

## Assessing Medical Device Risks in Radiology Departments: A Critical Review

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**Abstract:** Background: This study explores radiologists' perceptions of risks associated with medical devices in radiology departments within hospitals in Saudi Arabia. Given the increasing use of advanced medical technologies and devices in the healthcare sector, it is important to understand how healthcare professionals, particularly radiologists, perceive and manage these risks.

Methods: A total of 257 radiologists from hospitals across Saudi Arabia participated in the study. Data were collected through a self-administered online questionnaire designed to assess their perceptions of risk management practices and the effectiveness of current risk control measures in radiology departments. The data collected were analyzed using the Statistical Package for the Social Sciences (SPSS) to identify key trends and insights regarding the management of risks associated with medical devices in radiology.

Results: The results indicate that while most radiologists perceive their department's risk management systems to be effective, several areas need improvement. Many participants reported that formal risk management systems and committees are in place to oversee the control of medical device risks, but there are challenges in terms of policy clarity and the overall effectiveness of MoH regulations. Furthermore, predictive risk models were found to be used more frequently for electrical and overwork risks, while radiation dose risks were addressed less frequently.

Conclusion: The study reveals a generally positive perception of risk management practices among radiologists in Saudi Arabia, but gaps remain in policy clarity, risk prediction practices, and implementation. The results suggest that improving communication, improving the effectiveness of risk management policies, and increasing training and awareness of healthcare professionals could help mitigate risks associated with medical devices in radiology departments. These improvements could lead to safer healthcare environments and better patient outcomes.

**Keywords:** Risk Management, Medical Devices, Radiologists, Saudi Arabia.

## **1. Introduction**

### ***1.1 Background***

In recent years, the health sector has witnessed a revolution in the use of modern technology, which has contributed to raising health care and the level of medical and other services at the local and global levels (Junaid et al., 2022). Medical imaging and the modern devices used are considered one of the most important technologies and developments witnessed by the health sector, which plays a pivotal role in health care, as their use in health care has led to accurate diagnosis and then the development of treatment plans (Bercovich, & Javitt, 2018).

Radiology departments within hospitals and health care centers are considered one of the most important and dangerous departments (Ilyas, Burbridge & Babyn, 2019), as they contain many medical devices with diverse functions that are characterized by the advanced nature of their work and their reliance on X-rays, MRI, and CT scanners, with the aim of providing accurate information about the human body and diagnosing patients' conditions (Odeh, Abatli, & Qadi, 2023). However, these medical devices can pose unexpected risks to both health care providers in radiology departments and patients, which may occur due to a technical or technical defect in the medical devices and other unexpected risks, for example, the device may be damaged during treatment, explodes, or causes burns to the patient (ESR, 2019).

The process of interaction between medical devices and health care providers in radiology departments requires understanding and analyzing all potential risks, such as exposure to ionizing radiation, technical defects, or mechanical failures (Smith et al., 2021). This poses a challenge to health care systems and workers in radiology departments (Chong et al., 2019). Therefore, the use of these complex technology-based medical devices requires continuous training, competency assessment of healthcare workers to handle them and troubleshooting potential technical challenges (Hartley et al., 2010).

The current study aims to explore the potential risks associated with medical imaging equipment, especially within radiology departments. This will contribute to understanding, analyzing and treating these risks by healthcare providers, and will also provide recommendations to decision makers in the Saudi Ministry of Health to enhance security, safety and risk management procedures related to medical devices used in radiology departments in hospitals in the Kingdom. Kingdom of Saudi Arabia to enhance patient care and maintain the safety of health care worker.

### ***1.2 Research Problem***

The problem of the current study is the importance of assessing the risks related to medical devices used in radiology departments within hospitals in the Kingdom of Saudi Arabia. Despite their importance in diagnosing diseases, they are subject to many risks related to incorrect use or technical malfunction in these medical devices, which threatens the safety of patients and workers in radiology departments (Hyman, W, 2018). Therefore, it is necessary to understand and evaluate the risks associated with medical devices used in radiology departments to direct efforts and develop appropriate plans and strategies to reduce these risks and increase the efficiency and effectiveness of the use of medical devices in radiology departments (Chau, M., 2024).

### ***1.3 Significance of the study***

The importance of the study lies in understanding and analyzing the risks related to medical devices used in radiology departments within hospitals in the Kingdom of Saudi Arabia, due to the different types of these devices that rely on various techniques in diagnosing and treating patients. This analysis will contribute to enhancing risk management related to

these devices, as well as enhancing the health and safety of patients and workers in radiology departments. The results of this study will also contribute to developing plans and policies that contribute to effective risk management in radiology departments, which will enhance confidence in the health care system within the Kingdom of Saudi Arabia within the 2030 Vision of the Kingdom of Saudi Arabia.

#### **1.4 Research aim**

The study aims to Assess the risks of medical devices in radiology departments within hospitals in the Kingdom of Saudi Arabia.

This aim is achieved through the following objectives:

1. To assess the available risk management within radiation departments at hospitals.
2. To determine the level of knowledge among staff workers.
3. Exploring the extent to which there are standards for the use of medical devices within radiology departments in hospitals to reduce potential risks.

The results of this study have the potential to enrich the development of plans and strategies for managing medical device risks in radiology departments, thus contributing to enhancing patient health and worker safety in radiology departments.

This study aims to assess employee perception of governance application and its impact on their perceived performance in East Jeddah Hospital.

#### **1.5 Methodology**

This research will utilize a mixed-methods approach to aims to Assess the risks of medical devices in radiology departments within hospitals in the Kingdom of Saudi Arabia. The analytical descriptive approach provides an interpretation of the data with the aim of better understanding, evaluating, and presenting the changes that have occurred at work. Descriptive studies are the process of identifying and describing what is there, while analytical research works to determine the causes or how it became (Kim, Sefcik, & Bradway, 2017). The descriptive and analytical approach, which is the appropriate approach to examine many of the disparate hypotheses, was used to aims to Assess the risks of medical devices in radiology departments within hospitals in the Kingdom of Saudi Arabia, to obtain accurate and detailed knowledge about the research problem to reach a better understanding of the phenomena related to it and stand on it.

A structured questionnaire will be developed based on a comprehensive review of relevant literature (Craciun, Mankad & Lynch, 2015; Nguyen, & Tran, 2017; Al-Mazroua, & Al-Otaiby, 2020). The questionnaire will include sections to assess demographic information, Knowledge about the use of medical devices and the management of risks related to them, as well as the existence of a body specialized in monitoring, evaluating and managing these devices. Quantitative data collected through the survey will be analyzed using statistical software. Descriptive statistics will be used to summarize the demographic characteristics of the study population and the distribution of responses to survey questions. Inferential statistics, such as chi-square tests or regression analysis, may be employed chi-square tests or regression analysis, can be used to associations between demographic variables and radiology staff's knowledge about medical devices and related risk management.

