Strengthening the Radiation Safety of Patients by Controlling and Preventing Unnecessary Exposure in Radiological Diagnostic and Interventional Facilities

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Abstract. Unnecessary exposure is the situation of radiation exposure that should not be received by the patient, either in whole or in part, when undergoing radiation medical treatment. This situation occurs frequently but the impact on the patient is not always observable directly, so it was usually unnoticed and even ignored. An analytical descriptive study has been carried out regarding unnecessary exposure control profiles in diagnostic and interventional radiology facilities to propose recommendations for improving patient radiation safety through controlling and preventing unnecessary exposure. The profile mapping result shows that unnecessary exposure control and prevention in RDI facilities generally have been carried out but it has not been systematically built and only a few facilities have fully implemented it. This situation is caused by the absence of a direct effect observable on the patient (such as injury) resulting in the neglect of all potential risks that may arise including the follow-up system to control and prevent it. It needs a clear regulatory framework and guidelines to encourage the proper implementation of unnecessary exposure control and prevention.

Keywords: unnecessary exposure, patient safety, medical exposure

INTRODUCTION

In medical exposure, the patient is part of the object of investigation or medical treatment using ionizing radiation sources for diagnosis or disease therapy. The radiation dose given to these patients cannot be limited by the dose limit value, but using other constraints, for example, the guidance level and justification. Therefore, the risk that a patient could potentially accept was unnecessary radiation exposure. These risks must be managed properly and even prevented.

In the context of patient safety, Law Number 44 Year 2009 concerning Hospitals, Article 43, states that hospitals are required to apply patient safety standards, including risk assessment, identification and risk management of patients, incident reporting and analysis, the ability to learn, and following up on incidents, and implementing solutions to reduce and minimize the occurrence of risk [1]. In the IAEA document, GSR Part 3 has provided requirements to minimize the possibility of incidents of unintended radiation exposure to patients and follow-up for incident prevention [2]. Concerning the risk of incidents arising from the use of ionizing radiation, Government Regulation (GR) Number 33 Year 2007 concerning Safety of Ionizing Radiation and Security of Radioactive Sources, Article 22 and Article 34, mandates the implementation of justification and optimization principle of radiation protection and safety in every utilization of nuclear power including in medical sector to reduce the risk of unnecessary medical exposure [3].

Unnecessary exposure to patients is a radiation exposure situation that should not be received by patients, either in whole or in part, when undergoing radiation medical treatment. This situation is one of the risks that will be faced if medical exposure is not justified and adequately optimized. For example, patients get radiation exposure in an undesirable position/location (for example in the exposure for the thorax, X-ray beam reaches to the head area), patients get repeated radiation exposure (for example because the image does not match what the doctor needs, the film image is unclear, the process of radiation interrupted due to power outages, or patient imaging data lost due to power outages or software interruptions), patients get high doses of radiation because personnel does not notice radiation/time exposure indicators, and individuals get thorax exposure for an annual medical check-up.

Unnecessary exposure incidents occur frequently but their impact on patients is not always observable directly because in general, it is a stochastic effect. This causes unnecessary exposure incidents were unnoticed and even ignored. However, if this situation occurs repeatedly it will be detrimental to patient safety and will reflect that...
the performance of the facility is inadequate quality. This situation needs to be improved immediately to ensure radiation protection and safety for patients.

A study was conducted regarding the profile of controlling and preventing unnecessary exposure in diagnostic and interventional radiology facilities in Indonesia and identifying recommendations that can be proposed to improve the control and prevention system for unnecessary exposure. This paper provides recommendations for health facilities to strengthen radiation protection and safety systems for patients and for regulators both BAPETEN and the Ministry of Health (MOH) in developing policies related to radiation protection and safety for patients.

