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Comparative Analysis of Terminology and Classification Related to Risk Management of Radiotherapy

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We analyzed the terminology and classification related to the risk management of radiation treatment overseas to establish the terminology and classification system for Korea. This study investigated the terminology and classification for radiotherapy risk management through overseas research materials from related organizations and associations, including the IAEA, WHO, British group, EC, and AAPM. Overseas risk management commonly uses the terms "near miss", "incident", and "adverse event", classified according to the degree of severity. However, several organizations have ambiguous terminologies. They use the term "near miss" for events such as a near event, close call, and good catch; the term "incident" for an event; and the term "adverse event" for the likes of an accident and an event. In addition, different organizations use different classifications: a "near miss" is generally classified as "incident" in most cases but not classified as such in BIR et al. Confusion might also be caused by the disunity of the terminology and classification, and by the ambiguity of definitions. Patient safety management of medical institutions in Korea uses the terms "near miss", "adverse event", and "sentinel event", which it classifies into eight levels according to the severity of risk to the patient. Therefore, the terminology and classification for radiotherapy risk management based on the patient safety management of medical institutions in Korea will help in improving the safety and quality of radiotherapy.

Key Words: Radiotherapy, Risk management, Patient safety, Incident, Accident

Introduction

Radiotherapy, a high-dose irradiation therapy for treating cancer and relieving related symptoms, contributes fundamentally to the promotion of national health in the face of increasing numbers of cancer patients. However, its risk management for errors is extremely important because of the increasing complexity of the advanced equipment and technology and because of the nature of therapies that use high doses of radiation. For these reasons, the American Association of Physicists in Medicine (AAPM), the American Society for Radiation Oncology (ASTRO), the American College of Radiology (ACR), and the International Atomic Energy Agency (IAEA) have all proposed guidelines for quality control to provide safe and effective radiotherapy. The Nuclear Safety and Security Commission (NSSC) of Korea has also recommended radiation safety management standards in the medical field for the quality control of therapeutic radiation instruments. Although the existing radiation safety management

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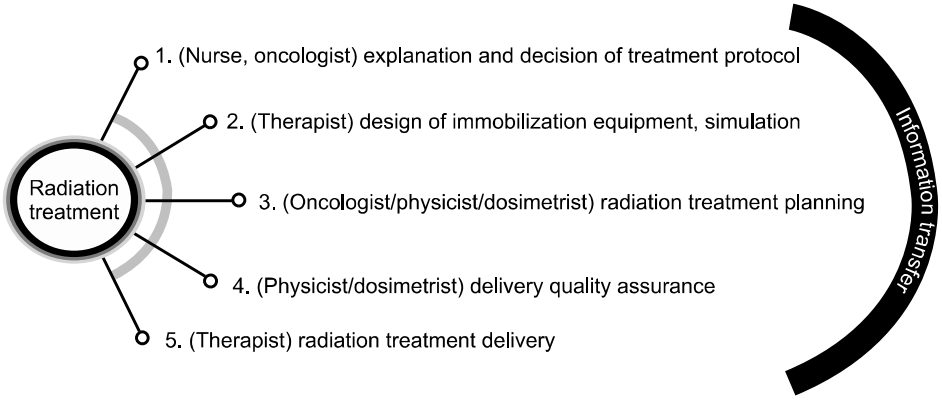

Fig. 1. General process of radiation treatment.

system covered the limited quality control areas of instruments and dose, recent studies on radiotherapy-related accidents are moving from managing hardware-related problems of instruments or software-related problems of therapeutic planning systems to analyzing the overall processes and the workflow of radiotherapy.[1-7)]

As the awareness of patient safety grew in the field of medicine in Korea, a healthcare accreditation system was introduced in 2004, and a Patient Safety act was first enforced in July 2016. Thereafter, healthcare organizations in Korea established and are acting upon systems for reporting patient safety hazards and patient safety management to prevent accidents related to patient safety, such as wrong-site surgery, medication errors, suicides, falls, or transfusion reactions. However, for such systems and enforcement regarding patient safety management, there are no specific statements on risk management and safety for radiotherapy.

