

Bioethical Study on Radiation Exposure in Medicine

Proposed Behavioral Changes During Radiological Examination in Medical Practice

Osamu KAMEI^{1,2}, Koichi SETOYAMA¹

¹Department of Biomedical Ethics, Kyoto Prefectural University of Medicine Graduate School of Medical Science

²School of Health Sciences, Nippon Bunri University

E-mail: kamei@nbu.ac.jp

Abstract

Radiation exposure in patients during radiological examinations is based on the “principle of beneficence,” which is one of the fundamental principles in biomedical ethics. It may be in conflict with the “principle of nonmaleficence.” The medical benefit of accurate diagnosis for patient treatment has historically been deemed to outweigh the disadvantage of radiation exposure and has been used to justify radiation exposure in patients. In this study, drawing on the insights of the International Commission on Radiological Protection, we propose that healthcare providers should adhere to the principles of patients’ “autonomy” and “prudence” by disclosing the risks of radiation exposure in accordance with the most recent and advanced scientific knowledge during the process of obtaining informed consent. One of the measures implemented involves the shift in awareness toward “tailor-made radiation protection standards” based on radiobiological findings. Herein, we explore the bioethical implications of radiation exposure during medical examinations, a topic that has been inadequately discussed so far, from a bioethics perspective. The study proposes medical care providers should modify their practices to increase awareness of the rationale behind radiation exposure.

Key Words: Medical Ethics, Medical Exposure, Informed Consent, Behavioral Changes

This paper is a secondary publication of a paper that was published after peer review at JOURNAL OF KYOTO PREFECTURAL UNIVERSITY OF MEDICINE, and no additional peer review was conducted at JPEHCM. The author has obtained permission to publish this paper from the editorial board of the journal in which it was first published.

Introduction

The primary objective of medicine is to alleviate the patient’s ailment. Medical ethics—the appropriate conduct for those engaged in the field of medicine—has been advocated since the ancient times of Hippocrates. The *Corpus Hippocraticum*, which was compiled by the disciples of Hippocrates, contains records of Greek medicine, which was the epitome of medical knowledge at the time. The Hippocratic Oath¹, an oath on the professional ethics of physicians, is one of these texts that has been transmitted through Western

medical education to the present day. One passage from this oath states, “I will use those dietary regimens which will benefit my patients according to my greatest ability and judgement, and I will do no harm or injustice to them.” (Source: <https://www.nlm.nih.gov/hmd/topics/greek-medicine/index.html>)

This passage forms the basis of two of the fundamental principles of present bioethics: “beneficence”—acting for the benefit of the patient—and “nonmaleficence”—doing no harm.

In the medical field, imaging studies such as X-ray examinations are indispensable. However, even at low doses, X-ray exposure carries a risk of

delayed effects, such as developing cancer². Furthermore, there are apprehensions regarding the adverse consequences of the growing exposure to CT scanning in Japan. The level of radiation exposure in Japanese patients is among the highest in developed countries, which may be attributed to the large number of CT machines in operation, which is the highest in the world.

A CT examination can result in an equivalent dose³ that exceeds 50 mSv, and the exposure can exceed 100 mSv in the event of multiple CT scans, depending on the area being scanned. Therefore, it must be acknowledged that the risks from radiation exposure in CT scans may already exceed permissible limits.

Diagnosing diseases using X-ray examinations is “beneficial to the patient,”; however, the risk of causing delayed adverse effects, such as cancer, as a result of X-ray exposure can also “cause harm to the patient.” This paper aims to examine this dualeffect of radiation exposure in medical settings from a perspective of bioethics.

1. Radiation Exposure and the Fundamental Principles of Bioethics

In their 1979 publication, *Principles of Biomedical Ethics* (translated into Japanese as *Seimei Igaku Rinri*, third edition in 1998), T. Beauchamp and J. Childress introduced the four fundamental principles of bioethics. These principles are “respect for

autonomy,” “nonmaleficence,” “beneficence,” and “justice.” These fundamental principles facilitated the engagement of individuals with varying ethical and moral perspectives in medical practice in discussions that were conducted within a common intellectual framework.

In the paper, “A Bioethical Study on Radiation Exposure in Medical Practice” (*Studia Humana et Naturalia* 51 (Kamei, Osamu: [2018: 61-72]), 52 (Kamei, Osamu et al [2019: 15-28])), published in the *Bulletin of Liberal Arts Education*, Kyoto Prefectural University of Medicine, we have already discussed the relationship between radiation exposure and bioethics. In these papers, we clarified the characteristics of the effects of radiation on the human body and the issues related to medical ethics. Currently, the International Commission on Radiological Protection (ICRP) (ICRP Publication 1, [1958]), which plays a leading international role in radiation protection, continues to adapt its recommendations to reflect advancements in science and shifts in societal values since its inception in 1928 (Figure 1). The primary objective of their endeavors is to present the effects and hazards of exposure with precision, leveraging scientific knowledge. Nevertheless, the ICRP had not provided comprehensive ethical explanations in their discussions.

