Application of HFMEA on risk assessment of radiology processes in public hospitals: a case study of Nyeri County Referral Hospital

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Abstract: *Use of radiology medical devices in hospitals pose a risk to the patients and medical practitioners. The device risks may be as a result of technical, operational, logistical or maintenance reasons. It for this reason, risk management practices should be employed in healthcare systems to ensure that risks hazards inherent in medical devices and those that come up as a result of interaction do not become a source of additional suffering to patients. Some of the reported unavailability of medical devices are attributed to non-adherence to risk management measures and failure to identify risks on time. Application of Healthcare Failure Mode Effect Analysis (HFMEA) technique in risk assessment of radiology processes is important because it ensures; that process mapping is done, hazards identified, risks from the identified hazards are assessed and a risk mitigation framework developed. This is otherwise referred to as risk impact assessment.It ensures that the risks identified are reduced and/or controlled to prevent recurrence. HFMEA as an assessment tool is preferred because it is well structured and healthcare specific.The technique determinesthrough 1-10 scale rating; the probability of hazard occurrence, the severity or the consequence of the hazard if it occurs to either the patient or the system and finally the detectability of the hazard before occurrence. The hazard ratings generated from risk assessment determine the hazard score and risk priority number. Depending on the rating results of each device, the clinical processes involved and the potential device risks; the risks are ranked from the most critical to the least critical. This assists the stakeholder to prioritize resources towards the high probability/high consequence risk events and develop mitigation strategies to optimise device availability.*
Keywords:HFMEA, risk assessment, Healthcare risks.

I.   Introduction

The healthcare system in Kenyan public hospitals has been marred by reported breakdowns and unavailability of critical medical devices, occasioned by long queues and prolonged waiting times. It is important to establish the root cause of this problem from the risk management point of view and especially the management of medical devices. The goal is to determine and analyse the risk factors or hazards that are inherent and those resulting from interaction with medical devices that can render them unavailable taking in consideration the life cycle of the devices. The motivation of the study was to come up with mitigation framework of the identified risks. The study focused on imaging devices in the radiology department at Nyeri County Referral Hospital.

The source of risks in medical devices are caused bytechnical, operational, logistical to maintenance reasons. Technical risks relates to power rating, loading capacity, rate of production and reliability of the device such as mechanical, electrical supply failure, design failure or use of wrong accessories. Operational risks relate to operation of the equipment, maintenance and the environment of use, human error and input and output data interpretation. Maintenance risks occur during different maintenance schedules or after the maintenance. Workers who carry out maintenance are exposed to a wide variety of hazards. These are: noise, vibrations, heat exposure, fumes, radiations, injuries, dust and electrical shocks among others (Work, 2009). Logistical risks relate to transportation of medical equipment, installation and disposal. Logistical delays of spare parts leads to prolonged downtime, delayed healthcare service and lost revenue(mfontanazza, 2012).

A pilot study was carried out, established that there are numerous challenges that the radiology practitioners in the Nyeri County referral hospital experienced. These challenges formed the justification that this study is worthy and viable. Maintenance and repair topped the list with 26.09% followed by shortage of staff at 21.74%, need for capacity building and power outages at 17.39% and lastly lack of radiologist and parts (consumables) at 8.7% as shown inFigure 1.
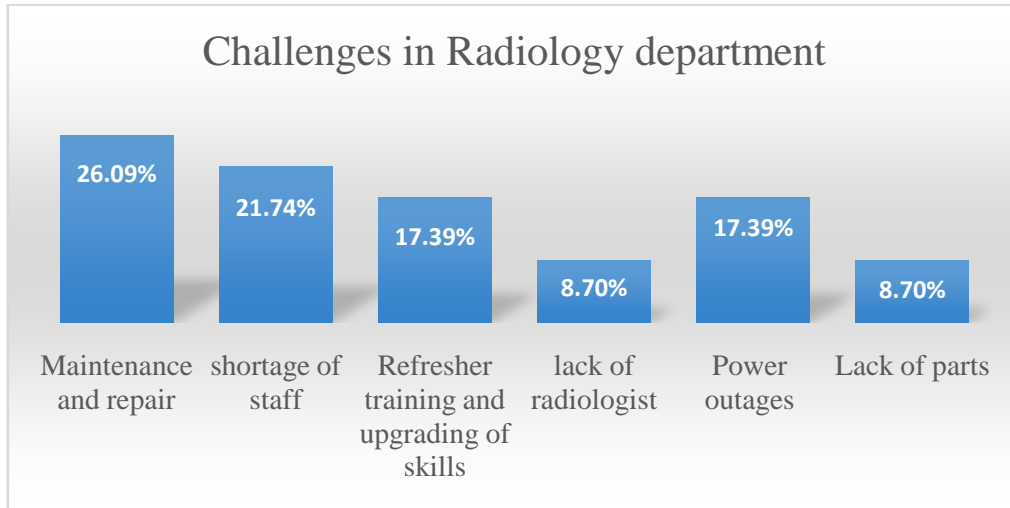