As shown in Fig. 1, radiotherapy consists of multiple steps from determining the treatment method for the patient to the actual treatment, and each step includes tasks and communications performed by medical personnel and healthcare professionals in various fields. Therefore, unless each step is monitored for safe, accurate execution and communication, there could be a decline in the safety and quality of radiotherapy. According to a report from the United States Nuclear Regulatory Commission (NRC), 60% of accidents in the field of radiotherapy are caused by human error.[8)] Table 1 summarizes the accidents in radiotherapy, showing cases of over-exposure to high doses on treatment sites or normal tissue because of errors during the processes of beam output and calibration, treatment planning, patient data management, treatment delivery, and treatment verification.[9-15)] As shown here, because humans are involved in every single step of radiotherapy, a more active, systematic risk management is necessary to prevent radiotherapy-related accidents.

Table 1. Risks in the radiotherapy process.

Process	Incidents
Beam output and calibration	■ Calibration problems of small fields ■ Intra-operative radiation-therapy beam-calibration problems ■ Beam output drift in tomotherapy
Treatment plan	■ Problems with dynamic wedges ■ Computer problems with intensity modulated radiation therapy ■ Errors in imaging for radiation therapy treatment planning ■ Treatment set-up errors from virtual simulation markers ■ Digitally reconstructed radiograph errors
Patient data management	■ Errors when using "record and verify" systems
Treatment delivery and treatment verification	■ Significant radiation exposure from electronic portal imaging ■ Errors with stereotactic radiosurgery field

Risk management is defined as the identification, analysis, and assessment of potential risk factors and the possibility of verifying the risk levels, followed by the continual management of setting up countermeasures, which requires establishing an effective reporting system. However, as Fig. 2 illustrates, understanding and establishing the terminology and the classification system for risk management must precede the

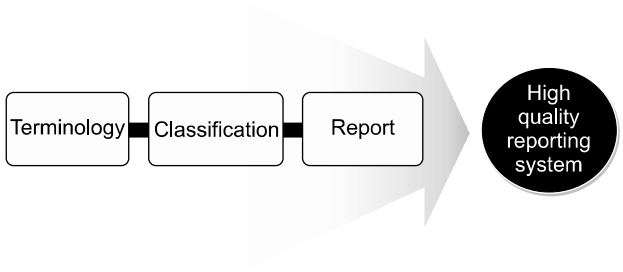

Fig. 2. Preceding conditions for high-quality reporting system.

collection of high-level data.

There are already recommended reporting systems on risk management in other countries, but the terms and definitions differ according to the governing organizations, leading to ambiguous classification.[16] Because no clear risk management terminology and classification systems have been established among countries and organizations, confusion is highly likely to arise while executing risk management by understanding, comparing, analyzing, and evaluating the reported errors to provide countermeasures. Therefore, this study investigates the terminology and classification systems for radiotherapy risk management to establish the terminology and classification system that should be adopted in Korea.

Materials and Methods

1. Overseas terminology and classification systems for risk management

In order to establish a radiotherapy risk management system in Korea, the current state of affairs in overseas was investigated and analyzed to assess the terminology and classification system for risk management. The risk terminology and classification systems used for the comparison are (i) "Safety Glossary: Terminology Used in Nuclear Safety and Radiation Protection" proposed by the IAEA,[1] (ii) "Radiotherapy Risk Profile" proposed by the WHO,[2] (iii) "Towards Safer Radiotherapy" published by the British Institute of Radiology, the Institute of Physics and Engineering in Medicine, the National Patient Safety Agency, the Society and College of Radiographers, and The Royal College of Radiologists (BIR et al.),[3] (iv) "Risk Management in Radiation Treatment Planning" published by the Japanese Radiotherapy Research Working Group,[4] (v) "General Guidelines on Risk Management in External Beam Radiotherapy (RP-181)" proposed by the European Commission (EC),[5] and (vi) "Application of Risk Analysis Methods to Radiation Therapy Quality Management (TG-100)" proposed by the AAPM.[6]

2. Terminology and classification system for patient safety management in Korea

In order to establish a radiotherapy risk management system in Korea, we investigated the terminology and classification used currently for patient safety management systems in healthcare institutions based on the healthcare accreditation system and the Patient Safety act. For this, we examined the accreditation guidelines for patient safety management of the medical institutions of Korea and the Korea Institute for Healthcare Accreditation for comparison.