The relationship between radiation exposure and bioethics has been comprehensively examined in ICRP Publication 109, which was published in 2008 (hereafter referred to as ICRP 109: *Advice on the Application of the 2007 Recommendations*) (ICRP Publication 109, [2009]). The publication

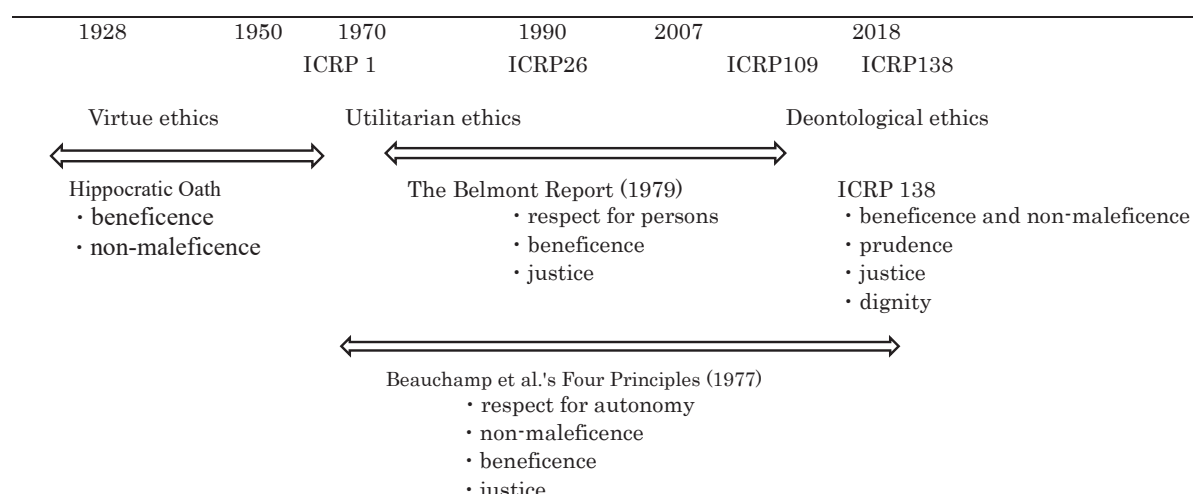


Figure 1: The Evolution of Ethical Values in the ICRP

specifically defines the changes in dominant ethical norms from 1928 to the 2007 recommendations. According to the ICRP Publication 109, recommendations from 1928 to 1950 emphasized “virtue ethics,” which prioritized proactive protection to prevent harm caused by radiation to individuals with the objective of ensuring safety for individuals (an act of beneficence).

During this period (from 1928 to 1950), there was an increased emphasis on preventing radiation-related diseases, including skin cancer and leukemia, as the use of X-rays (discovered by Dr. Roentgen in 1895) and radioactive materials such as radium advanced, leading to a rise in mortality caused by these radiation hazards.

Additionally, in the international community, “utilitarian ethics,” which prioritizes cost-effectiveness and regard for the overall benefit of society, gained prominence in the 1960s and 1970s. Hence, ICRP Publication 22 (1973 Recommendations) and ICRP Publication 26 (1977 Recommendations) (ICRP Publication 26, [1977]) stipulated that radiation protection was predicated on the application of “dose limits” to the radiation doses individuals received from all sources.

The 1990 and 2007 recommendations have since emphasized “deontological ethics,”³⁴ a moral theory that asserts that morally right actions are determined by the process of laws and rules rather than evaluating outcomes (consequentialism). This approach emphasizes the evaluation of actions based on their positive intentions rather than the outcomes of those actions.

In 2018, ICRP Publication 138: Ethical Foundations of the System of Radiological Protection (hereinafter referred to as ICRP 138) (ICRP Publication 138, [2018]) was published. This recommendation provided a clear explanation of the Ethical Foundations of the System of Radiological Protection and its role. In the same recommendation, two fundamental ethical principles were newly introduced: “prudence,” and “dignity.”