Figure 1: Challenges in the Radiology department

II. Risk Management framework

This is a systematic application of management policies, procedures and practices to the tasks of analysing, evaluating, controlling and monitoring risk (ISO-14971, 2007). According to the standard it is a requirement that an organisation should establish, document and maintain throughout the life-cycle an on-going process for identifying hazards associated with a medical device, estimating and evaluating the associated risks, controlling these risks, and monitoring the effectiveness of the controls. In other words risk management refers to the principles, framework and process for managing risks effectively. It is within the risk management framework that risk assessment is carried out to identify, analyse and evaluate risks (ISO-31000, 2009).

2.1   Risk Assessment

Risk assessment is an important component of managing equipment failures risks in hospitals. It is important that medical device manufacturers implement a full risk assessment process of a medical device and ensure that a solid risk management is also implemented (Dumbrique, 2010). This way, the potential risk of a product is readily addressed throughout the life cycle of the equipment including post-market phase.The Figure 2 shows the relationship between risk management and risk assessment, otherwise referred to as risk impact assessment. It involves assessing the probabilities and consequences of risk events if they are realized. The results of this assessment is used to prioritize risks to establish a most-to-least-critical importance ranking. Ranking risks in terms of their criticality or importance provides insights to the project's management on where resources may be needed to manage or mitigate the realization of high probability/high consequence risk events (Mitre.org, 2017). In the context of medical devices, risk assessment entails tracing and identifying device failure modes, analysing their probability of occurrence, severity or consequences, detectability and evaluation in relation to prescribed levels. Several techniques are prescribed in several studies as discussed below.
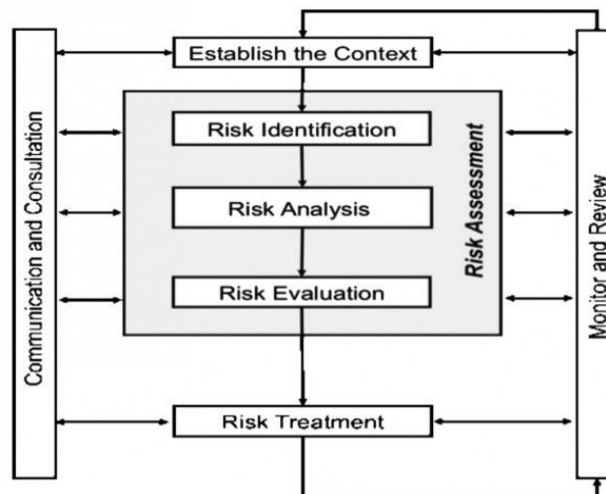

Figure 2: Risk Management process (Source: ISO-31000, 2009)