Results and Discussion

1. Overseas terminology and classification systems for risk management

Overseas states and institutions commonly use the risk-related terms "near miss", "incident", and "adverse event" according to the severity of the hazard to patients. The IAEA[1] expresses a possible "incident" with the terms "accident" and "near miss." An "accident" means a hazardous event that affected radiation protection or had a potential to do so, such as operational error, equipment failure, and other incidents, whereas a "near miss" is an error that had the potential to cause an incident but did not because it was prevented. An "incident" means a general incident including an accident, accident precursors, near misses or other mishaps, or unauthorized act, malicious or non-malicious, the consequences or potential consequences of which are not negligible from the point of view of protection or safety.

The WHO[2] uses the terms "adverse event" and "near miss" for "incident." An "adverse event" means a hazardous event that harmed the patient, whereas a "near miss" did not harm the patient. An "incident" includes an "adverse event" and "near miss", meaning a general event or situation that could or did harm the patient unnecessarily. Both the IAEA and WHO define an "incident" as a general event including both an acci-

dent and near miss, as shown in Fig. 3. The IAEA marks a hazardous event as an "accident" if it occurred and was important from the perspective of radiation protection and safety, and as a "near miss" if it was discovered before an incident and did not actually occur. The WHO marks a hazardous event as an "adverse event" if any harm occurred to patients, and as a "near miss" if no harm was done to patients. As described, there is a difference in the criteria and marked terms that distinguish between the classification of a hazardous event and a near miss.

BIR et al.[3] uses the terms "reportable radiation incident", "non-reportable radiation incident", "near miss", "minor radiation incident" and "other non-conformance", thus classifying the potential errors into five classes. A "reportable radiation incident" is an event of overdose, which must be reported as defined in "IR(ME)R", the "Ionizing Radiation (Medical Exposure) Radiations." A "non-reportable radiation incident" does not need to be reported, but may need to be self-reported and managed as being clinically important, such as underdose. A "minor radiation incident" describes a radiation incident in the technical sense but one of no potential or actual clinical significance. A "near miss" represents a prevented error found before radiotherapy, and "other non-conformance" means a non-compliance with some other aspect of a documented procedure but it is not directly affecting radiotherapy delivery. As far as the terms defined by BIR et al. are concerned, as shown in Fig. 4, a "near miss" would not be included in the category of an event, and an "incident" is what was defined above in the previous overseas data plus a near miss that was prevented before an incident occurred.

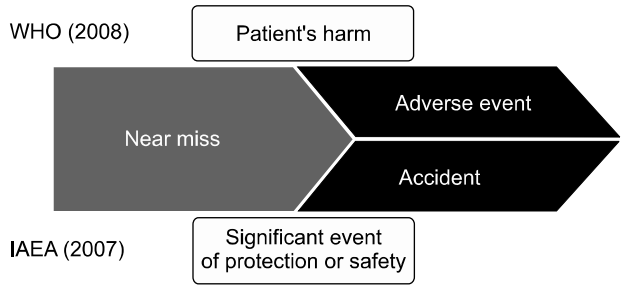

Fig. 3. Comparison of terminology of WHO and IAEA.

The Japanese Radiotherapy Research Working Group[4] terms a plausible error as a "near miss", "incident", and "accident." A "near miss" stands for a hazardous event that either did not reach the patient or reached them with no harm. An "incident" means an event that was either discovered before an error occurred or that reached the patient without any effect, which is defined as a "near miss" unlike the previous definitions from the overseas materials. An accident holds the same definition as medical malpractice as an injury that occurs during medicinal procedures at medically related institutions involving patients and healthcare professionals.

The EC[5] uses the term "event" instead of "incident", and categorizes an "event" as an "adverse error-event", "no harm or minor event", or "near miss." An "adverse error-event" represents a hazardous event that harmed the patient because of an error, such as no or erroneous performance during workflow. A "no harm or minor event" involves an error that reached the patient with no harm, and a "near miss" event is an incident in which the error did not reach the patient. An "event" means a general incident or situation that could or did harm the patient unnecessarily, including the "adverse error-event", "no harm or minor event", and "near miss."

