary staffing levels are then agreed by both the administrative staff and radiation oncologists. The timeline is typically kept dynamic, unanticipated delays in any part of the process (e.g, late delivery) could cause a corresponding change to the anticipated clinical start date. It would be against best practices to begin patient treatments prior to completion of commissioning the relevant aspects of the systems.

Principles applied: Several principles apply in this example: beneficence and non-maleficence, prudence and precaution, accountability and liability all come into the process as described above. Further, the principles described in Section 4.1.3 (code of conduct), 4.1.4 (maintenance of competence) and 4.1.5 (resources) provide guidance on the response of the CQMP.

5.3.2. Scenario F

Situation: A CQMP is engaged by a colleague who is working alone at another institution to perform an external practice audit. The colleague offers a very well-paid contract to perform the service, but also provides a review checklist that is already filled out, indicating that the review could result in the report as provided a priori.

Response: CQMPs who find themselves in such a situation engage the colleague in a discussion regarding the typical process for and benefits of a careful and well-designed practice audit, offering references to professional standards as guidance. They decline to use the proffered checklist with predetermined results. Instead, they create, in consultation with the reviewed colleague, a plan for the scope and detail of the review. If they mutually agree on a process, the contracted review proceeds. If not, the medical physicist declines the opportunity to be a reviewer. The attempt of suggesting that an auditor review an already populated audit checklist is unprofessional behaviour and might be reported officially to the relevant authority.

Principles applied: Honesty and transparency are relevant to this response. The general principles regarding the purpose and performance of practice audits in section 4.1.2 also offers the necessary guidance.

5.4. EXAMPLES IN RADIATION SAFETY AND PROTECTION

5.4.1. Scenario G

Situation: The interlock on the door leading to the linear accelerator vault malfunctions. An immediate repair is not possible. Local regulations require an operational door interlock, but there is a waiting room full of patients in need of treatments.

Potential response: The CQMP recognizes the need for patients to receive their daily treatment and understands the radiobiological effects of a postponed radiation fraction. If there is no radiation hazard, the CQMP mitigates the situation associated with the absent door interlock by stationing a staff member at the door continuously to control access to the treatment room. Although technically in violation of local regulations, the medical physicist judges that treatments can proceed in a safe manner.

Principles applied: The relevant principles are prudence and precaution, combined with the application of maintenance of competence described in Section 4.1.4. The medical physicist is obligated to make an informed judgement in the best interest of patients, while assuring general staff safety.

5.4.2. Scenario H

Situation: An institution decides to review the contract for personnel radiation monitors and asks the CQMP who is the Radiation Safety Officer (RSO) to provide an analysis of competing technologies and make a recommendation. One of the vendors mentions to the RSO that, should their product be selected, they would be interested in contracting the RSO to evaluate certain performance characteristics of the dosimeter.

Response: The vendor has posed a clear conflict of interest for the RSO by creating an incentive to influence the selection of their product. The RSO informs the vendor that they will not consider such a contractual arrangement, and also informs the institutional management of the inappropriate offer. Assuming that the institutional policy permits it, the RSO then completes an objective analysis of the competing technologies from all of the vendors.

Principles applied: Honesty and transparency as well as accountability and liability apply in this situation, and the stewardship of resources described in Section 4.1.3 offers further guidance to the medical physicist, as does Section 4.1.8 pertaining to conflicts of interest.

5.5. EXAMPLES IN PROFESSIONAL MATTERS

5.5.1. Scenario I

Situation: A high-dose rate brachytherapy afterloader has not received a source exchange, despite the requests raised officially by the medical physics department of the hospital and the planned date for its replacement, as part of the maintenance contract. The hospital management insists that patients are treated as usual and has requested the radiation oncology department to schedule treatments as per the usual routine. The time of treatment of patients has now become excessively long.

Response: All CQMPs of the department communicate through the lead medical physicist that they refuse to continue performing high-dose rate brachytherapy treatment planning under such

conditions, especially since resources are at hand. The medical physicists can also escalate the issue through the whistle blower system of the hospital.

Principles applied: The principles of beneficence and non-maleficence apply in this situation, as well as prudence. The medical physicist will also be guided by the discussions in section 4.1.5 and 4.1.7 on resources and whistle blower protection, respectively.

5.5.2. Scenario J

Situation: A CQMP is engaged by a facility to provide clinical services based on a monthly payment rate. As part of that contractual work, the CQMP develops and implements a software package that becomes integral to the clinic practice. At the end of the year, the contract for their services is not renewed. Upon departing, the CQMP declines to leave either the code or relevant passwords on site for the clinic to access, claiming intellectual property ownership of the software.

Response: In the absence of specific contractual language or local case law affirming the contrary, the ownership rights to the software reside in the hospital. The CQMP was engaged to provide services that included software development and implementation, so the clinic has a justified claim to the ownership of the work product (the software) and access to the passwords. In line with ethical principles as well as legal requirements, the CQMP facilitates an orderly transfer of the software and its functions.