2.1.1 Risk assessment techniques

The ISO/IEC 31010 standard for risk assessment techniques propose several attributes necessary for applying generic risk assessment techniques (International Electrotechnical Commission, 2009). However, the proposed attributes are rather general and seldom linked to specific competencies (Peter Chemweno et al, 2015). These techniques follow a similar pattern (Cohrssen & Covello, 1989) but modified depending on individual situation and applicability of the tool to capture data accurately and the intended purpose (Duc Dang Vu, Tom Trappeniers, 2010). In this study, HFMEA was used, which is a modified form of FMEA developed by National centre for patient safety of the US; department of Veterans Affairs (NCPS, 2001). It is a systematic approach to identify and prevent problems in products and processes before they occur (Dyro, 2004),that improves steps in a process thereby reasonably ensuring a safe and clinically desirable outcome (NCPS, 2001). HFMEA streamlines the hazard analysis steps found in the traditional FMEA into an algorithm presented in a decision tree. It also replaces the calculation of the risk priority numbers with a hazard score that is read directly from a hazard matrix. It is a preferred technique because it is well structured and healthcare specific. Several studies indicates that HFMEA is a promising technique, but its disadvantage is time consuming and to an extent subjective,however itresults in thorough risk analysis and understanding of the process. The multidisciplinary team approach ensures that no failure modes are neglected or forgotten.

2.1.2 HFMEA Application process

The HFMEA process follows five steps as shown in Figure 3. This is according to (NCPS, 2001) and (ISO/IEC-31010, 2009).The steps are:
1) *Definition of the HFMEA*: Clearly defining the topic and narrowing down to manageable size;
2) Assembling a multi-disciplinary team of experts;
3) Graphically describing the process and sub-processes through a flowchart and recording in HFMEA worksheet whose sample is shown in Table 1

4) *Conducting a hazard analysis* by:
a) Listing all possible failure modes per sub process and recording it in the HFMEA worksheet through brainstorming sessions, database reviews, usability tests and patient safety rounds;
b) Determination of probability of occurrence and severity rating using respective ratings on Table 2.
c) Determination of hazard score by multiplying the occurrence rating and severity rating, and the results is filled in the HFMEA worksheet. The hazard score is presented in form of a matrix for evaluation purposesTable 3.
d) Determining if further action is required by using the decision tree shown in Figure 3 and record in the HFMEA worksheet.
e) Listing all causes for the important failure modes on the HFMEA worksheet and deciding whether they need to be taken care of or not.
5) *Actions and outcome measures*: Recording corrective or preventive actions for each of the causes and define mitigation measures. If the measures are applied to reduce risks, they should be retested again to establish if the control measures are effective or they have generated other risks.

Table 1: HFMEA Worksheet

Problem Area or Activity	Potential Failure Mode	Potential Causes	Probability of Occurrence (O) 1 to 10	Severity Rating (S) 1 to 10	Hazard Score (O×S)	Detectability (D) 1 to 10	RPN (O×S×D)	Existing Measures	Mitigation Strategy
Image Requisition	Insufficient patient's clinical data on image requisition Form	The form does not have a provision for the data	8	5	40	2	80	Patient data stored in a patient file	The RRF to have adequate patient data
		The hospital records do not have patients biod data	7	4	28	5	140	The hospital in the process of automate patient data	Putting in place efficient and reliable Healthcare information System
		oversight by the clinician requesting the image	5	5	25	6	150	Automation process started	conducting refresher and capacity building of clinicians and technicians
	Failure to record patient's contraindications	patient with conditions or gadgets that may cause a risk upon imaging is unknown to the clinician or the patient does not divulge the information	4	8	32	4	128	Due diligence by the clinician to record relevant patient information	
	Incorrect image requested	The manifestation of the ailment according to the patient may indicate a position away from the actual position	4	5	20	4	80	Emphasis on proper diagnosis	

The risk evaluation of this study was done on the risk analysis results to make a judgment on acceptability of the risks based on an agreed criteria in a risk management plan (AAMI, 2015). Decisions have to be made on the degree of risk acceptability, whose criteria is based on the hospital standards, prescription by the product specific standards of the manufacturer and international regulatory bodies such as WHO (WHO,