## **2. Literature Review**

This chapter presents the risks of medical devices in radiology departments. Therefore, it is important for workers in radiology departments to have knowledge of the risks associated with medical devices used in radiology departments and the security and safety factors that must be taken. Emphasis will also be placed on the types of medical devices used in radiology departments and their impact on patients and workers in radiology departments within hospitals

in the Kingdom of Saudi Arabia.

### **2.1 Medical devices**

Medical devices are usually characterized by complexity as a result of their connection to health care information systems, which led to the concept of Computerized Maintenance Management Systems (CMMSs) (Almomani, H., & Aldaihani, A, 2021). Therefore, the process of classifying medical devices is complex and diverse. Medical devices can usually be classified into three categories (Ferner & Aronson, 2020):

- Diagnostic devices: This includes medical imaging devices.
- Analytical devices: This includes medical devices used in medical laboratories.
- Surgical devices: These include physical therapy devices, electric scalpels, and others.

The identification of malfunctions was considered during the manufacturing process of these medical devices, with the aim of protecting patients and healthcare workers from the risks posed by these devices (Mattox, E., 2012). Medical devices and the technologies that rely on them have become a huge challenge for both their makers and their users (Ventola, C, 2008). Medical devices, whether diagnostic or imaging, used in radiology departments are considered among the most complex and dangerous devices, as well as their connection to the lives of patients and the safety of workers in radiology departments (Rockall, et al., 2022).

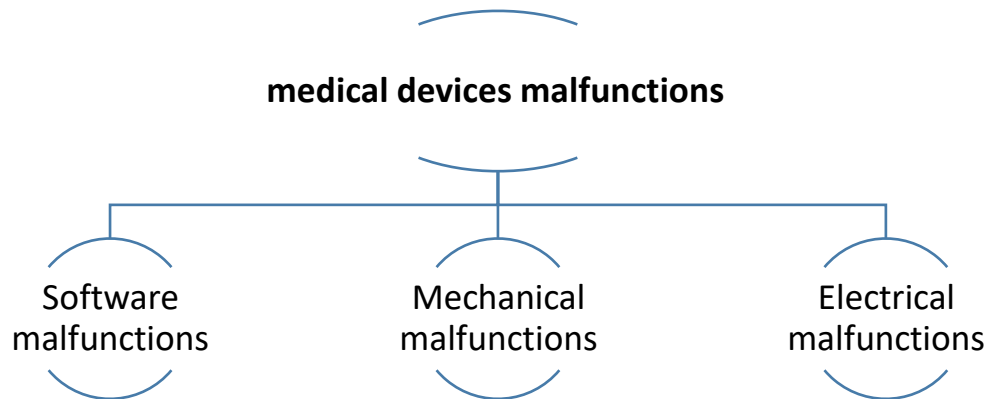
### **2.2 Medical Devices Risk**

Medical devices are considered one of the most important components of health care, as they are used in diagnosing, treating, and monitoring health care (Srivastava et al., 2021). Therefore, effective management of medical devices is of utmost importance to achieve a high level of health care and quality of services provided to patients, in addition to its importance in reducing the risks associated with these medical devices (Li, Mao, & Zhang, 2022).

The causes of risks related to medical devices are usually attributed to their malfunctions, as the causes of malfunctions in medical devices are due to:

1. Acts of Nature: Natural events such as earthquakes, floods, or lightning can cause physical damage to medical devices or disrupt their functioning, leading to malfunctions (Salam et al., 2023).
2. Hardware Failures: Physical defects or wear and tear in the components of the medical device, such as malfunctioning circuits, broken sensors, or damaged connectors, can result in failure of the device (Amoore J, 2014).
3. Human Error: Mistakes made by users, including improper handling, incorrect setup, or misinterpretation of instructions, can lead to incorrect operation or damage to the device (Bogner, 2018).
4. Vandalism: Intentional damage to medical devices, often as a result of malicious actions, can compromise their performance or render them inoperable (Johnson, 2012).
5. Software Failures: Bugs, glitches, or incompatibilities in the software controlling the medical device can lead to inaccurate readings, incorrect operations, or device crashes (Vogel, 2011)

Therefore, malfunctions in medical devices are divided into three main categories:



**Figure 0.1.** *Malfunctions in medical devices.*

1. **Software Malfunctions:** These occur when there is a flaw in the software programming or functionality. Software issues may include bugs, glitches, or incorrect algorithms that cause the device to operate improperly, leading to inaccurate data or device failure (Natella et al., 2018).
2. **Mechanical Malfunctions:** These are related to the physical components of the device. Mechanical failures can arise from worn-out parts, broken mechanisms, or faulty assemblies, leading to dysfunction or inability to perform the intended task (Holloway et al., 2012).
3. **Electrical Malfunctions:** These happen when there are issues with the device's electrical components, such as power supply problems, circuit failures, or short circuits. Electrical malfunctions can lead to the medical device shutting down, malfunctioning, or even posing a safety risk (Aljamali et al., 2021).

These malfunctions often affect medical devices that rely on computerized medical technology (Wolbarst, A, 1999)., especially devices used in radiology departments such as X-Ray, CT, Ultrasound, and MRI. Noting that malfunctions vary depending on the device, manufacturer, generation, etc.

Medical devices shall be classified into the following four classes, in accordance with risk classification rules:

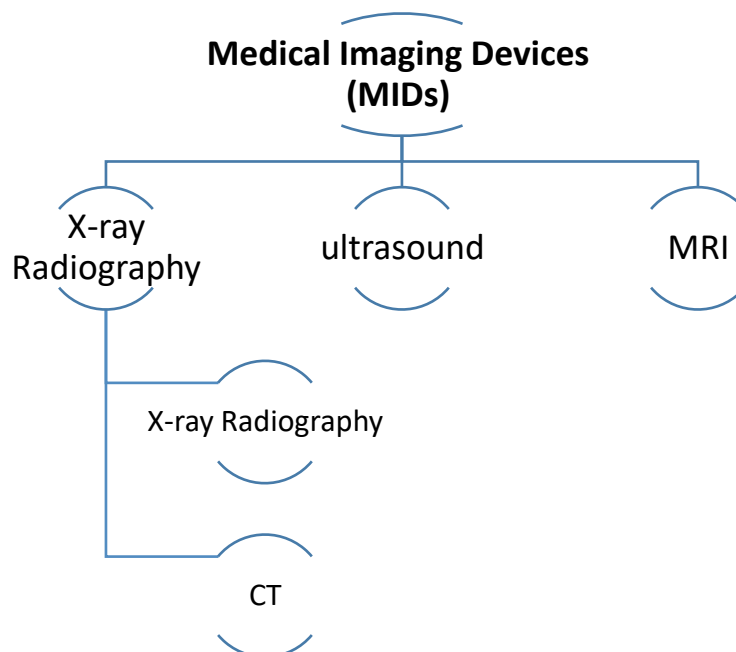
**Table 0.1.** Classification of medical devices according to risk.