Within this recommendation, the “principle of beneficence” and the “principle of nonmaleficence” are interpreted as a single ethical principle. It was contended that the integration of these two principles is logical, as “nonmaleficence,” or “the removal of harm,” is designed to eliminate or mitigate potential hazards, thereby enhancing “happiness.” This indirectly results in an improvement in the quality of social life, which ultimately equates

to “beneficence,” as indicated in the recommendation.

However, Beauchamp and Childress maintain that “beneficence” and “nonmaleficence” should not be equated and should be distinguished. In their work, they define “nonmaleficence” in a more restricted context, as simply “do no harm or injury.” Conversely, “beneficence” is considered from three perspectives: “the prevention of harm or injury,” “the removal of harm or injury,” and “the promotion and execution of good.”

Furthermore, the new ethical value of “prudence” is not defined in Beauchamp’s four principles. In ICRP 138, “prudence” is explained in the context of the LNT (Linear No Threshold) model, which serves as the basis for cautiousness in radiation protection, particularly at low doses and low-dose rates. The recommendation underscores that this cautious approach is the most practical method for managing radiation exposure risks and is consistent with the “precautionary principle”³⁵.

Additionally, “prudence” and the “precautionary principle” should not be interpreted as necessitating “zero risk or the selection of the smallest risk when considering the effects of exposure” (ICRP 138: p.28). In other words, when it comes to low-dose exposure, such as medical radiation exposure, it does not demand that the risk of exposure be zero or reduced to the absolute minimum. Rather, the true essence of “prudence” lies in its rational and practical application.

Furthermore, as explained in the recommendation, the ethical value of “prudence” is defined as “the knowledge, experience, and sound judgment necessary to make and follow through on reasonable decisions” in the event of a conflict between the “principle of beneficence” and the “principle of nonmaleficence.” This represents the original meaning of the Latin term “*providentia*,” which means “foresight” or “the ability to anticipate” (ICRP Publication 138, [2018]).

Additionally, the same recommendation discusses several procedural value principles (“procedural values”) aimed at supporting practical implementation, specifically “accountability,” “transparency,” and “inclusiveness.” In this context, “accountability” refers to “the obligation to be prepared to explain the effects of radiation exposure” (ICRP 138: p. 35). Furthermore, “transparency” has already been integrated into previous recommendations and is employed in the context

of “providing information on the risks of radiation and the associated precautionary measures” as well as the “decision-making process for choosing protective measures” (ICRP 138: p. 36).

Therefore, the procedural value principles outlined in ICRP 138 are consistent with the widely recognized definition of informed consent, which entails “the disclosure of information, comprehension of the disclosed content, and agreement to the information” (ICRP 138: p. 37).

As stated above, although the ethical norms of radiological protection have undergone significant changes over time, it can be inferred that the fundamental ethical values have consistently been dominated by utilitarian ethics, which balances the “principle of beneficence to maximize the benefit to the patient” and the “principle of non-maleficence to avoid causing harm to the patient.”

2. Justification of Exposure and Bioethics

In ICRP Publication 60 (1990 Recommendations) (ICRP Publication 60, [1991]), it has been proposed that to justify any practice involving the use of radiation sources, “No practice involving exposure to radiation should be adopted unless it produces sufficient benefit to the exposed individuals or to society to outweigh the radiation detriment it causes” (ICRP 60: p. 86).

In particular, there is a historical precedent in the nuclear industry, including nuclear power generation, which has public implications, where societal benefits were prioritized over individual interests. In other words, even if the radiation exposure of individual radiation workers at each nuclear facility posed a disadvantage to them, the practice was justified if the cumulative disadvantages were outweighed by the aggregate public benefit to society.

Conversely, in the context of medical practice, for the exposure to be justified, the benefit of alleviating the disease or its symptoms must outweigh the detrimental effect of the exposure. The preceding illustrations show that the ethical value of exposure has historically been supported by the principle of “act utilitarianism”⁶.

As previously mentioned, “act utilitarianism” has been used to justify the use of radiation in medical examinations, with the objective of facilitating the patient’s recovery from illness. In

other words, the act of exposing the body to radiation is only permissible if it would be anticipated that the benefit of curing the disease or alleviating symptoms will outweigh the damage resulting from the exposure.

Furthermore, the physician’s discretion in clinical practice would be limited by restricting the use of radiation in treatments or examinations. Utilization of radiation in medical examinations is definitively permissible under the “principle of beneficence” in the physician’s duties.

However, from another perspective, radiation exposure, despite being for medical purposes, entails certain hazards, including the occurrence of adverse events, which may conflict with the “principle of nonmaleficence.” Thus, it is essential to evaluate the utilization of hazardous radiation on the human body for medical purposes from the perspective of the conflict between the “principle of nonmaleficence” and the “principle of beneficence.” A method of balancing these principles is recommended by Beauchamp and Childress to address cases where these principles conflict according to the context of a specific case.