2003). This process informed the methodology that was applied to collect and analyse data as discussed in the section below.
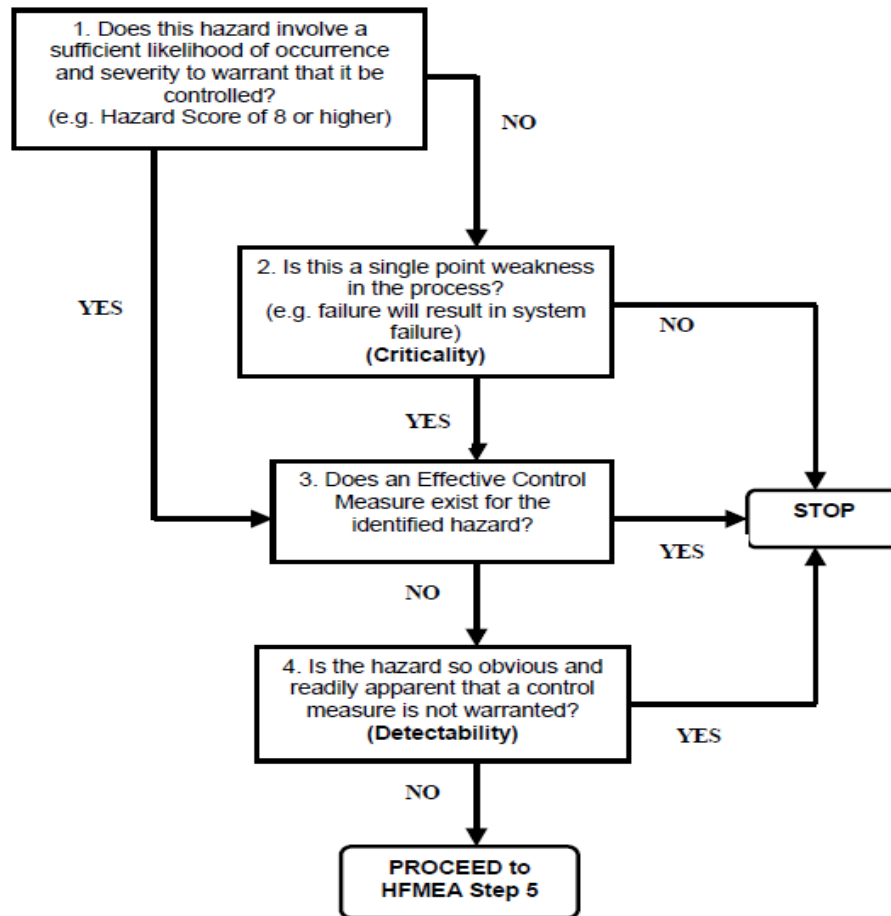

Figure 3: Decision tree(NCPS, 2001)