Principles applied: A general application of the principles of accountability and liability may apply here. Healthcare professionals are required to maximize benefits to patients and are held accountable for contractual obligations, avoiding using the threat of withholding patient care tools for personal financial advantage. Further guidance in intellectual property can be found in Section 4.3.3.

6. EDUCATION IN PROFESSIONAL ETHICS FOR MEDICAL PHYSICISTS

Ideally national guidelines on core ethical values, professional standards and research ethics in the healthcare environment are developed consultatively by experts in ethics, and then adopted and published by the certification body, health authority and/or professional organizations of all healthcare professions. The widespread lack of recognition and certification of medical physicists as healthcare professionals [9, 11] has resulted in limited education and training opportunities. Since CQMP also need competencies in ethical principles to obtain certification and practice effectively, education in professional ethics is needed as part of medical physics academic programmes, clinical training programmes and for continuous professional development.

6.1. POSTGRADUATE LEVEL ACADEMIC DEGREE

In alignment with international best practices [4, 6-9], the pathway toward becoming a CQMP commences with a postgraduate level academic programme in medical physics. The IAEA published a syllabus for such a programme that was endorsed by the IOMP [55], which includes content on professional ethics.

6.1.1. Syllabus and the ethics component

In Training Course Series No. 56 Rev.1 [55], ethics is included in the syllabus among the core modules as a component of the module “Professional and Scientific Development” and

encompasses insights on the World Medical Association Ethical Guidelines [56], the basis of clinical trials, the role of ethics review committees and ethical principles. The module generally aims to convey aspects of the history and development of ethics and its impact on healthcare professionalism. In the framework of the postgraduate level academic programme, particular attention is also given to ethics as it relates to research methodology and data collection, and to the authorship, integrity and plagiarism of research output.

6.1.2. Assessment

Academic programmes have, in general, well-established mechanisms to assess the level of knowledge students achieve in the individual modules composing the programme; this might include formal knowledge testing, as well as informal, such as observations during class discussions and/or group work. Additionally, "Research ethics and integrity may be verified through a variety of methods, for instance the use of invigilation, plagiarism software or oral performance assessment." [55]

6.2. CLINICAL TRAINING PROGRAMME

As health professionals, CQMPs can be exposed to situations that may present ethical challenges. As independent professionals, they might be confronted with complex decisions that involve several ethical principles. It is therefore appropriate that dedicated training is provided to residents in medical physics to prepare them to manage ethical dilemmas in the most appropriate way. If national guidelines on ethics for healthcare professionals exist as well as institutions with experts in ethics, residents must be made aware of these resources during the programme.

6.2.1. Curriculum (competencies)

Clinical training will necessarily include direct interactions with patients and handling of patient data, records, images and/or samples. Competencies in professional ethics are therefore integrated into various modules of clinical training in all specialties of medical physics [6-8].

6.2.2. Assessment

Since professional ethics is an integral part of the clinical training curriculum, it is also part of the portfolio of the resident and can therefore be assessed formally and informally throughout the programme. This includes ensuring that the residents are able to apply the principles of ethics in practice, such as to describe the clearance processes by the relevant research ethics committee. Additionally, the supervisor might observe how the resident manages situations of conflict of interest and other ethical challenges as they arise in the clinical environment. Role playing of scenarios such as those presented in Section 5 can also be useful in developing the analytical and communication skills necessary for resolving ethical dilemmas.

6.3. CONTINUOUS PROFESSIONAL DEVELOPMENT

After a CQMP qualifies as a health professional, it is important to maintain competencies by embarking on activities that provide evidence of having acquired updated knowledge or skills in order to be re-certified [9]. These activities are not only applicable to research, or scientific and technical developments in the field of medical physics, but also to developments in professional ethics.

6.4. CORE RESOURCES IN ETHICS

A list of core knowledge sources that could be used to develop an educational programme for medical physicists in professional ethics is provided below:

- Beauchamp and Childress (2019) [13];
- World Medical Association – Medical Ethics (2022)[2];
- National guidelines on ethical principles and/or good practice and/or codes of conduct for healthcare professionals.

[2] https://www.wma.net/what-we-do/medical-ethics/

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CONTRIBUTORS TO DRAFTING AND REVIEW

Elger, B.	Institute for Biomedical Ethics, Basel, Switzerland
Gershan, V.	International Atomic Energy Agency
Holmberg, O.	International Atomic Energy Agency
Loreti, G.	International Atomic Energy Agency
Rae, W.I.D.	Prince of Wales Hospital, Australia
Skourou, C.	St. Luke's Radiation Oncology Network, Dublin, Ireland
van der Merwe, D.	International Atomic Energy Agency
White, G.	Colorado Associates in Medical Physics, Colorado Springs, United States of America

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