Class	Risk Level
A	Low risk
B	Low-moderate risk
C	Moderate-high risk
D	High risk

### **2.3 Medical Imaging Devices (MIDs)**

The following figure shows the types of medical devices used in radiology departments in hospitals around the world. Each device has specific applications and technologies that suit the functions and tasks it is designed to accomplish, as it uses high-frequency sound waves are used in ultrasound, X-rays are used in CT, radio frequency (RF) is used in MRI (Islam et al., 2023). The safety of patients and workers in radiology departments depends on the strength of

the energy emitted from the device (Park, S., Kim, M., & Kim, J., 2022). It should be noted that increasing the energy leads to improving the image quality, but it leads to tissue damage.



**Figure 0.2.** Types of medical devices used in radiology departments in hospitals.

#### X-ray Radiography.

X-ray imaging (radiography) is a non-invasive medical test that helps doctors diagnose and treat medical conditions (Northrop, R, 2017). X-ray imaging involves exposing part of the body to a small dose of ionizing radiation to produce images of the inside of the body (Wall, et al., 2011). This is due to their properties, such as displaying different tissue densities on the image, that make the use of X-rays very popular in many medical fields, such as diagnosing bone fractures, lung diseases (including cancer), or dental diagnosis (Lftta et al., 2024).

X-rays are a form of radiation like light waves or radio waves. X-rays pass through most materials, including the body. Once carefully targeted at the part of the body being examined, the X-ray machine produces a small burst of radiation that passes through the body, recording an image on photographic film or a special detector (Martz et al., 2016). Different parts of the body absorb X-rays to varying degrees. Dense bones absorb a lot of radiation while soft tissues, such as muscle, fat, and organs, allow more X-rays to pass through them (Lftta et al., 2024).

Risks related to exposure to X-rays include tissue and skin damage and an increased risk of cancer. The degree of risk varies according to the sensitivity of the tissues exposed to radiation (Sinnott, Ron, & Schneider, 2010).

#### Magnetic resonance imaging (MRI).

Magnetic resonance imaging (MRI) uses a strong magnetic field and high-frequency radio waves to produce highly detailed images (Caverly, R, 2015). MRI is preferred over CT when doctors need more details about soft tissues, such as imaging malformations and abnormalities in the brain, spinal cord, muscles, and liver. MRI is particularly useful for identifying tumors in these tissues (Hussain et al., 2023).

Furthermore, MRI is used when CT risks are high; MRI is preferred for people who have had a reaction to the iodinated contrast agents used in CT scans and for pregnant women, because radiation can cause problems with the fetus (Gatta et al., 2021). However, the time needed for an MRI is longer than that for a CT scan. MRI is also usually not immediately available compared to a CT scan. Thus, a CT scan may be better in emergency situations (Nayak

et al., 2022), such as serious injuries and stroke. Brain imaging. MRI is also more expensive than CT. For this reason, MRI scans may not be appropriate for individual patients, such as pediatric patients and patients who cannot remain still for some time (Wald, et al, 2022). Furthermore, the use of large magnetic fields prevents patients with pacemakers or other implanted metallic devices from having MRI scans (Yang, et al., 2022).

#### Ultrasound.

Ultrasound a device that images internal organs and uses sound waves to produce images of structures inside the body (Sehmbi, & Perlas, 2022). The use of this device in the medical field is considered one of the most important achievements of the century, due to its accuracy, ease of use, and speed of conducting the examination, in addition to its relatively low cost compared to other imaging methods such as magnetic resonance imaging or computed tomography (Lobo et al., 2024).

The ultrasound device sends a group of high-frequency ultrasound waves (higher than the frequency of human hearing), meaning its frequency is higher than twenty thousand hertz, to the organ to be diagnosed, and then the device reflects it and sends it to a computer that turns it into an image that can be seen and inspected (Moyano, et al., 2022). The ultrasound device sends a group of high-frequency ultrasound waves (higher than the frequency of human hearing), that is, its frequency is higher than twenty thousand hertz, to the organ to be diagnosed, and then the device reflects it and sends it to a computer that turns it into an image that can be easily seen and inspected (Moyano, et al., 2022; Patey, & Corcoran, 2021).

### **2.4 Medical Device Risk Management Systems**

To manage risks related to medical devices in radiology departments, health care institutions should develop plans and strategies that include appointing a specialized department that assumes overall responsibility for the management of medical devices (Chau, M, 2024). As well as establishing a specialized system to ensure reporting of device problems, including:

- Design an effective system for storing medical devices.
- Periodically monitor the condition of medical devices and evaluate their performance, including reporting device malfunctions and problems, use, performance and maintenance, Repair and calibration history
- Develop plans for investment, replacement, and disposal.

Moreover, there must be an organizational structure that defines roles and responsibilities, and it must also clarify accountability procedures from employees to the board of directors level, as it is important to determine who bears responsibility, and when joint accountability arrangements are needed (Sharpe Jr et al., 2015).

Furthermore, healthcare providers should establish a long-term approach and goals for medical device management, including both strategic planning for equipment replacement and upgrades, and a comprehensive medical device management strategy that defines medium- and long-term regulatory requirements for assets while considering cost, performance, and risk across the life cycle (Huebner & Flessa, 2022). This strategic approach must also be aligned with the overall strategy of the organizations responsible (Sharpe Jr et al., 2015).

### **2.5 Medical Device Risk Management policy**

The medical device management policy is responsible for ensuring that the risks associated with the use of medical devices in radiology departments are minimized (Code, S, 2024). Therefore, the medical device management policy includes the following:

- equipment deployment, tracking and utilisation
- the equipment life cycle (including selection, acquisition, acceptance, maintenance, repair, monitoring, traceability and disposal/replacement) of all medical devices.
- training and access to manufacturer's instructions
- records, including device inventory.

- risk management including adverse incident reporting and actions required on National Patient Safety Alerts.

- Decontamination.
- equipment financing.

This policy, when implemented and reviewed periodically, allows us to ensure the condition of the medical device used, which must be (Fiedler, 2016):

- used in line with the manufacturer's instructions.
- suitable for its intended purpose.
- maintained in a safe and reliable condition, with associated records kept.
- disposed of appropriately at the end of its useful life.

## **2.6 Application of Risk Management in Medical Device**

Risk management principles are typically applied to medical imaging modalities: X-rays, MRIs, and CT scans. As follows:

X-rays:

Medical X-ray imaging is considered one of the most general and most common methods used to take pictures from inside the human body to diagnose health conditions. This method relies on X-rays from the electromagnetic spectrum. They are often used to display pictures of parties.