III. III Methodology

The study approach employed two designs; a survey methodology and a targeted group discussion forum as prescribed HFMEA application process with minor variations without compromising the validity of the results. Due to shift distribution of staff in the department, the discussion forum was conducted in the evenings when the patient traffic was low with two or three radiographers on duty, and the findings recorded were subjected for validation by whole group. Where there were conflict of views and opinions, further discussion was carried out for clarification and agreement. This ensured that the opinions of every member of the group was factored in and agreed upon. The group comprised of; the lead researcher, the hospital biomedical engineer, five radiographers and a master's student in engineering. The team was selected based on relevant experience and expertise in radiology and knowledge of risk management. The methodology followed the process as shown in the Figure 4, and outlined below as process mapping, identification of risks, risk assessment and development of risk mitigation framework.
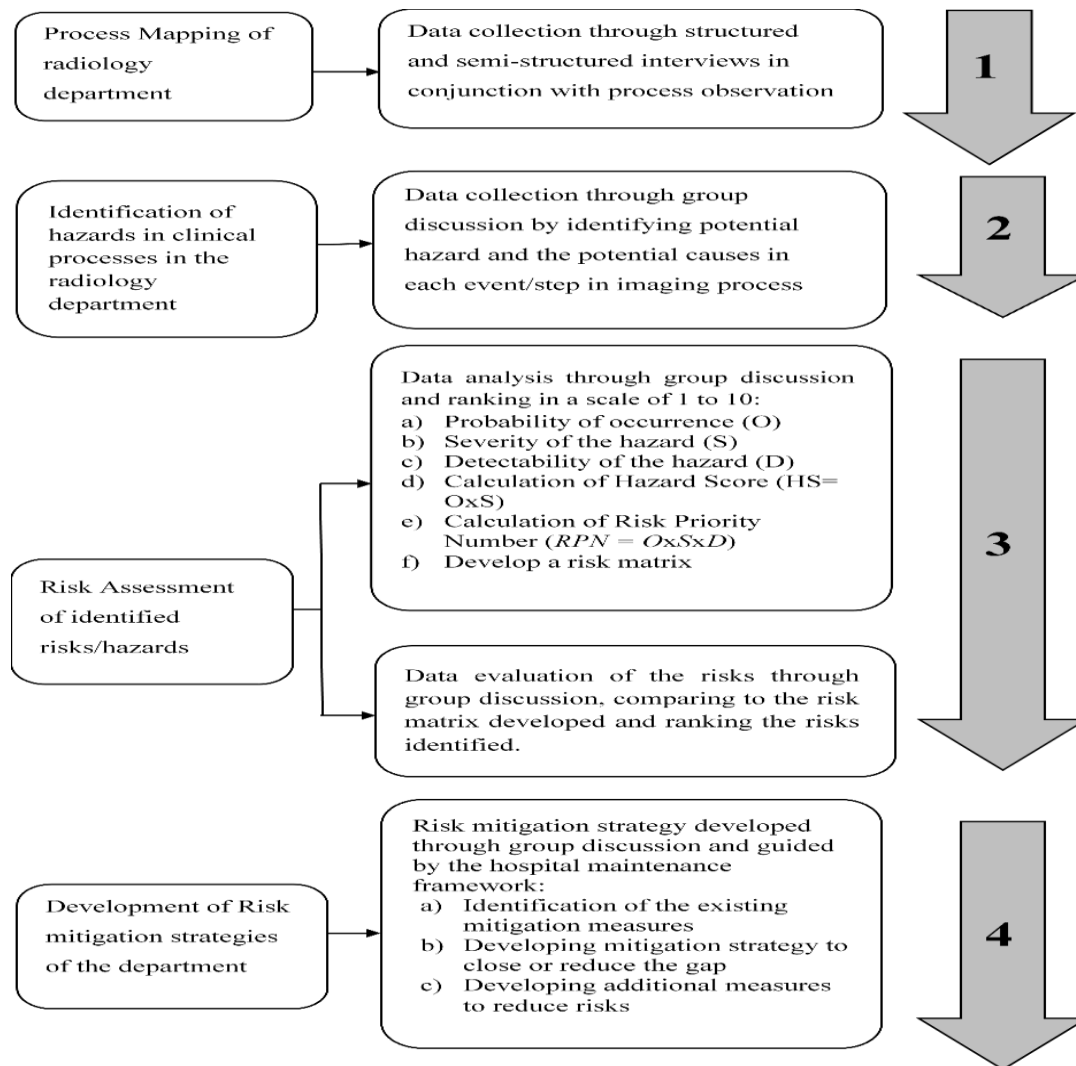
Figure 4: Steps followed in methodology

3.1 Process Mapping of Radiology Department
This stage was achieved through structured and semi-structured interviews and process observation. The output was to generate a process flow diagram shown Figure 5: Process map. This was done by looking at activities and events in the department to determining the healthcare process of each device.

3.2 Identification of risks and analysis
Through discussion forum, every mapped event in the imaging process was looked and a potential hazard identified together with its potential causes. On identified hazards and risks, assessment was done that started with risk analysis and then risk evaluation of the same. Risk analysis entails analysis and ranking probability of occurrence (O), severity of the hazard (S) detectability of the hazard (D), and all ranked in a scale of 1 to 10 using ranking criteria shown in Table 2. The calculation of the hazard score (HS = O×S) was calculated to determine the effect of the risk on the system. The Risk Priority Number was also calculated.