**METHODOLOGY**

![Figure 1: Methodology](image)

As illustrated in **FIGURE 1**, the study began by collecting survey data on the control and preventing system of unnecessary exposure to patients from respondents. The respondent was 38 hospitals of radiology diagnostic and interventional facilities in the region of Central Java, Yogyakarta, Jakarta, Bandung, and Medan. Parameters in the questionnaire were compiled and summarized from some of the requirements in IAEA documents such as GSR part 3 and SSG 46 and regulations such as GR Number 33 Year 2007, BCR Number 4 Year 2013, and BCR Number 8 Year 2011. These parameters contained questions that describe the readiness of the system to control and prevent unnecessary exposure to patients for each facility. Then the mapping of the profile of the questionnaire results was carried out. Aspects of the mapping process and discussion follow the aspects of the incident learning system as presented in **FIGURE 2**.

**RESULTS AND DISCUSSION**

There were 38 questionnaires distributed to respondents, but only 27 questionnaires were filled out. The results of data processing are presented in **FIGURE 3, 4, & 5**.
Based on FIGURE 3, it appears that 52.8% of facilities have management supports for patient's radiation protection and safety and 40.3% of facilities have prepared a system for following up incidents and utilizing incident data to improve the radiation protection and safety system of patients. This means that controlling and preventing unnecessary exposure, in general, have been done but have not been applied systematically. Facility management generally supports, but only at the macro level. They only ensure the safety of hospital patients in general but do not cover the safety aspects of radiation.

**Identification and Reporting**

Unnecessary exposure incidents generally do not have any direct impact that can be observed, therefore the awareness of medical personnel to identify proactively is very important. But in FIGURE 4 shows that less than 50% of facilities implement the identification system against the possibility of unnecessary exposure, i.e. 38.9% of facilities establish criteria of conditions that are categorized as unnecessary exposure to the patient, 44.4% of facilities are carried out the identification process routinely and 50.0% of facilities are documented the identification process through procedures and records. It reinforces the hypothesis that the absence of an observable impact directly ignores any potential risks that may arise.

Identification of the possibility of unnecessary exposure to patients should be done through monitoring and/or evaluation of the dose received by the patient and the examination process undertaken. This evaluation should be carried out by radiographers, medical physicists, and/or radiation specialists. Information or parameters related to patient doses can generally be obtained from visual displays on X-ray modality, from examination results (i.e radiographs image), and logbooks of irradiation conditions. The facility should locally set conditions criteria that can be categorized as unnecessary exposure so that they can be used as indicators in incident identification.

Information or parameters related to the patient's dose to be evaluated include [5], [6]: kerma area product (KAP), tube voltage, current irradiation time, length of time for exposure when termination of exposure fails, CT dose index average volume (CTDiVol), dose-length product (DLP), mean glandular dose (MGD), target/filter combination, breast compression thickness, cumulative air kerma both from the fluoroscopy process and from image acquisition, cumulative fluoroscopy time, number of fluoroscopy images recorded, and other relevant dose metrics. Data that are still in the form of radiation parameters should be converted into the patient's dose quantity by medical physicists and then be evaluated. Evaluation of patient doses is conducted by comparing patient doses to the available local or national Diagnostic Reference Level (DRL) values. If the comparison results show that the patient's dose is higher than DRL then unnecessary exposure may occur so that further analysis and corrective actions are needed.

Evaluation of the patient's radiograph also needs to recheck the suitability of the irradiation area and target image with the irradiation area and target requested by the referring physician. If there is any difference, for example, exceeds or less than or does not fit so as it is requested for re-exposure, the patient may get unnecessary exposure.

Identified incidents must be recorded and reported, as required in GSR Part 3 Requirements 9 paragraph 3.15 (g) that licensees shall establish procedures for reporting on and learning from accidents and other incidents [2]. However, based on Figure 4 shows that less than 50% of facilities that implement the recording and reporting of unnecessary exposure incidents, namely 38.9% of facilities that prepare a reporting scheme for unnecessary exposure to the patient and only 44.4% of facilities that documenting the reporting system into procedures and records.
In general, the facility has prepared an incident reporting system as the mandate of the Decree of the Minister of Health of the Republic of Indonesia Number HK.02.02/MENKES/535/2016 concerning the National Committee for Hospital Patient Safety. In that regulation hospitals must prepare an incident reporting system that includes the establishment of policies, reporting flow, reporting forms, and reporting procedures [7]. However, the incident category used in that regulation was the patient with an injury. So that radiation incidents with unnecessary exposure types are not included in the reporting system because they are considered harmless. Also, some respondents think that reporting an incident is sometimes reluctant to do because they are afraid of getting sanctions or being opposed by other personnel.