- Identify risks: The risks are that the patient will be exposed to unwanted radiation, which may cause cancer, even though the amount of radiation released is small. The danger from X-rays lies in the radiation, which may harm living tissue. This risk is relatively small but increases with cumulative exposure (Nordenskjöld ,2018).

- Risk assessment: Exposure to high doses of radiation may lead to internal damage to human organs and cells, which may lead to cancer. Furthermore, exposure to high radiation standards can lead to problems such as hair loss, skin redness, vomiting, and fainting (Talapko et al., 2024).

- Risk control: Tests are only performed when needed. Safety features include that the X-ray equipment is equipped with internal locks and built-in shields. In fact, faulty locks may lead to unintended exposures (Panichello, 2017). Moreover, maintaining the perfect distance as a safe barrier is mandatory.

CT:

CT scans are performed through a modern device based on X-rays, and it works as a scanner to obtain a three-dimensional image of the human body, which is cut into very thin slices so that the doctor can see the bones and some organic organs (Hermena & Young, 2023).

- Identifying risks: The step of CT scan is that the patient is exposed to a large amount of radiation within a short period, which leads to diseases (Power, et al, 2016). Furthermore, if contrast dye is used, it may cause an allergic reaction to the dye, leading to internal injuries. As for the technicians who supervise the cameras, their work is exposed daily to large amounts of radiation, which leads to damage to their organs (de Paula Freitas, 2020).

- Risk assessment: Exposure to high doses of radiation leads to internal damage to human organs and cells, which may lead to cancer (Hermena & Young, 2023).

- Risk control: This is done by reducing the number of sessions to which the patient is exposed and thus reducing the dose taken. As for radiology technicians, they must wear their personal protective equipment, in addition to placing the CT scan machine in a pre-prepared protected room and at an ideal distance from the control room to protect the radiologists (Al-Okshi, 2017).

MRI

Magnetic resonance imaging is considered one of the most important advanced devices that helps see tissues and organs inside the human body. One of its advantages is that it does not use radiation, but rather imagine using magnetic fields, which makes it safe.

- Identification of risks: There are no risks to the patient when performing an MRI. However, it has environmental harm because it relies on a large and variable magnetic field. The strong magnetic field attracts metal objects, which may cause burns to patients who have implanted external devices, in addition to pollution resulting from the loud sound of the device (Hoff, et al, 2019).

- Risk assessment: The risks lie in the magnetic field attracting metal objects which can damage the scanner, harm the patient and the radiologist. In addition to the inconvenience caused by sound, which may harm the patient's hearing (Winter et al., 2021).

- Risk control: The problem of the magnetic field attracting metal objects to the device can be managed and controlled by placing the device in a room whose walls and floors are specifically designed to resist the magnetic field and by having devices and tools designated for that. As well as specifying a specific distance that cannot be exceeded so that the magnetic field of the device is not penetrated (Cross, et al., 2018).

### **2.7 Recommendations for an effective risk management system**

- The existence of a system and strategy in hospitals regarding the management of medical devices that ensures the evaluation of all potential risks associated with medical devices.

- a medical devices group with representation from a wide range of staff.

- Mechanisms to distribute manufacturer field safety notices and MHRA safety information to the appropriate people in the organization and to report incidents.

- Clarify responsibility for medical device management and establish clear lines of accountability throughout the organization.

- Linking the healthcare organization's strategic plan to equipment life cycle management activities.

- Risk management is inherent in medical device management.

### **2.8 Literature Review**

To understand the risks related to medical devices in radiology departments and to determine ways to manage and reduce risks, it is necessary to identify these risks and the reasons that may lead to their occurrence.

Many studies, including the study (Craciun et al., 2015), which is a study of risk management in the radiology department, sought to conduct a comprehensive evaluation of the risk control measures used in the radiology department. The study concluded that risk management is limited to reducing or eliminating harm and preventing infection of patients by integrating various medical precautions. The study recommended the need to develop a risk management plan in radiology departments to ensure the protection of patients and radiologists.

Jamshidi et al. (2014) proposed a Failure mode and effects analysis (FMEA) approach to prioritize failure modes of medical devices, relying on the evaluation of multiple risk factors that affect the optimal operation of medical devices, such as device age and use condition. Based on the risk factors evaluated, the authors propose a method to select appropriate maintenance strategies based on the criticality scores for each device, where some of the selected strategies include corrective maintenance, time-based maintenance, condition-based maintenance, and predictive maintenance.

This study conducted by (Smith, J., & Johnson, A., 2018) aimed to evaluate the radiation dose and associated risks from computed tomography (CT) scans performed in a tertiary care hospital. Using a sample of patients undergoing various CT procedures, radiation doses were measured and linked to potential risks, with an emphasis on patient safety and quality of care. The results revealed insights into dose optimization strategies and radiation protection practices within the radiology department. In addition, the study conducted by (Nguyen, T., & Tran, H, 2017) aimed to evaluate occupational radiation exposure among radiographers in diagnostic

radiology departments. Using dosimetry and surveys, the study quantifies radiation doses received by radiology technicians during routine activities and identifies factors that contribute to exposure. The results highlighted the importance of radiation protection practices and ongoing safety training for radiographers.

The prospective study conducted by (Al-Mazroua, S., & Al-Otaiby, N, 2020) aims to evaluate radiation exposure and dose to staff in interventional radiology (IR) procedures. Real-time dosimetry measurements were performed on radiology technicians and other staff during various IR interventions. The results revealed that radiation exposure varies depending on the complexity of the procedure, with higher doses observed for individuals near the x-ray source or the patient. However, the total radiation remained within acceptable limits according to regulatory guidelines. To further enhance radiation safety, recommendations include implementing additional protective measures such as shielding and positioning aids, along with regular training sessions on radiation safety protocols for infrared personnel. Also, A study aimed to evaluate radiation exposure and dose to technicians in radiology departments, where dosimetry was performed in real time on radiology technicians and other employees during radiology interventions. The results revealed that radiation exposure varies depending on the complexity of the procedure, with higher doses observed for individuals near the x-ray source or the patient. The study recommended the need to implement additional preventive measures such as shielding and positioning aids, in addition to regular training courses on radiation safety protocols for technicians in radiology departments (Al-Mazroua, S., & Al-Otaiby, N., 2020).

## **2.9 Research Gap**

Although previous studies have provided valuable insights into the risks associated with medical devices in radiology departments, there are several gaps that require further research. The risks related to technical failures of devices and their impact on the safety of patients and technicians have not been adequately addressed, and these studies have not included all types of medical devices in radiology departments, nor have they studied the impact of failures on operational efficiency within hospitals. In addition, the impact of modern technologies on radiation-related risks has not been adequately studied, although some studies have addressed workers' exposure to radiation in interventional radiology, without considering the development of modern devices and technologies.