3.3 Risk Evaluation
To evaluate the risks, an acceptable evaluation criteria was formulated since the hospital had no documented procedure or guideline. The criteria was based on a requirement that any hazard in a medical device that is likely to cause an injury to the patient, user, the device or the system was unacceptable. For the foregoing reason the decisions below were arrived at:

a)   *Acceptable risks:* Any severity rating below a scale of 4 was considered acceptable. Equally probability of occurrence below a Scale 5 (Moderate Probability) was also considered acceptable. Therefore any hazard score below 20 (4x5) was considered acceptable.

b)   *Unacceptable risks:* The severity rating of 7 and above is considered dangerous thus not acceptable. The frequency of occurrence scaled 7 (Very High probability) and above is unacceptable. Therefore a hazard score above 49 (7x7) is unacceptable

c)   *Acceptable if reduced to "As Low as Reasonably Possible" (ALARP)*: Between the totally acceptable and totally unacceptable hazard scare rating, there is a range between 20 and 49 that is always considered acceptable if it is reduced to acceptable levels. This range is characterised severity rating that is above 4 that happens frequently thus patients denied services. Equally the frequency may be low with high severity. This situations happens as a result of device breakdown of failure. Mostly hazards in this range can be reduced by correcting the root cause.

With the Hazard score determined, the product of hazard score with detectability determines the Risk Priority Number (RPN). The detectability score of 4 (High probability of detection) and below is acceptable. Therefore the most acceptable Risk Priority Number is 80 or (4x5x4). The criteria was used to rank and evaluate the results obtained in the study.

Table 2: Probability, Severity and detection rating (Source (Eavan Thornton et al, 2011)

PROBABILITY OF OCCURRENCE RATING	SCORE	SEVERITY RATING	SCORE	DETECTION RATING	SCORE
Remote – no known occurrence	1	**Slight annoyance –** No injury to the patient or impact on the system	1	**Certain –** error will always be detected	1
Low probability – rare failures (Yearly)	2	**Slight danger –** No injury to the patient	2	**Very high probability** that error is detected	2
Moderate probability – occasional failures (quarterly)	3,4	**Low to moderate danger –** Very minor or no injury to the patient	3,4	**High probability** of detection	3,4
Moderately high probability (monthly)	5,6	**Moderate Danger –** Minor or no injury to the patient	5,6	**Moderate chance** that error is detected	5
Very high probability – frequent (weekly)	7,8	**Dangerous –** Minor to moderate injury to the patient	7	**Remote chance** of detection only	6,7
Inevitable and predictable failure	9	**Very dangerous –** May result in major injury to the patient	8,9	**Remote or low** likelihood of detection	8,9
Certain probability – daily or every time	10	**Extremely Dangerous –** May cause death to the patient	10	**No chance** that error is detected; no mechanism exists	10

IV. Results and Discussions

        The process mapping generated a nearly common feature for all the radiology devices, and summarized as shown in Figure 5: Process map. This process map was used to generate potential failure modes, potential causes and subsequently analysis of the processes using criteria on Table 2. All these data was recorded in the HFMEA worksheet as shown in Table 1.