Research from Hwang, et.al and Iskandar, et al have identified non-technical aspects that hinder reporting actions, which are as follows [8], [9]: blaming culture, legal sanctions or social sanction cause the incident to be deliberately covered up, lack of personnel’s concern so reports are often late or reports are incomplete or even not reported, unclear reporting system so that the roles and responsibilities of the parties related to the reporting system are unclear, unclear conditions criteria to be reported so that they are not aware of situations that must be reported, high workloads so that they do not have time to do report and lack of management commitment in following up on reporting so that reporting does not have a positive influence on improving patient safety.

Therefore, efforts are needed to avoid those obstacles. One of them is conducting regular socialization of the reporting system to all hospital employees, especially those working in facilities that use ionizing radiation modalities. Besides that, training of personnel regarding the incident reporting system also needs to be done, which includes the purpose and benefits of the report, reporting flow, how to fill out the reporting form, when time to report, the notions used in the reporting system and how to analyze the report [8]. A reporting system needs to build, for example, an online-based electronic reporting system (e-reporting system) platform. BAPETEN can act as a promoter to build an online-based reporting system that facilitates the reporting of radiation incidents in radiological facilities, including unnecessary exposure to patients. In addition to ease of reporting, this system will also function as a platform for joint learning to optimize radiation protection and safety for patients in medical exposure situations.

Although unnecessary exposure incidents to patients have not led to emergency exposure situations or cause injury to patients, recording, and reporting are important as an effort to improve the system of patient’s radiation safety. Valid and accurate incident data records will determine the evaluation accuracy of the patient's radiation safety system, underlie improvements in the service system based on patient radiation safety, and prevent the recurrence of radiation incidents in patients [10].

In the case of unnecessary exposure incidents, reporting should be addressed to the physician in charge, the head of the installation or management at the level above it, the team related to patient safety, or based on the reporting hierarchy set by the hospital. Information related to the incident unnecessary exposure to the patient, although it does not cause injury or other severity effects, must also be notified to the referring physician and the patient himself or the patient's family [2].

**Investigation, Cause Analyze, and Corrective Actions**

The unnecessary exposure incidents that have been identified, recorded, and reported to management should be investigated as required in GSR Part 3 Requirements 41 that licensees shall prompt any investigations such as...
incident exposures and, if appropriate, shall implement corrective actions [2]. The investigation process is designed to provide an explanation of the specific underlying cause of the incident and produce recommendations for following up and ensuring resolution for each root cause [4]. However, based on FIGURE 5, it appears that only 44.4% of facilities conducted investigation and evaluation of root causes, 27.8% of facilities documented investigation and evaluation of root causes process, and 38.9% of facilities conducted corrective actions. In their opinion, unnecessary exposure is considered as a harmless incident or does not cause injury so no further follow up is needed.

Although unnecessary exposure incidents to patients, in this context, do not lead to emergency exposure situations, it still needs to be investigated/analyzed using a structured approach such as Root Cause Analysis (RCA). A series of investigations and RCA should be carried out by the team so that the information collected and analysis point of view can be more comprehensive. Various tools can help to conduct RCA, such as fishbone diagrams and others. If the root causes of the problem have been identified, recommendations, plans, or strategies can be identified as the basis for implementing corrective actions to prevent the recurrence of the same incidents [11].

Based on survey data, it was identified that several causal factors that have contributed to unnecessary exposure are human and equipment/infrastructure as presented in TABLE 1 [5], [12], [13]:

**TABLE 1. The causal factors of unnecessary exposure incidents**

<table>
<thead>
<tr>
<th>Causal Factors</th>
<th>Human</th>
<th>Equipment and infrastructure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevention</td>
<td>- Error in understanding prescriptions/requests from referring doctors.</td>
<td>- Incorrect or outdated use of files, forms, protocols.</td>
</tr>
<tr>
<td>Prevention</td>
<td>- Error in understanding examination protocols.</td>
<td>- Digital image data is lost/erased before image evaluation is performed.</td>
</tr>
<tr>
<td>Prevention</td>
<td>- Error in understanding information displayed on the monitor or from the software</td>
<td>- The radiograph/image is not clear.</td>
</tr>
<tr>
<td>Evaluation</td>
<td>- Error in identifying patients.</td>
<td>- Error in software upgrade affecting protocol and image processing settings.</td>
</tr>
<tr>
<td>Identification of the root causes of the unnecessary exposure incident</td>
<td>- Error in recognizing dose indicator and error messages that appear on the monitor display (sometimes personnel even ignore it).</td>
<td>- The electrical power suddenly stopped (power outages).</td>
</tr>
<tr>
<td>Corrective action</td>
<td>- The patient uncooperative or moving when irradiated.</td>
<td>- Poor equipment reliability due to age and workload.</td>
</tr>
<tr>
<td>Corrective action</td>
<td>- Error in setting irradiation target / location / position.</td>
<td>- Malfunction of AEC (Automatic Exposure Control).</td>
</tr>
<tr>
<td>Identification of the root cause and its corrective actions are documented in an SOP</td>
<td>- Use inconsistent quantities and units when measuring, testing, or calculating</td>
<td>- The AEC chamber is not in line with the X-ray tube.</td>
</tr>
<tr>
<td>Identification of the root cause and its corrective actions are documented in an SOP</td>
<td>- Prevention of a warning system related to an overdose.</td>
<td>- Malfunction of the exposure timer.</td>
</tr>
<tr>
<td>Identification of the root cause and its corrective actions are documented in an SOP</td>
<td>- The CT Scan position setting is reset so that the patient scanned in the wrong position</td>
<td>- Unavailability of a warning system related to an overdose.</td>
</tr>
<tr>
<td>Identification of the root cause and its corrective actions are documented in an SOP</td>
<td>- Internal parameters no longer match after the equipment is repaired</td>
<td>- The CT Scan position setting is reset so that the patient scanned in the wrong position</td>
</tr>
<tr>
<td>Identification of the root cause and its corrective actions are documented in an SOP</td>
<td>- Technical errors in imaging systems, such as Picture Archiving and Communication Systems (PACS), and Radiology Information Systems (RIS)</td>
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</tr>
</tbody>
</table>

**FIGURE 5. Profile of the incidents follow-up.**
Based on the causal factors identified in Table 1, it can be illustrated that the root causes of unnecessary exposure incidents are presented in **TABLE 2** [4], [5], [12], [13].

<table>
<thead>
<tr>
<th>Root Causes</th>
</tr>
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<tbody>
<tr>
<td><strong>Management</strong></td>
</tr>
<tr>
<td>• Lack of commitment from management and radiation workers in implementing safety culture.</td>
</tr>
<tr>
<td>• Communication problems, both vertical and horizontal communication, and communication to the patient.</td>
</tr>
<tr>
<td>• Unclear functions and lines of authority and accountability.</td>
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<tr>
<td>• Inadequate design assessment of ergonomic impacts and operational capabilities.</td>
</tr>
<tr>
<td>• Inadequate resource requirements planning and risk assessment.</td>
</tr>
<tr>
<td><strong>Personnel</strong></td>
</tr>
<tr>
<td>• Inadequate training and education for personnel in terms of radiation protection and safety and technical or clinical topics related to their area of work including the operation/use of equipment.</td>
</tr>
<tr>
<td>• Lack of review of the competence and availability of personnel after the purchase of new equipment and after the workload has increased.</td>
</tr>
<tr>
<td>• Lack of supervision for inexperienced personnel.</td>
</tr>
<tr>
<td>• Lack of personnel availability or high personnel turnover cycle.</td>
</tr>
<tr>
<td>• Lack of awareness of workers for work responsibilities assigned (due to health conditions, motivation, fatigue, psychological pressure, etc.).</td>
</tr>
<tr>
<td>• Doctors do not consider the signs and symptoms of patients or alternative medical measures that are more appropriate.</td>
</tr>
<tr>
<td><strong>Protocol</strong></td>
</tr>
<tr>
<td>• Inadequate protocols or operational procedures that are difficult to be understood by personnel so that they are not implemented or even violated.</td>
</tr>
<tr>
<td>• The lack of operational protocols or procedures causes the wrong activities to be carried out.</td>
</tr>
<tr>
<td><strong>Equipment</strong></td>
</tr>
<tr>
<td>• Inadequate implementation of quality assurance and multi-layered defense systems, for example, periodic evaluations of protocols and quality control of equipment.</td>
</tr>
<tr>
<td>• Lack of programs for acceptance testing, commissioning testing, and quality control of equipment (both treatment equipment and radiation protection equipment).</td>
</tr>
</tbody>
</table>