Hence, it is asserted that it is essential to meticulously deliberate on the relative weight and strength of these principles and ascertain the principle that is more significant in each circumstance, thereby assigning an order of priority. However, in the context of the “justification of action” regarding exposure, simply resolving the conflict between the physician’s duty to avoid the harmful effects of radiation (the “principle of nonmaleficence,” which would provide physical benefits) and the duty to diagnose and treat the patient (the “principle of beneficence,” which offers medical benefits) solely through comparative balancing is insufficient. In other words, the sole act of weighing these two principles neglects the consideration of respect for individual patients’ (or subjects’) autonomy (self-determination), resulting in an excessive focus on “act utilitarianism.” This leads to a vulnerability in terms of safeguarding the individuals subjected to exposure. In the subsequent section, we will explore potential solutions to this issue.

3. Utilitarianism and Justification of Actions

In June 1964, the Declaration of Helsinki (adopted

by the World Medical Association) (Helsinki, Finland, June [1964]) was developed, stating that “Medical research involving human participants is subject to ethical standards that promote and ensure respect for all participants and protect their health and rights.” (General Principle 6). As previously addressed in Beauchamp et al.’s *Principles of Biomedical Ethics*, in the context of “respect for persons,” it is emphasized that ethical treatment of individuals primarily requires respecting their autonomy. This entails that, if it is evident that no harm will be inflicted upon others, one must not interfere with that person’s actions.

Additionally, regarding “beneficence,” it is observed that there is a duty to optimize the benefits arising from research, and thus, minimize potential risks. Hence, it is imperative to prioritize the welfare of individuals in addition to safeguarding them from damage (principle of nonmaleficence/beneficence).

Since the 1960s, especially in Europe and the United States, the traditional concept of entrusting medical decisions entirely to physicians has been increasingly recognized as inadequate for safeguarding patients, especially in cases involving medical research, invasive testing, or treatments. Consequently, the right of patients to make their own decisions has become increasingly significant, facilitated through explanations of the medical procedures to be conducted, and ensuring patients’ comprehension.

The Declaration of Helsinki established the necessity for informed consent for these reasons. The Declaration of Helsinki mandates that “patients and subjects must receive adequate explanations, comprehend the content, and provide consent” in relation to informed consent. Furthermore, the significance of disclosing risk information in the explanation is underscored.

Additionally, the Declaration points out the importance of ensuring that the content of the explanation is understood. This includes special consideration for subjects who may lack the capacity to consent, such as children or those with cognitive impairments. Consent is only considered valid when it is given voluntarily by the subject themselves.

As previously stated, the ICRP recommendations in the 1970s were concentrated on the concept of “justification of actions” based on act utilitarianism. Nevertheless, the content of action

justification witnessed a substantial transformation in ICRP 26 (1977 Recommendations). This shift was predominantly influenced by the introduction of the concept of individual exposure limits within the principles of radiation protection in these recommendations. This suggests that the principles of respect for persons and their autonomy have become more prominent in the medical field.

Therefore, the concept of “justification of actions” that exclusively predicated the absolute authority of physicians was superseded by a requirement that the instructions must be based on medical (scientific) evidence. Without this evidence-based foundation, such as that presented in imaging guidelines (Diagnostic Imaging Guidelines [2016]) and other medical resources, the physician’s instructions cannot be justified.

Additionally, it is imperative to mitigate the extent to which radiation exposure results in adverse effects on individuals, thereby preventing any infringements of autonomy. Therefore, the approach to radiation exposure in medical practice has evolved from act utilitarianism to rule utilitarianism⁶. As a result, for justification of actions to be established, it is deemed necessary to fulfill both medical evidence and informed consent as essential requirements.

5. Low-dose Radiation Exposure and the LNT Model

Radiation exposure, whether in a medical context or not, is characterized by the same physical effects on the body at a specific dose. However, the action of causing physical “harm” through radiation exposure is justified from a utilitarian perspective in the case of medical exposure, as the individual receives medical benefits. This understanding has achieved a certain degree of social consensus.

If the risks of exposure are known, it is possible to compare them to the medical benefits when evaluating the justification for X-ray examinations. However, when the risks of exposure are unknown, such comparisons cannot be made, which results in the lack of any basis for justifying the exposure.