        The interpretation of the results was done using the hazard score matrix Table 3 and RPN ranking Figure 7. Interpretation of the results is discussed in section 4.1 below.
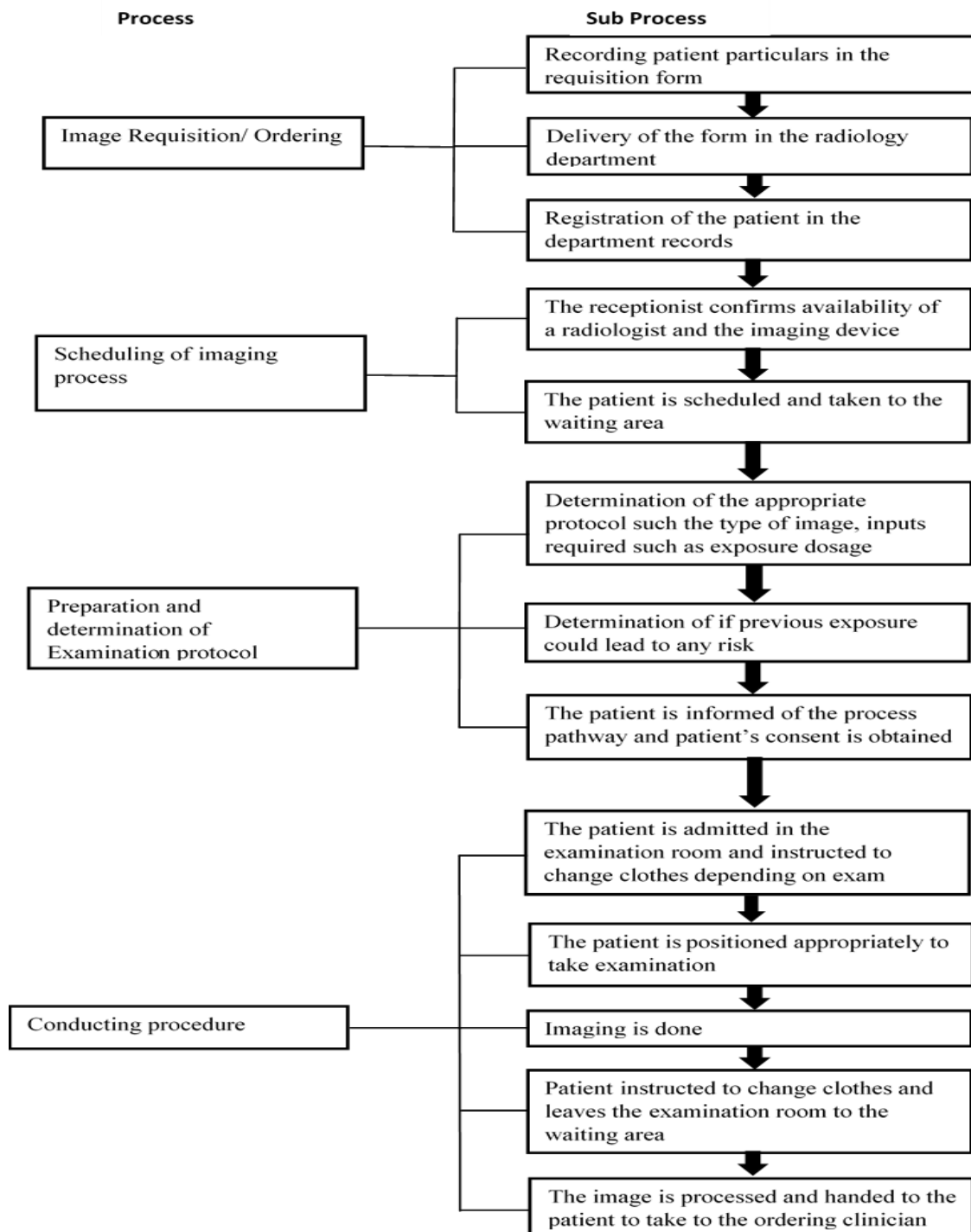
Process   **Sub Process**

Process	Sub Process

Image Requisition/ Ordering

Recording patient particulars in the requisition form

Delivery of the form in the radiology department

Registration of the patient in the department records

Scheduling of imaging process

The receptionist confirms availability of a radiologist and the imaging device

The patient is scheduled and taken to the waiting area

Preparation and determination of Examination protocol

Determination of the appropriate protocol such the type of image, inputs required such as exposure dosage

Determination of if previous exposure could lead to any risk

The patient is informed of the process pathway and patient's consent is obtained

Conducting procedure

The patient is admitted in the examination room and instructed to change clothes depending on exam

The patient is positioned appropriately to take examination

Imaging is done

Patient instructed to change clothes and leaves the examination room to the waiting area

The image is processed and handed to the patient to take to the ordering clinician