The current study aims to fill these gaps by conducting a comprehensive assessment of the risks associated with medical devices in radiology departments, focusing on technical failures and technological developments in devices, and studying the impact of these updates on the safety of patients and technicians.

## **3. Methodology**

### **3.1 Research design**

A descriptive analytical cross-sectional study design was used to assess the risks of medical devices in radiology departments within hospitals in Saudi Arabia. This method is suitable for describing the status of the phenomenon, its relationship, and comparing variables. The advantages of this type of study design are that it is straightforward, relatively inexpensive, and can be conducted quickly. Therefore, this type of design facilitated the completion of this study

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### 3.2 Data Collection

A web-based questionnaire was the primary research instrument. The instrument was adapted from a previous study and modified to suit the objectives of this study (Craciun, Mankad & Lynch, 2015; Nguyen, & Tran, 2017; Al-Mazroua, & Al-Otaiby, 2020). The questionnaire comprised two sections consisting of 27 questions and was framed, where the first included demographic data with three items. The remaining 22 questions were used to assess the Risks of medical devices in radiology departments. Literature review was the primary source of secondary data since the researcher compared the primary data findings with those of previous scholars on a similar topic. The final questionnaire underwent a face validity assessment to ensure the effectiveness of the questions in aligning with the study's objectives. The questions were measured on a Likert scale. The internal consistency in the scale was assessed in the previous study using the Cronbach alpha coefficient, which was found to be .956. The Arabic version showed good internal consistency with Cronbach's alpha of 0.88.

### 3.3 Data Collection methods

This chapter discussed the approach used in collecting the data for research and methods of analysis. It also illustrates the sampling procedures, research design, sources of data and data analysis techniques including correlation and regression. In all, (270) participants were sampled for the study, however, only (257), representing 95%, responded adequately by fully completing the questionnaires. The study further discusses the study population, sample and sampling technique, data analysis, means of validity and ethical considerations.

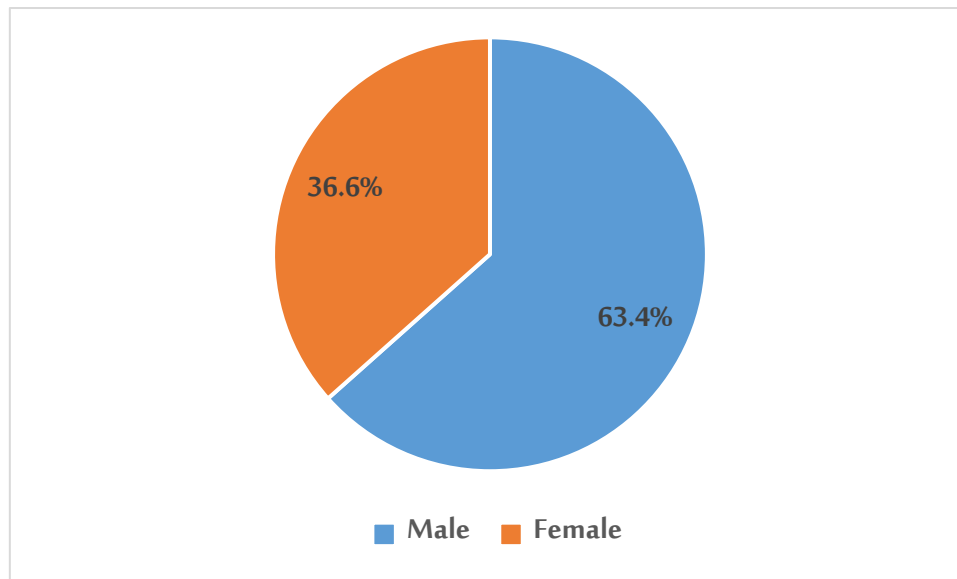
## 4. Results

### 4.1 Socio-Demographic Information

**Table 0.1.** Demographic information (N=257).

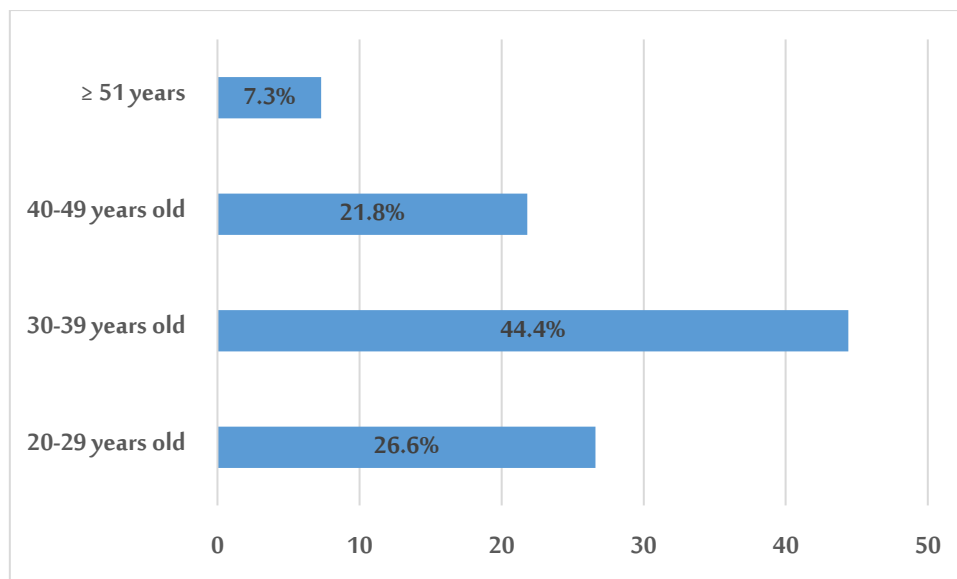
	Categories	Frequency	Percent %
Gender	Male	163	63.4%
	Female	94	36.6%
Age (years)	20-29 years old	68	26.6%
	30-39 years old	114	44.4%
	40-49 years old	56	21.8%
	≥ 50 years	19	7.3%
Educational level	Diploma or less	12	4.5%
	Bachelor's	159	61.9%
	Master's	62	24.2%
	Ph.D.	24	9.4%
Years of experience	less than 5 year	33	12.8%
	5-10 year	72	28.2%
	10-15 year	99	38.5%
	15-20 year	40	15.4%
	more than 20 year	13	5.1%
Job title	Manager	20	7.7%
	Head Of Department	33	12.8%
	Head Of Division	59	23.1%
	Employee	145	56.4%

A total of 257 radiologists participated in the study as illustrated in table (4.1). More than half of the study population in the study population were male (63.4%), while (36.6%) were females. This could be attributed to the fact that the majority of the radiologists are male (Figure 4.1).