The epidemiological data that serves as an optimal sample for assessing the risks of low-dose exposure is derived from the atomic bomb

survivors of Hiroshima and Nagasaki. The Radiation Effects Research Foundation's Life Span Study cohort comprises survivors for whom exposure doses are reasonably well-determined. The average exposure dose for individuals within 2,500 meters of the hypocenter is 200 mSv, with a statistically significant risk at a minimal dose of 150 mSv (Ozasa, K, [2012:229–243]). The dose-response relationship from the relevant study (Ohsawa et al.) (Ozasa, k [2011:903-911]) is depicted in Figure 2.



Figure 2 Excessive Relative Risk (ERR)

Source: Epidemiological survey of the atomic bomb survivor in Hiroshima and Nagasaki.

The probability of cancer (excess relative risk) caused by exposure increases in direct proportion to the increase in dose within the range of 0–2 Gy (2,000 mSv) of exposure, as illustrated in Figure 2. This type of dose-response model is known as the LNT model, which assumes that excess risk increases proportionally with the dose. The ICRP has implemented the LNT model as the foundation for considering radiation protection in low-dose ranges. Consequently, regarding cancer and genetic effects, it is presumed that there is no threshold dose (the dose at which effects appear in 1% of the population), and the incidence rate increases linearly with increasing doses from zero.

However, in the case of low-dose exposure, such as those observed in medical exposures, the risk assessment for doses below 100 mSv (the dashed portion in Figure 2) has not yielded statistically significant figures, even when extrapolating the findings from studies on atomic bomb survivors toward a zero dose. Therefore, the dose-response relationship for such low doses is depicted by a dashed line in Figure 2 to indicate that it is “statistically non-assessable.” Based on current

scientific knowledge, it is believed that the cancer risk caused by low-dose radiation exposure (below 100 mSv) is so negligible that it is obscured by other factors contributing to cancer development, rendering it difficult to establish the cancer risk from exposure.

Furthermore, scientific methods other than epidemiological studies have been employed to elucidate the cancer risk; however, they have not yet succeeded in elucidating the risk of low-dose exposure in humans (Health Risks from Exposure to Low Levels of Ionizing Radiation [2006:43–64]). This implies that the evaluation of low-dose exposure risks is regarded as having limitations when approached through conventional natural scientific methods.

6. Customization of Radiation Protection Standards

The ICRP 103 (2007 Recommendations) (ICRP Publication 103, [2007]) established radiation protection standards, which include a maximum annual effective dose⁷ of 50 mSv for “radiation workers” engaged in occupational activities that involve radiation exposure, based on scientific findings from epidemiological data. Furthermore, the upper threshold is established at a total of 100 mSv over the course of five years, with an average of 20 mSv over that time (Table 1, see below).

The annual exposure limit for the general public is set at 1 mSv. The term “general public” incorporates everyone who is not a radiation worker, regardless of gender, encompassing all age groups, from highly radiation-sensitive infants (0 years old) to adults.

Conventionally, the approach to protection against radiation exposure has been a uniform regulation applied to all individuals subject to exposure. However, analyses of the epidemiological data obtained from Hiroshima and Nagasaki atomic bomb survivors have revealed disparities in radiation sensitivity that are based on age and sex (Ozasa, k [2011:903-911]).

The ICRP's fundamental philosophy contends that “there is no reason to differentiate between genders for the purpose of managing occupational exposure.” However, under Japanese law (Law Concerning the Regulation of Radioisotopes: Act No. 167 of 1957), the limit for women of childbearing potential is set at 5 mSv over a period

Table 1: The 2007 recommendations in ICRP Publication 103

Type of limit	Occupational	Public
Effective dose	20 mSv per year, averaged over defined periods of 5 years. With the further provision that the effective dose should not exceed 50 mSv in any single year.	1 mSv in a year In special circumstances, a higher value of effective dose could be allowed in a single year, provided that the average over 5 years does not exceed 1 mSv per year.
Annual equivalent dose in		
Lens of the eye	The limit of 150 mSv has been amended in the "ICRP Publication 118 Recommendations on Tissue Reactions (2011)" to "an average of 20 mSv per year over a defined period of 5 years, with no single year exceeding 50 mSv.	15mSv
Skin	500mSv	50mSv
Hands and feet	500mSv	—
For occupationally exposed individuals (in the case of women)	after a pregnancy declaration, the effective dose to the embryo/fetus must not exceed 1 mSv for the remainder of the pregnancy.	

"Recommended dose limit values in planned exposure situations (Modified from Table 6 of the same recommendations)"

of three months, and there is a provision requiring the measurement of effective dose limits every three months to prevent inadvertent exposure until pregnancy is confirmed.