Figure 5: Process map

		Severity rating									
		Extremely Dangerous	Very dangerous	Very dangerous	Dangerous	Moderate Danger	Moderate Danger	Low to moderate danger	Low to moderate danger	Slight danger	Slight annoyance
Probability of Occurrence	Certain Probability	100	90	80	70	60	50	40	30	20	10
	Inevitable / Predictable failure	90	81	72	63	54	45	36	27	18	9
	Very High Probability	80	72	64	56	48	40	32	24	16	8
	Very High Probability	70	63	56	49	42	35	28	21	14	7
	Moderately High probability	60	54	48	42	36	30	24	18	12	6
	Moderately High probability	50	45	40	35	30	25	20	15	10	5
	moderate probability	40	36	32	28	24	20	16	12	8	4
	moderate probability	30	27	24	21	18	15	12	9	6	3
	Low Probability	20	18	16	14	12	10	8	6	4	2
	Remote	10	9	8	7	6	5	4	3	2	1

KEY

Unacceptable
As Low as Reasonably Possible (ALARP)
Acceptable

Table 3: Hazard Score Matrix

4.1 Risk ranking and mitigation measures
4.1.1 Hazard Score

A total of 25 potential risks were identified in the study as shown in Figure 6. It was noted one risk (Unavailability of imaging devices) was ranked unacceptable at 63. Nine risks were ranked ALARP, three of which are related to the request form and the rest are potential failures during imaging procedure and related to oversite on the part of the radiographers or the requesting clinician. These are risks that can be reduced through capacity building and sensitization. The 15 failure modes ranked 20 and below were considered acceptable, though mitigation measure should put in place to ensure they do not escalate to the ALARP or unacceptable region.

Figure 6: Hazard Score ranking

4.1.2   Risk priority number

The RPN ranking as shown in Figure 7, added a factor of detectability on the potential failure modes identified and analysed. Based on the acceptability criteria discussed in section 3.4, any RPN over 80 is deemed unacceptable. "Over-exposure of patients to radiations" ranked highest among the risks at 216, followed by "failure to obtain consent from the patient before the procedure is done". It can be noted that risks related to the radiology request form information causes a trail of other risks thus ranked higher. It was noted that some hazard scores that were in ALARP region and due to detectability developed unacceptability. Like hazard scores, mitigation measure should be employed to reduce the risks. Individual mitigation measure are discussed in Table 3:) and general recommendations given below. Most of the potential failure modes can be prevented without incurring very high costs.

Figure 7: Risk Priority Number ranking

4.2   Existing Measures and Mitigation strategies

From data available and through the discussion forum, it was observed that the hospital has some mitigation measures to some of the risks, but in some cases there were no measures put in place. It is prudent that all risks should be reduced to as low as reasonably possible. In some cases where there were no measures in place to prevent the risks, mitigation measures were suggested. The completed table 1 formed the risk management profile of the radiology department of Nyeri County referral hospital. The ranking of risks will inform the hospital management on the risks that they will give high priority.

4.3   Conclusion and Recommendations

The study findings necessitated several recommendations, that once addressed will mitigate the risks in the radiology department and in some cases spill over to other departments with similar procedures. The recommendations suggested are:

a)   Insufficient data in the radiographic request form is the source of high risks, a correction measure should be put in place by either amending the form to have sufficient data or putting in place a management information system that can capture the data.

b) The hospital administration should consider taking radiographer, biomedical engineers, clinicians and any other medical personnel directly involved with radiology process through some refresher training on emerging trends and imaging requirements. This will ensure that some minor hazards such as requirements of knowing the patients contraindications, previous exposure or the right devices for the different ailment diagnosis is mastered. This can also include a forum whereby radiographers and clinicians discuss and standardize procedures

c) The hospital should consider developing a comprehensive maintenance strategy to ensure that all medical devices are available at optimal level. The strategies should include periodic maintenance, and preventive maintenance.

d) The hospital can also consider developing a process chart in several departments to inform patients the general treatment pathway. This ensures that the patients have an idea of the steps they will take and thus reduce stress and anxiety.

e) It will be prudent to implement a policy that ensures safety of patients, users and the machines are guaranteed. This includes ensuring that the radiation leakages are within the legal limit.

f) The study itself was limited to the radiology department, and can be extended to other departments that highly require risk assessment. A general survey of other departments, revealed that the HFMEA tool can be used in the Physiotherapy, Hospital laboratory, renal department, and maintenance department.

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