The root cause that has been identified will be the basis for establishing appropriate corrective action. Corrective action has the aim of eliminating the root causes of the nonconformity that have occurred so that the same nonconformity is not repeated [14]. However, in **FIGURE 5** it appears that only 38.9% of facilities followed up the investigation through corrective actions and documented the corrective action process. This is because unnecessary exposure is considered as a harmless incident or does not cause injury so it does not require to follow up. Some respondents even said that corrective action is a time-wasting activity that is only intended for accreditation activities. This means that there was no awareness that corrective action will be one of the efforts in improving the system of protection and safety of radiology patients.

Corrective actions can be formulated appropriately if the investigation or analysis of the causes is done properly as well. In the context of unnecessary exposure incidents, corrective actions that can be taken are presented as follows: [4], [5], [12], [13], [2]

- Quality control on each stage of the process routinely.
- Quality control of equipment, for example, X-ray modalities, supporting equipment (imaging systems, software, hardware, information systems, decision support systems), and radiation protection equipment.
- Establish clearly and detailed protocols/procedures for each process and activity including testing activities for quality control and activities for the justification process.
- Ensure the ability and updating of the protocol/procedure.
- Provide personnel training, with applicative technical topics under their area of assignment.
- Clearly define the roles, responsibilities, and functions of personnel in the radiology facility.
- Providing patient radiation dosimetry information, either through direct measurement, calculation, or from the dose indicator in the modality.
- Implementation of DRL.

Corrective actions plans and results of must be documented, usually combined with investigative or root cause analysis reports. This includes the parties assigned to execute corrective actions and the deadline. After implementing corrective actions, monitoring is needed to assess their effectiveness in eliminating repeated incidents of the same incident. If the same incident still happens this indicates that the investigation/analysis is not accurate enough to identify the right root cause or in planning the right corrective action.
Preventive Actions

Corrective action is a follow-up action if an incident has occurred. Facilities should not only focus on problems that have occurred but also need to pay attention to prevention systems. In the case of preventive measures, a facility must identify potential problems or identify risks that may occur during the implementation of activities to minimize or prevent potential problems or non-conformities. However, from Figure 5 it appears that only 44.4% of facilities carry out preventive measures. This is because unnecessary exposure is considered as a harmless incident or does not cause injury so it is not a priority in the risk assessment process, even some respondents did not include these parameters in the assessment of patient safety risk.

Prevention systems through the identification of potential problems or identification of risks must begin at an early stage. Based on the identification results, the facility can carry out mitigation actions that are integrated into the established quality management system. In general, steps that can be taken to establish preventive actions are as follows:

a) Identifying critical points in the process of radiation examination. Tools that can be used include a map of the process of the examination of patients in radiology facilities.

b) Identifying potential risks that occur at those critical points, including potential obstacles in achieving safety (safety barrier). For identifying risks appropriately, it is necessary to understand the factors that can influence the risk. In the case of unnecessary exposure to patients, factors that influence include human resources, equipment, materials, processes, working flow, work environment, and others. Tools that can be used for this activity are the 'fishbone diagram' method, the 'five whys' method, the '5W2H' method, the Health Care Failure Mode and Effect Analysis (HFMEA) method, and others.

c) Analyze the risks identified in step b). In this stage, all types of risks, sources of risk, root causes of risks, controls or existing protections, opportunities for the occurrence of risks, the consequences that may arise will be discussed in detail, and results will be reported as completely as possible.

d) Evaluate the level of risk based on the impact of the risk and the chance of the risk occurring.

e) Mapping and prioritizing risks that significantly affect the incidence of unnecessary exposure in patients.

f) Based on the analysis and assessment of risk from steps c) to e), then plans and actions are taken to anticipate and/or reduce and prevent risks to acceptable limits based on applicable regulations and standards.

g) Monitor the effectiveness of the implementation of preventive measures. In the context of unnecessary exposure to patients, effective criteria can be shown by decreasing the tendency of situations that can trigger unnecessary exposure to patients.