The primary goal of this regulation is to minimize exposure to the fetus during pregnancy. Hence, it is stipulated that "if a female worker declares her pregnancy (when she herself reports it to her employer), additional management must be considered to protect the embryo/fetus." Furthermore, the equivalent dose limit for the abdominal surface during pregnancy is established at "no more than 2 mSv."

In recent years, advancements at the genetic level have elucidated the individual differences in "sensitivity" to exposure. For instance, cases of increased sensitivity (Ekaterina Royba [2015]) to radiation due to specific genes, including ATM (ataxia-telangiectasia) and Brca1 heterozygotes, have been identified. Additionally, Wilson and colleagues have reported that in familial retinoblastoma (RB) patients, the RB1 gene⁸ demonstrated significantly elevated sensitivity to radiation (Paul F Wilson [2018:483-494]), even in family members who did not exhibit the condition.

These results indicate that establishing uniform radiation protection standards may lead to excessive protection for some individuals, while others may receive inadequate protection. Consequently, by incorporating individual genetic information and accounting for differences in radiation "sensitivity," it is feasible to establish "tailor-made" radiation protection standards. This

method enables protection against radiation exposure that is more closely aligned with the genetic sensitivity of each individual to radiation.

With advances in genetic diagnostic technologies and the reduction in associated costs, it is envisaged that estimating cancer risk based on the presence or absence of tumor suppressor genes⁹ (note 9) and simplifying the calculation of individual risks from exposure will eventually become practical. This would facilitate the transition from conventional uniform radiation protection standards to customized radiation protection standards that consider sex, age, and genetic information.

Nevertheless, a new challenge has emerged in the integration of these newly established benchmarks into the legal framework for radiation protection and the association of an individual's genetic information with radiation protection standards. To resolve this, it will be crucial for international radiation-related organizations such as the ICRP to collaborate and work together on developing such systems.

Furthermore, the concept of "tailor-made radiation protection standards" necessitates a careful consideration of ethical concerns related to bioethics. Specifically, when determining individual dose limits based on differences in sensitivity informed (Lin Shi [2018:424-432] by genetic data, it is imperative to meticulously evaluate the issue of disclosing pertinent genetic information about radiation sensitivity to individuals while ensuring the privacy of their genetic information.

Thus, implementing individualized protection

standards will necessitate the development of a more sophisticated understanding of the relationship between radiation dose and associated risks.

Conclusion

By considering the complex relationship between radiation exposure for patients undergoing radiological examinations and stated principles of bioethics, we find that the incorporation of a new value judgment standard of “prudence” in conjunction with the principles of “beneficence” and “nonmaleficence,” enables the optimization of benefits for the patients while minimizing their radiation exposure. These are essential bioethical principles, when considering the rationale for actions related to radiation exposure for testing purposes.

In medical settings where radiological tests are performed, it is imperative to first explain to the patients that the test aligns with the “medical rationale” delineated in radiation testing guidelines based on the ethical principles mentioned, including prudence. Furthermore, it is imperative to provide a comprehensive explanation of the medical advantages and disadvantages of the test.

The effects of low-dose exposure are scientifically unproven. Based on current scientific understanding, the hazards of exposure must be explained, considering age, sex, and the individual’s hereditary vulnerability to radiation.

These explanations may cause some patients to become apprehensive about the potential risks of exposure and opt to decline the test. In such cases, it is vital to provide an explanation of the potential medical disadvantage of refusing the test. If there are alternate methods, such as MRI scans, that do not entail radiation exposure, it is crucial to offer these options as well. Providing comprehensive, personalized responses to these choices is essential.

Furthermore, it is imperative to obtain the patient’s informed consent prior to conducting the examination, after ensuring that the patient comprehends both the medical advantages of the test and the risks associated with exposure.

By permitting the patients to determine whether to undergo examinations involving radiation exposure, the “respect for autonomy” of the patient is ensured, which is crucial for informed consent. However, the ability to accurately convey

the risks of radiation exposure depends on the patient’s level of understanding, which may vary. In cases where the patient’s understanding is restricted, such as in children or individuals with cognitive impairments, it becomes necessary to consider alternate approaches such as surrogate decision-making or decision-making support that are tailored to the patient’s level of understanding.

Based on these considerations, this paper recommends the implementation of informed consent procedures that correspond to the level of risk posed by examinations involving exposure. Additionally, it highlights the necessity for future reassessment of medical practices, including establishing personalized protection standards that consider each patient’s sensitivity and decision-making capacity.

Acknowledgments

I would like to extend my deepest gratitude to Professor Emeritus Naoki Morishita of Hamamatsu University School of Medicine for his meticulous corrections and invaluable advice on the content and wording related to bioethics during the writing of this paper. I take this opportunity to express my sincere thanks. There are no potential conflicts of interest to disclose.