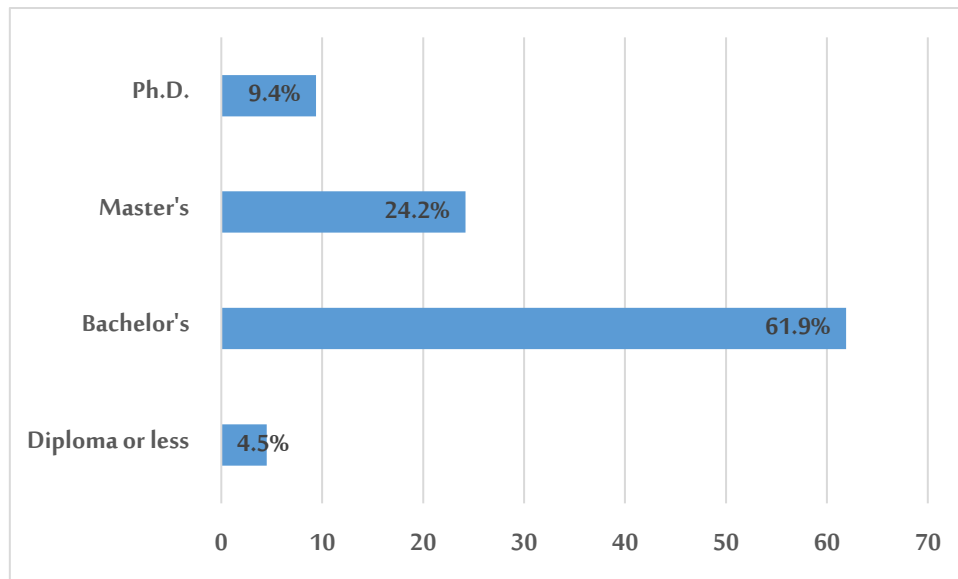
**Figure 0.1.** Distribution of study population according to their gender.

Table (4.1) showed that the majority (44.4%) of the participants are in the age group (30-39) years, (26.6%) are between (20-29) years, followed by (21.8%) are between (40-49) years, while those who are more than 50 years old constitute (7.3%) of the study sample, as shown in (Figure 4.2).



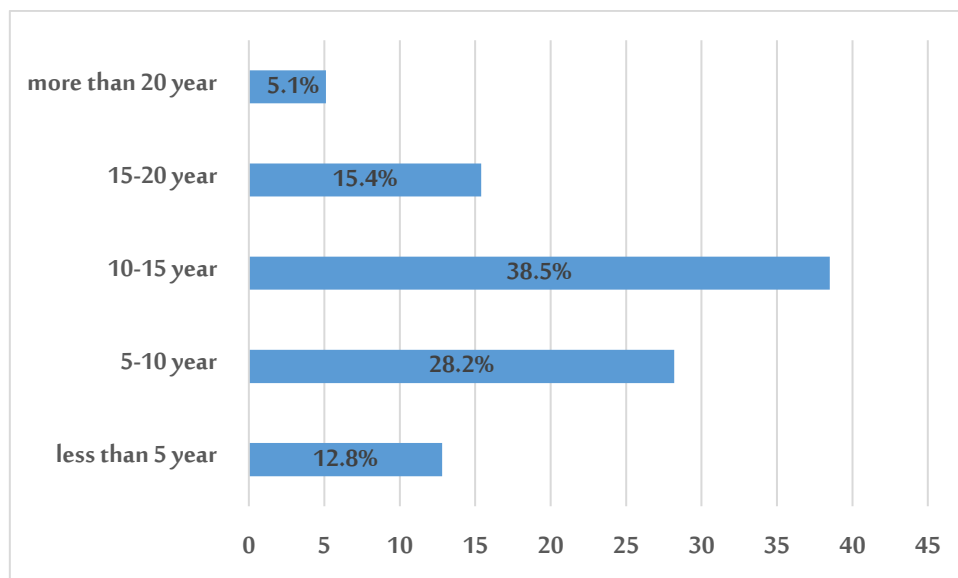
**Figure 0.2.** Distribution of study population according to their Age.

The distributions of the study participants according to educational level showed that the highest group of the study participants finished the bachelor's degree (61.9%), (24.2%) finished the master's degree, (9.4%) was finished the PhD degree. The results illustrated that only (4.5%) of them have a diploma degree and less, as shown in (Figure 4.3).



**Figure 0.3.** Distribution of study population according to their educational level.

The distributions of the study participants according to Years of experience showed that the majority (38.5%) of the participants are in the age group (10-15) years, (28.2 %) are between (5-10) years, followed by (15.4%) are between (15-20) years, while those who are more than 20 years constitute (5.1%) of the study sample, as shown in(Figure 4.4).



**Figure 0.4.** Distribution of study population according to their Years of experience.

#### 4.2 Analysis of Risk Management field.

The results of the statistical analysis in Table (4.2) indicate that most of the study participants have a good assessment of the existence of an effective administrative system for risk management in the radiology departments of hospitals in the Kingdom of Saudi Arabia. In general, the arithmetic means of the paragraphs ranged between 3.72 and 4.44, indicating a high agreement about the effectiveness of the medical devices risk management system in radiology departments. The first paragraph, which states "the existence of a formal risk management system in the radiology department", had an average of 4.44 and a standard deviation of 0.82, indicating a high consensus about the existence of an effective system for risk management in radiology departments in hospitals in the Kingdom of Saudi Arabia. This trend was repeated in many other paragraphs such as the second and third paragraphs, which obtained averages close

to 4.30 and 4.24, indicating a positive assessment. However, there are some paragraphs that witnessed greater variation in answers. Paragraph 16, which states “The risk management policy issued by the Ministry of Health or the hospital administration contributes to the safety of workers in radiology departments”, had a relatively low mean of 3.72 with a high standard deviation (1.42), indicating a variance in opinions about the effectiveness of these policies. Also, in paragraph 20, “Risk management policies and procedures are clear to radiology staff”, the mean was 3.88 and the standard deviation was 1.36, indicating that there is a need to improve the clarity of policies for participants. Moreover, all p-values were less than 0.05, which means that the results are statistically significant. This indicates that the obtained assessments are reliable and reflect a real reality in the radiology department. Based on these results, it can be concluded that there is an effective risk management system in the radiology department, but there are some areas that need improvement, such as the clarity of policies and procedures related to risk management and the effectiveness of the Ministry of Health policies in risk device in radiology department.

**Table 0.2.** Mean, Standard Deviation, and Chi-Square for the statement on the axis " Analysis of Risk Management field ".