The AAPM[6] uses the terms "event" and "near event." An "event" is an overall process that contributed to reducing the quality of treatment, whereas a "near event" is an error that could have potentially reduced the treatment quality if it had

Fig. 4. Comparison of terminology of BIR et al., IAEA, and WHO.

not been verified or revised, defined in the same manner as the other terms for near miss such as “close call”, “near miss”, or “good catch.” Moreover, as shown in Table 2, the potential errors for radiotherapy are classified into 10 ranks depending on the severity. Rank 1 describes an event with no effect, ranks 2～3 involve inconvenience, and rank 4 stands for a suboptimal treatment plan or a minor dosimetric error if the treatment plan was executed. Ranks 5～8 describe events involving an incorrect dose, dose distribution, therapeutic site, or volume that caused harm or tumor under-dose. Ranks 9～10 are when serious harm was done because of a very incorrect dose, dose distribution, location, or volume.

Table 3 describes the terminology and classification systems of risk management collected from six related organizations overseas. In general, an incident means an overall situation that caused or could have caused unnecessary harm for the patient, including both a hazardous event and near miss. The exception is BIR et al., which does not include a near miss in the category of incident because it defines an incident as being when harm was done to the patient by unintended, erroneous radiation. The term “incident” is used as terminology for any incident in most cases, whereas the EC chooses the term “event” instead. Moreover, there is a difference in defining and classifying a “near miss” event by organization. BIR et al. defines a near-miss event as an error that was prevented before treatment, and therefore does not classify it as an “incident.” The EC defines a near miss as an already-occurred error that did not reach the patient, and thus classifies it as an “event.” The EC also makes use of the additional term “no harm or minor event”, meaning an error that reached the patients without any harm, which is classified as an “event.”

The Japanese Radiotherapy Research Working Group defines

Table 2. Descriptions relating to severity used in the AAPM TG-100.

Rank	Severity term	Description
1		No effect
2	Inconvenience	Inconvenience
3		
4	Suboptimal plan or treatment	Minor dosimetric error
5	Wrong dose, dose, distribution, location, or volume	Limited toxicity or tumor under-dose
6		
7		Potentially serious toxicity or tumor under-dose
8		
9	Very wrong dose, dose distribution, location, or volume	Possible very serious toxicity or tumor under-dose
10		Catastrophic

Table 3. Terminology for risk proposed in the guidelines.

Organization	Terminology					
IAEA (2007)	Incident			Near miss		
	Accident					
WHO (2008)	Incident			Near miss		
	Adverse event					
BIR et al (2008)	Incident				Near miss	Other non-conformance
	Reportable incident	Non-Reportable incident	Minor incident			
JAPAN (2010)	Accident			Near miss (=Incident)		
EC (2015)	Event					
	Adverse error event		No harm event	Near miss		
AAPM (2016)	Event			Near event		

a near miss as an error that did not reach the patient or reached them without any harm, displaying a mixed use of the terms “near miss” and “incident.” As shown in these reported overseas data, there are differences in terminology and classification systems among the states and organizations, with ambiguity in definitions and categories that can easily be expected to cause confusion in radiotherapy risk management.

2. Terminology and classification for patient safety management in Korea

According to the patient safety management accreditation data of medical institutions in Korea and the Korea Institute of Healthcare Accreditation, patient safety accidents can have the stepwise definitions of near miss, adverse event, and sentinel event, as in Table 4, which can be classified into levels 0～8 depending on the severity of the harm for the patient, as in Table 5. A near miss is when the error was found beforehand and did not reach the patient or when it reached the patient without any harm, and is classified into levels 0～3 depending on whether a patient safety incident occurred and whether the patient was injured. There are medical institutes that use their own term “no harm event”, meaning the error reached the patient with no harm, because there is a fine line between a near miss and an accident depending on whether a patient safety incident occurred and whether the patient was injured. An adverse event is when harm was done to the patient during the treatment process, classified as levels 4～6 depending on the severity of the injury to the patient. A sentinel event is when severe harm was done to the patient, classified as levels 7～8 depending on whether the patient died. As such, the patient safety incident classification system in Korea aims at safety management related to medical practice such as general healthcare services, administration of medications and/or blood products, transfer of patient information, diagnosis and tests procedures, and operations and anesthetic procedures; no specific standards or classification system for radiotherapy risk management was clearly stated. Besides, the proposed terminology and classification system are defined in relation to the patient’s condition caused by the patient safety incident, and therefore it is difficult to categorize the errors that occur without any visible injury to the patient.