References

- Diagnostic Imaging Guidelines. Japan Radiological Society, 2016. http://www.radiology.jp/content/files/diagnostic_imaging_guidelines_2016.pdf
- Ekaterina Royba, Tatsuo Miyamoto, Silvia Natsuko Akutsu, Kosuke Hosoba, Hiroshi Tauchi, Yoshiki Kudo, Satoshi Tashiro, Takashi Yamamoto & Shinya Matsuura. Evaluation of ATM heterozygous mutations underlying individual differences in radiosensitivity using genome editing in human cultured cells. Scientific Reports volume 7, Article number: 5996, 2017. <https://www.nature.com/articles/s41598-017-06393-8>
- General Principle 6, <https://www.wma.net/policies-post/wma-declaration-of-helsinki/>
- Helsinki, Finland, June 1964. Adopted by the 18th WMA General Assembly, WMA DECLARATION OF HELSINKI – ETHICAL PRINCIPLES FOR MEDICAL RESEARCH

- INVOLVING HUMAN SUBJECTS, 2018. <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/> 2013.
- Health Risks from Exposure to Low Levels of Ionizing Radiation: BEIR VII - Phase 2. pp43-64,2006. (<http://books.nap.edu/catalog/11340.html>) <https://pubmed.ncbi.nlm.nih.gov/28826776/>
- ICRP Publication 1,1958. Recommendations of the International Commission on Radiological Protection. Now known as ICRP Publication 1. Pergamon Press, New York. <http://www.icrp.org/publication.asp?id=ICRP+Publication+1>
- ICRP Publication 26,1977. Recommendations of the International Commission on Radiological Protection. ICRP 1 (3),1977. <http://www.icrp.org/publication.asp?id=ICRP+Publication+26> (Accessed on 2020-12-15)
- ICRP Publication 60,1991. Recommendations of the International Commission on Radiological Protection. ICRP 21 (1-3), 1991. <https://www.icrp.org/publication.asp?id=ICRP%20Publication%2060>
- ICRP Publication 103, 2007.The 2007 Recommendations of the International Commission on Radiological Protection. ICRP Publication 103. Ann. ICRP 37 (2-4), 2007.<https://www.icrp.org/publication.asp?id=ICRP%20Publication%20103>
- ICRP Publication 109, 2009. Application of the Commission's Recommendations for the Protection of People in Emergency Exposure Situations. Ann. ICRP 39 (1). <https://www.icrp.org/publication.asp?id=ICRP%20Publication%20109>
- ICRP Publication 138, 2018. Ethical foundations of the system of radiological protection. Ann. ICRP 47(1), 2018. <https://www.icrp.org/publication.asp?id=ICRP%20Publication%20138>
- Kamei, Osamu. "A Medical Bioethical Study on Radiation Exposure in Medical Practice." *Studia Humana et Naturalia*, Faculty of Medicine, Kyoto Prefectural University of Medicine (Liberal Arts Education), (51), February 2018: pp61-72. (Published in 2017).
- Kamei, Osamu. "A Medical Bioethical Study on Radiation Exposure in Medical Practice (Part A Guideline to Tailor-Made Radiation Protection)." *Studia Humana et Naturalia*, Faculty of Medicine, Kyoto Prefectural University of Medicine (Liberal Arts Education), (52), March 2019: pp15-28. (Published in 2018).
- Lin Shi, Kurumi Fujioka, Nami Sakurai-Ozato , Wataru Fukumoto, Kenichi Satoh, Jiying Sun, Akinori Awazu, Kimio Tanaka, Mari Ishida, Takafumi Ishida, Yukiko Nakano, Yasuki Kihara, C Nelson Hayes, Hiroshi Aikata, Kazuaki Chayama, Takashi Ito, Kazuo Awai, Satoshi Tashiro. Chromosomal Abnormalities in Human Lymphocytes after Computed Tomography Scan procedure, Radiation Research. 190(4): pp424-432, 2018. <https://pubmed.ncbi.nlm.nih.gov/3004004>
- Ozasa, K. Epidemiological studies of atomic bomb survivors in Hiroshima and Nagasaki: Journal of Kyoto Prefectural University of Medicine, 120(12): pp903-911, 2011.
- Ozasa, K., Shimizu, Y., Suyama, A., Kasagi, F., Soda, M., Grant, E. J., Sakata, R., Sugiyama, H., and Kodama, K. Studies of the mortality of atomic bomb survivors, report 14; 1950-2003. An overview of cancer and noncancer diseases. *Radiat. Res.* 177, pp229-243 (2012). doi: 10.1667/rr2629.1.
- Paul F Wilson, Hatsumi Nagasawa, Christy L Warner, Markus M Fitzek, John B Little, Joel S Bedford. Radiation sensitivity of primary fibroblasts from hereditary retinoblastoma family members and some apparently normal controls: colony formation ability during continuous low-dose-rate gamma irradiation. *Radiation Research.*169(5): pp483-494, 2018. <https://pubmed.ncbi.nlm.nih.gov/18439048/>
- Tom L. Beauchamp, James F. Childress. *Biomedical Ethics* (Translated by Yukimasa Eian and Takao Tatsuki, Supervisors). Seibundou, 1998. Originally published in English under the title *Principles of Biomedical Ethics*, Third Edition, Oxford University Press, 1989.