Paragraph	Mean	Std. Deviation	Chi-Square	p-value
1	4.44	0.82	404.51	.000
2	4.30	0.89	305.63	.000
3	4.24	0.95	274.66	.000
4	4.17	1.04	251.22	.000
5	4.32	0.93	334.66	.000
6	4.06	1.11	200.71	.000
7	4.24	1.05	307.72	.000
8	4.29	0.96	316.96	.000
9	4.11	1.06	218.41	.000
10	4.16	1.08	261.04	.000
11	4.26	0.91	288.41	.000
12	4.31	0.89	314.30	.000
13	4.18	1.05	258.62	.000
14	4.34	0.90	341.31	.000
15	4.16	1.05	247.93	.000
16	3.72	1.42	116.87	.000
17	3.75	1.46	149.05	.000
18	4.44	0.85	424.51	.000
19	4.23	0.96	274.45	.000
20	3.88	1.36	171.67	.000
21	4.21	0.72	434.51	.000
The Average	4.18	1.02		

Table 0.3. Frequency and percentage of use of prediction models.

Does the radiology department use any model to predict risk	Yes		No	
	F	%	F	%
Radiation dose risk	88	34.1%	169	65.9%
Equipment damage rate risk	133	51.8%	124	48.2%
Over loud work risk	157	61.2%	100	38.8%
High voltage electric risk	155	60.2%	102	39.8%

The results of Table 4.3 show the percentage of use of predictive models in the radiology department. The results indicate that radiology departments in Saudi hospitals do not use predictive models for risks uniformly, with lower use in some areas such as “Radiation Dose Risk”, where only 34.1% of participants reported using a predictive model for this risk, while 65.9% of participants did not. In contrast, the use of predictive models for “Equipment Damage” risks was more balanced, with 51.8% of participants using these models, while 48.2% did not. As for “Overwork” risks, the use of predictive models was very high, with 61.2% of participants reporting using them, while 38.8% did not. Finally, with regard to “High Voltage Electric Current” risks, 60.2% of participants indicated that they use a model to predict these risks, while 39.8% did not use any model.

#### 4.3 Medical Device Risk Management in Radiology Departments and gender

Table 0.4. Differences between Medical Device Risk Management in Radiology Departments and gender.

Topics	Gender	N	Mean	Std	T	Sig
Medical Device Risk Management in Radiology Departments	Male	163	78.62	14.69	1.653	0.122
	Female	94	80.21	15.24		

Although there are no statistically significant differences between gender and Medical Device Risk Management in Radiology Departments (sig. > 0.05), Table (4.4) reveals that the mean score for males was higher than the mean score for males. All information indicates that there are no statistically significant differences in the level of medical device risk management in radiology departments within hospitals in the Kingdom of Saudi Arabia based on the gender of workers in radiology departments.

#### 4.4 Medical Device Risk Management in Radiology Departments and Age

Table 0.5. Medical Device Risk Management in Radiology Departments and Age.

Topics	Age	N	Mean	Std	T	Sig
Medical Device Risk Management in Radiology Departments	20-29 years old	68	78.59	16.24	3.589	0.021
	30-39 years old	114	81.32	15.03		
	40-49 years old	56	73.17	12.89		
	≥ 51 years	19	74.25	13.42		
	total	257	77.24	14.86		

Table (4.5) demonstrates statistically significant differences (sig. < 0.05) between the Medical Device Risk Management in Radiology Departments and age, with the age group 30–39 years old having the largest advantage with an average of (81.32), followed by the age group 20-29 years old with an average of (78.59). In terms of age and the Medical Device Risk Management in Radiology Departments, the majority of healthcare professionals are individuals who have earned undergraduate and graduate degrees (Bachelor's, Master's, PhD). Given the knowledge and expertise of medical professionals in both science and practice, this helped hospitals better prepare Medical Device Risk Management in Radiology Departments.

#### 4.5 Medical Device Risk Management in Radiology Departments and Years of Experience.

Table 0.6. Medical Device Risk Management in Radiology Departments and Years of Experience.

Topics	Years of Experience.	N	Mean	Std	T	Sig
Medical Device Risk Management in Radiology Departments	≤ 5 years	133	79.48	16.40	5.13	0.003
	5-10 year	85	79.27	13.12		
	10-15 year	92	76.30	15.44		
	15-20 year	54	76.28	10.53		
	5-10 year	364	78.01	15.38		
	total	257	77.86	14.17		

According to Table (4.9), there are statistically significant differences (sig. < 0.05) between the between the Medical Device Risk Management in Radiology Departments and experience, with the experience ≤ 5 years and those with experience from 5 to 10 years showed the biggest differences, with the former having an average of 79.48 and the latter having an average of 79.27.

#### 4.6 Medical Device Risk Management in Radiology Departments and educational level.

Table 0.6. Medical Device Risk Management in Radiology Departments and educational level.

Topics	Educational level	N	Mean	Std	T	Sig
Medical Device Risk Management in Radiology Departments	Diploma or less	12	73.84	15.2	2.981	0.034
	Bachelor's	159	75.77	14.78		
	Master's	62	79.38	15.87		
	Ph.D.	24	62.29	11.32		
	total	257	71.77	14.12		

Table (4.7) demonstrates that there are statistically significant differences (sig. <0.05) between the educational level and the Medical Device Risk Management in Radiology Departments. The bachelor's degree showed the largest variances, with an average of (79.38), followed by. The diploma degree states that the average score is (75.77). Regarding the degree of education and the Medical Device Risk Management in Radiology Departments, the majority of participants are vital individuals who need a high level of education in order to cope with the risk.

#### 4.7 Medical Device Risk Management in Radiology Departments and Job title.

Table 0.7. Medical Device Risk Management in Radiology Departments and Job title.

Topics	Job title	N	Mean	Std	T	Sig
Medical Device Risk Management in Radiology Departments	Manager	20	80.43	15.72	1.329	0.285
	Head Of Department	33	82.14	16.10		
	Head Of Division	59	76.23	17.58		
	Employee	145	79.71	8.67		
	total	257	79.63	14.52		

Table (4.8) demonstrates that there are no statistically significant differences (sig. > 0.05) between the Job title and the Medical Device Risk Management in Radiology Departments.

#### 4.8 Chapter Summary

This chapter presents the results of the statistical analysis of the current study, which aims to assess the risks related to medical devices in radiology departments in Saudi hospitals. Data were collected from 257 radiologist via an electronic questionnaire and were analyzed using SPSS. The results indicate that the majority of participants were male (63.4%), and the most representative age group was between 30-39 years (44.4%). It was also found that most

of the participants hold a bachelor's degree (61.9%), and most of them have experience between 10-15 years (38.5%). Regarding the analysis of the risk management system, the results showed a positive agreement in assessing the existence of effective risk management systems, with averages ranging between 3.72 and 4.44. However, there are areas that need improvement, such as clarity of policies and risk procedures. The study also showed that the use of predictive risk models differed according to the type of risk, as the use was higher in areas such as "overwork risks" and "high electrical current", while it was lower in "radiation dose risks" (34.1%). Regarding demographic factors and their impact on risk management, the results did not indicate significant differences according to gender or job title.