Therefore, this study proposes a radiotherapy risk management terminology and classification system based on the terminology and classification system of patient safety management that are currently executed and the severity of the radiotherapy risk of the AAPM TG-35,[17] as shown in Table 6. A near miss is defined as an error that did not reach the patient because it was prevented during the treatment planning step, found and fixed during the radiotherapy preparation step, or reached the patient during radiotherapy delivery with little risk of pro-

Table 4. Definitions of terminology for patient safety incidents used in Korea.

Term	Definition
Near miss	Process error such as a patient safety incident occurred but did not reach the patient, or did reach the patient without any harm but was capable of causing severe harm if it reoccurred
Adverse event	Occurred during the treatment stage for the patient and caused an observable harm (i.e., unexpected, unfavorable situations including a fall, medication error, major accident, prolonged hospitalization, moved to ICU, etc.)
Sentinel event	Permanent damage or death due to the patient safety incident

Table 5. Definitions of levels for patient safety incidents used in Korea.

Level		Definition
Near Miss	Level 0	Surroundings or cases containing an element that could cause a safety incident
	Level 1	Found before the actual occurrence of a safety incident
	Level 2	A safety incident occurred but did not reach the patient
	Level 3	A safety incident occurred without any harm to the patient; required observation or intervention
Adverse Event	Level 4	Intervention required because of a reversible injury
	Level 5	Extended hospitalization period due to a reversible injury
Sentinel Event	Level 6	Entered ICU (Intensive Care Unit) for intensive care because of threat to life
	Level 7	Permanent injury occurred (lost consciousness, lost organ function, etc.)
	Level 8	Patient death

Table 6. Definitions of terminology and classification for radiotherapy risk management.

Term	Definition
Near miss	Found out at the treatment planning stage before the incident occurred, found out at the radiotherapy delivery stage before it reached the patient, or after it reached the patient with little risk of prolonged damage
Adverse event	The case that increase the probability of unacceptable outcome, but usually do not pose a threat to life. (total exposed dose exceeded the allowed dose on critical organ by 5～25%, underdose on the treatment site, etc.)
Sentinel event	The case of directly responsible for life-threatening complcations for the patinet. (total exposed dose exceeded the allowed dose on critical organ by more than 25%, etc.)

longed damage. An adverse event is when an overdose was radiated to the patient that could have caused prolonged damage but that did not threaten the patient's life, including cases of exceeding the allowed dose on major organs by 5～25% and underdose on the treatment site. A sentinel event is when an overdose was radiated to the patient that could have threated the patient's life, including cases of exceeding the allowed dose on major organs by 25% or more.

Ford et al.[18] proposed a 10-level classification depending on the radiotherapy risk severity, occurrence rate, and possibility of discovery, but did not include any terminology. In addition, they proposed only two levels of dose difference as well as four levels of patient impact, and there were also differences in classifications and definitions from the patient safety management classification system used by the medical institutes in Korea.

In this study, the risk management terminology and classification system is proposed by using a patient safety management system of the accreditation guidelines of medical institutes. In addition, the application of the risk severity of radiotherapy from the AAPM TG-35 to consider the differences of radiotherapy procedures and prescribed dose can also help to classify the potential error for radiotherapy. If presented the standard of more detailed and specific terminology and classification to radiation therapy based on the physical theory and clinical experience from a domestic-related society, It could be improve the risk management in radiation therapy.

Conclusion

Risk management for radiotherapy is important for preventing radiotherapy accidents and improving treatment quality. Risk management is based on the collection of high-quality data from incident reporting system, which requires the establishment of risk management terminology and a classification system. There is currently a patient safety management system under enforcement in Korea, but no specifications on radiotherapy risk management exist. There are radiotherapy risk management systems overseas, but different terms and definitions could cause confusion in risk management because the terminology and classification systems differ by organization. Therefore, this study proposes a terminology and classification system that considers compatibility with and connectivity to the reporting system of medical institutions in Korea. The proposal is made after applying the level of radiotherapy risk based on the patient safety management system from the accreditation guidelines for medical institutions provided by the Korea Institute for Healthcare Accreditation. In the future, radiation safety and treatment results will be enhanced if a terminology and classification system for radiotherapy risk management is established. Based on this, a radiotherapy risk management system can be constructed after thorough discussion and review through the likes of radiotherapy-related conferences on the criteria for the level of hazard, as well as on treatment errors in terms of the radiotherapy incidents and accidents discussed in this study.

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