Endnotes

- 1 Hippocratic Oath: Hippocrates was a Greek physician born in the 5th century BCE. He is credited with laying the foundation for scientific medicine by rejecting the mystical practices that preceded his time. He is often referred to as the "Father of Medicine."
- 2 Late-Onset Effects: Radiation exposure can cause a variety of symptoms depending on the dose received, with effects appearing at different times. Radiation effects are often classified into early-onset effects, which occur within a few months after

exposure, and late-onset effects, which occur after a longer period. Late-onset effects include cancer and genetic impacts. While the mechanisms are not fully understood, it is hypothesized that although DNA damage may be the initial cause, factors such as chromosomal instability, chronic inflammation, and aging also play a role.

- 3 Equivalent Dose: This concept indicates the extent of radiation exposure a person has received. Equivalent dose is measured in sieverts (Sv) and is a standardized metric used to express the biological effect of absorbed radiation energy (measured in grays, Gy). It adjusts the absorbed dose by a radiation weighting factor based on the type and energy of the radiation. The equivalent dose, H_T , RH_T , RHT , R , is calculated by multiplying the absorbed dose, DT , RD_T , RDT , R , (measured in grays, Gy) by the radiation weighting factor, WRW_RWR . The formula is H_T , $R=WR \times DT$, RH_T , $R = W_R \times D_T$, RHT , $R=WR \times DT$, R .
- 4 Deontology (Deontological Ethics): In ethics, deontology is a position that asserts the moral value of an action lies not in its consequences or subjectivity but in adherence to duty. This stance contrasts with consequentialism, which includes utilitarianism.
- 5 Precautionary Principle: This principle applies to cases where there are potential hypotheses about significant and irreversible environmental harm (e.g., from chemicals or genetic modification), even if the scientific proof of causality is incomplete. It allows for regulatory measures in such circumstances. The precautionary principle has been widely adopted in Europe and North America since the 1990s and is also referred to as the precautionary measures principle.
- 6 Act Utilitarianism and Rule Utilitarianism: Utilitarianism is the ethical theory that the morally right action is the one that maximizes happiness for all

those affected. Act utilitarianism states that in any given situation, the right action is determined by directly applying the principle of utility (i.e., calculating the action's overall consequences). Rule utilitarianism, on the other hand, posits that actions are judged right or wrong based on the rules that generally maximize happiness, with utility being calculated when formulating these rules. (Source: Introduction to Medical Ethics, edited by Akabayashi Akira, 2016, pp. 33-38)

- 7 Effective Dose: This is a measure used to express the degree of radiation exposure a person has received. It takes into account the different sensitivities of various tissues and organs to radiation by multiplying the equivalent dose by a tissue weighting factor. The effective dose is the sum of these tissue-weighted equivalent doses for the entire body. It is used in radiation protection management and is expressed in sieverts (Sv). (Source: ICRP 103: 2007 Recommendations)
- 8 Retinoblastoma: Retinoblastoma is a malignant tumor that usually develops in children under the age of five and occurs in the developing retina. It originates from cells where both copies of the RB1 gene have mutations that predispose the cells to cancer. Retinoblastoma can occur as a unilateral (affecting one eye) or bilateral (affecting both eyes) condition. (Source: Retinoblastoma, by Dietmar R. Lohmann, MD and Brenda L. Gallie, MD, National Library of Medicine, November 21, 2018)
- 9 Tumor Suppressor Gene: These are genes that encode proteins responsible for suppressing cancer formation. When these genes are damaged or malfunction, they lose their ability to prevent cancer, leading to increased susceptibility to cancer. Tumor suppressor genes are involved in various functions such as regulating the cell cycle, repairing DNA, and controlling gene transcription.