The series of a preventive process as described above should be carried out by the team so that the information/data collected can be comprehensive and viewpoints can be more diverse so that the solution will be easily accepted by all parties.

Based on discussions with respondents and studies from literature, actions to prevent potential incidents of unnecessary exposure based on the approach of justification and optimization principle of radiation protection are as follows [15] [13] [12]:

• Promote a safe and secure utilization of ionizing radiation modalities.
• Promote clinical decision-making processes based on complete information.
• Develop and foster the implementation of culture to work with awareness and alertness in the context of quality and safety.
• Provide clear and detailed protocols and procedures for each process and activity, including activities related to quality control.
• Provide educated and trained personnel at an appropriate level and in an adequate number.
• Conduct supervision for new personnel.
• Increase the professionalism of personnel through applicable technical training under their area of assignment.
• Clearly define the roles, responsibilities, authorities, and functions of each person in the radiation facility (doctors, medical physicists, radiographers, nurses, administrative staff, and others).
• Provide a complete quality assurance program.
• Provide adequate and reliable resources (personnel, equipment, infrastructure, software, and hardware, etc.) according to the needs identified through risk assessment.
• Enhancing patient education regarding safety culture in various ways, for example, socializing the importance of a patient history record card stored by the patient himself.
• Lesson learning of unnecessary exposure incidents that have occurred.
Lesson Learned

Lesson learned is considered as one of the most effective incident prevention efforts. Lesson learned is part of knowledge management, which is a knowledge artifact that states knowledge in the form of experience, applies to an activity, decision, or process that, if reused, will have a positive impact on organizational results [16]. However, Figure 5 shows that 50% of facilities realized that incident record data give feedback on the improvement of radiation protection and safety systems for patients but only 16.7% of facilities implemented lessons learned from the incident. This is because most DIR facilities do not have a system that facilitates lessons learned, which of course is due to the mindset that there is no risk in DIR facilities. To overcome this, regulators (BAPETEN and MOH) and professional associations must collaborate to promote a system of lessons learned from an incident, for example by building frameworks or providing support for the following efforts:

• Review of the effectiveness of the corrective actions taken and communicates lessons learned from the incident to personnel involved in the incident and the investigation phase, and to the wide audience, for example by staff meetings, management meetings, incident review meetings at all facilities, or meetings between similar organizations.
• Establishment of a team that has functions to regularly review the lessons learned from all incidents, at least once a year. The purpose of this review is to identify any improvements throughout the system including systems that might not be identified because the incident was previously investigated and considered separately. The results of this review will be communicated to all staff.
• Review of some lessons periodically that have been identified from past incidents, in the context of investigating more recent incidents.
• Establishment of an online-based incident lesson learned system as a learning platform to optimize radiation protection and safety for patients in medical exposure situations. This system is generally integrated with an online reporting system.

CONCLUSION

In the profile mapping, unnecessary exposure control and prevention in DIR facilities generally has been carried out but it has not been systematically built, which is shown from the aspect of implementing incident identification was 44.4%, incidents recording and reporting was 38.9%, investigation and analysis was 44.4%, corrective action was 38.9%, preventive action through risk control was 44.4% and lesson learned was 16.7%. This situation is caused by the absence of a direct observed effect on the patient (such as injury) resulting in the neglect of all potential risks that may arise including the follow-up system to control and prevent it.

Unnecessary exposure incidents can occur at any time repeatedly and have a detrimental effect on patients, therefore safety culture needs to be promoted in each stakeholder. Leaders or top management must arrange concrete steps in preventing and controlling unnecessary exposure to patients by using various effective approaches for each facility, for example, the 3A approach (awareness, appropriateness, audit). BAPETEN, Ministry of Health, and professional association should support the efforts to control and prevent unnecessary exposure by establishing a clear regulatory and supervisory framework.

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