## **5. Discussion**

The results of the study showed that the majority of participants had a positive assessment of the risk management systems in radiology departments. With a mean score of 4.32, the results indicated general agreement on the existence of formal risk management systems, with some variability in responses. This finding is consistent with similar studies, such as that conducted by Cracione et al. (2015), which emphasized the importance of risk management systems in radiology to prevent harm and infection. However, this study also found areas for improvement, particularly in the clarity of risk management policies and the effectiveness of regulations set by the Ministry of Health. These findings suggest that while systems are in place, the operation and communication of these systems could be improved. Cracione et al. (2015) found that incorporating various medical precautions in radiology departments is key to reducing risk, which is consistent with the result of the current study in which most participants agreed on the existence of formal risk management systems. However, similar to Jamshidi et al. (2014), this study suggests that there is a need to improve the clarity of procedures and policies, which would enhance the overall effectiveness of risk management in radiology departments.

The study also examined the use of predictive models in radiology departments. The results showed that the application of predictive models was not consistent across different types of hazards. For example, the use of models for radiation dose hazards was relatively low (34.1%), while the use of predictive models for overwork and high-voltage electrical hazards was higher, with 61.2% and 60.2% of participants reporting their use, respectively. This suggests that radiology departments in Saudi hospitals are more proactive in managing risks associated with overwork and electrical hazards, compared to radiation dose hazards. This finding contrasts with some of the studies reviewed, such as Smith and Johnson (2018), which focused on optimizing radiation doses in CT scans. While radiation dose hazards are recognized as critical in radiology, the lower use of predictive models for this type of hazard in the current study suggests a gap in the application of modern predictive tools to radiation safety. This finding suggests a need for more systematic implementation of predictive models for radiation exposure, especially given the technological advances in medical devices.

The results also indicated that there were no statistically significant differences between gender and medical device risk management in radiology departments, with the p-value  $> 0.05$  (0.122), indicating that gender does not significantly affect the assessment of the effectiveness of the risk management system. However, the average assessment was higher among males than females, but this difference was not statistically significant. On the other hand, the study showed statistically significant differences between age groups and medical device risk management, with the p-value  $< 0.05$  (0.021), indicating the influence of age on the assessment of the effectiveness of risk management. The age group 30-39 years showed the highest average assessment with an average of 81.32, followed by the age group 20-29 years with an average of 78.59, while older age groups such as 40-49 years and  $\geq 50$  years had lower assessments. These findings are consistent with previous studies, such as Smith, J., & Johnson (2018), which

found that younger people are more adaptable to new technologies, which is reflected in their evaluation of the effectiveness of technological systems such as risk management systems. In contrast, other studies, such as Winter et al (2021), have found that older individuals may have more difficulty adapting to technological changes, which may lead to lower evaluations of new systems. The findings suggest that younger individuals may be more familiar with new technologies and risk management methods, while older individuals may face challenges in adapting to new technological innovations. Therefore, it can be argued that ongoing training programs in risk management should target all ages and nationalities to ensure that risks are managed safely and effectively in the radiology environment.

## **6. Conclusion**

The current study aims to identify the risks of medical devices in radiology departments in Saudi Arabian hospitals and their tools, while studying the effect of demographic factors such as gender, age, educational level, and years of experience in medical device risk management and their impact on medical device risk management in radiology departments. The results indicate that while there were no significant gender differences in the perception of risk management effectiveness, age showed a clear effect. Younger age groups, especially those aged 30–39 years, showed higher ratings of the effectiveness of medical device risk management systems, while older age groups, especially those aged 50 years and above, had lower ratings. These findings are consistent with existing literature indicating that younger individuals are more adaptable to technological innovations and systems than older age groups, who may face challenges in adopting new technologies. The results also reflect the importance of continuous training and education for all age groups in healthcare settings. With the rapid advancement of medical technologies, it is crucial for healthcare professionals to stay up to date with the latest risk management protocols. Although there are no significant gender differences, attention still needs to be paid to the comprehensiveness of training programs to ensure that all employees, regardless of gender or age, are equipped with the knowledge and skills necessary to effectively deal with potential risks associated with medical devices.

In conclusion, the current findings indicate a generally positive perception of risk management systems in radiology departments in Saudi hospitals. However, there are areas that require improvement, such as clarity of risk management policies and adoption of predictive models for radiation dose risk. In addition, demographic factors such as education and experience play an important role in shaping risk management perceptions, suggesting that ongoing training and updating of protocols are essential to maintaining an effective safety culture in radiology departments.

## **7. Recommendations**

Considering the results of this investigation, the following suggestions are offered. Based on the study results, the researcher recommends that the concerned authorities develop training programs dedicated to qualifying radiologist to deal with risks in radiology departments, so that the programs focus on advanced risk management technology for radiologist. Moreover, it is important to implement periodic awareness campaigns to highlight the importance of risk management protocols, in addition to focusing on modern technologies and their impact on improving risk management systems. It is also recommended to integrate continuous technological developments into risk management systems, while ensuring that these systems are regularly updated and employees are trained to use them effectively. On the other hand, healthcare institutions should contribute to promoting a supportive organizational culture that encourages continuous learning and adaptation to modern technologies, and allows employees to provide feedback on risk management systems, which ensures the optimal use of

these systems and contributes to proactively identifying risks before they turn into problems that affect patient safety.

### **Research Contributions**

This study makes valuable contributions to the understanding of risk management systems in healthcare settings. First, it highlights how demographic factors such as age, experience, and education influence healthcare professionals' perceptions and practices regarding risk management systems. The findings underscore the need for tailored training programs based on these factors to enhance risk management effectiveness. Second, the research explores the role of technological advances, such as artificial intelligence and electronic health records, in improving risk management systems. It emphasizes the importance of integrating new technologies into risk management frameworks to improve patient safety and organizational efficiency. In addition, the study provides empirical evidence on the strengths and weaknesses of current risk management systems and offers actionable recommendations for healthcare organizations to improve their strategies. These insights can help improve the implementation and application of risk management systems to better protect patients and staff. The research also underscores the importance of institutional support and a culture of continuous learning in promoting effective risk management practices. It suggests that a supportive organizational culture is critical to the successful adoption and sustainability of risk management systems, ensuring that healthcare professionals remain engaged and informed.

### **Direction for Further Research**

This research is an important step towards understanding the effectiveness of medical device risk management systems in radiology departments, but there are several areas that need further exploration. Future research could focus on studying the long-term effects of different risk management interventions on improving radiologist and patient health and hospital performance. Longitudinal studies may provide a deeper understanding of how these systems evolve and improve over time. In addition, research needs to explore the effectiveness of emerging technologies such as artificial intelligence, machine learning, and predictive analytics in radiology work settings. How these tools contribute to early detection of risks and integrate with existing systems could be studied. The role of organizational leadership and corporate culture in shaping the success of risk management initiatives should also be investigated. Such studies may help provide practical guidance for improving risk management.

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