المركز السعودي لسلامة المرضى
SAUDI PATIENT SAFETY CENTER

Sentinel Event Reporting and Management Policy

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V1

Introduction

Maintaining safety and quality standards is essential for the effective delivery of healthcare services. Enhancing safety begins with understanding and addressing the risks associated with unsafe practices and conditions. Despite the inherent risks, many adverse events can be prevented through proactive measures such as identifying contributing factors, fostering a safety culture, and tackling system flaws. Hence, these precautions lead to reduce process inconsistencies and patient harm. As the groundwork for learning from sentinel events, unified and robust mechanisms should be implemented for reporting and standardized approaches. These efforts help feeding the system and promoting the culture of safety and continuous improvement in healthcare facilities.

Accordingly, the Saudi Patient Safety Center (SPSC) is mandated to establish a mechanism for reporting sentinel events in alignment with the Saudi Health Council resolution (5/83) dated 28/12/1439 H and Ministerial approval (64570) dated 1/12/1441 H. Therefore, this policy outlines the ground rules for the healthcare facilities across the Kingdom of Saudi Arabia with a standardized framework to ensure robust reporting and analyzing sentinel events, including a detailed list of reportable sentinel events to assure consistency and accountability to improve patient safety.

Acknowledgement

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1. Policy Statement

This policy aims to standardize the process of reporting, identifying, tracking, investigating, and managing sentinel events. It encourages healthcare organizations to develop tailored policies and procedures that align with their unique needs and available resources. By fostering a structured approach, the policy seeks to promote learning from sentinel events and prevent their recurrence.

2. Scope

- This policy applies to all healthcare facilities.
- Legal and Disciplinary processes are outside the scope of the framework.

3. Definitions / Abbreviations

Adverse Event
An unintended event occurring during healthcare provision that results or has the potential to result in physical or psychological harm to patient (1).

Contributory Factors
A circumstance, action or influence which is thought to have played a part in the origin or development of an incident or to increase the risk of an incident. Also known as causation or causative factors (2).

Corrective Action Plan (CAP)
A step-by-step plan of action that is developed to achieve targeted outcomes for resolution of identified errors in an effort to identify the most cost-effective actions that can be implemented to correct error causes, develop and implement a plan of action to improve processes or methods so that outcomes are more effective and efficient, achieve measurable improvement in the highest priority areas, eliminate repeated deficient practices.

Event Discovery Date
The event discovery date refers to the date when a sentinel event or adverse event is first identified or recognized by healthcare personnel or the healthcare facility.

Harm
An outcome that negatively affects a patient's health and/or quality of life (3).

Healthcare Facility
Facilities that provide health care services. They include, but are not limited to hospitals, clinics, outpatient care centers, primary healthcare centers, and specialized care centers.

Just Culture
A culture in which frontline personnel are comfortable disclosing errors, including their own, while maintaining professional accountability, recognizing individual practitioners should not be held accountable for system failings over which they have no control, yet does not tolerate conscious disregard of clear risks to patients or gross misconduct.

Open Disclosure
The open discussion of an incident that results in harm (or might result in future harm) to a patient while receiving health care. The elements of Open Disclosure are an expression of regret, a factual explanation of what happened, the potential consequences and the steps being taken to manage the event and prevent recurrence.

Patient Safety
Freedom from unintended or unexpected harm during healthcare provision (1).

Permanent Harm
Life-changing unintended outcomes or suffering. This can include events resulting in permanent loss of organ, limb, or vital physiologic or neurologic function. There is no expected change in the patient's status or condition (4).

Severe temporary harm
Critical, potentially life-threatening unintended outcomes or suffering. Response to this deviation can include: a prolonged transfer to a higher level of care/ monitoring; an additional major surgery, procedure or substantial

treatment to resolve the condition; or an unnecessary significant treatment or procedure. The unintended outcomes last for a limited period of time with no permanent residual (4).

Sentinel Event (SE)
An adverse event leading to patient death, severe or permanent physical or psychological harm (1)

Root Cause Analysis (RCA)
A comprehensive and systematic analysis method using tools that focus on systems and processes for identifying the causal and contributing factors that resulted in the event.

4. Policy

4.1 All healthcare facilities should establish their own internal reporting mechanism and develop a Sentinel Events policy that aligns with this policy.

4.2 Any identified event related to patient safety must be reported immediately through the healthcare facility's internal reporting system.

4.3 The healthcare facility's Chief Executive Officer (CEO) or their designee should be notified within 24 hours.

4.4 The Patient Safety Investigation Team should be activated promptly to conduct a Root Cause Analysis (RCA) of the Sentinel Event.

4.5 All Sentinel Events included but not limited to the categories outlined in the **(Annex.1)** should be reported within 48 hours of the Event Discovery Date to the SPSC Platform.

4.6 All Sentinel Event Root Cause Analysis (RCA) and Corrective Action Plans (CAP) must be completed and submitted within 30 working days of the Event Discovery Date to the SPSC Platform.

4.7 All healthcare facilities should have a patient safety event Disclosure Policy aligned with the SPSC Disclosure Policy.

4.8 All healthcare facilities should have a fair response mechanism to the staff involved in the event by applying Just Culture principles.

4.9 All healthcare facilities need to train and encourage their staff about incident reporting.

4.10 All healthcare facilities should collaborate and response in a timely manner to the events detected by SPSC.

4.11 All healthcare facilities should implement all necessary measures to ensure the confidentiality and security of reported events.

5. Procedures

5.1 Immediate Response:

5.1.1 As an immediate response, the staff (discoverer) must prioritize patient and environmental safety after an event has occurred or a hazardous condition has been identified. The staff should also notify the treating physician or attending team as necessary.

5.1.2 Upon discovery of the event, the disclosure must be conducted to the patient and their family using understandable language, in accordance with the SPSC Disclosure Policy.

5.2 Reporting Procedures:

5.2.1 The staff (discoverer) must report the identified events to Quality and Patient Safety department through the healthcare facility reporting system and notify direct manager or department head.

5.2.2 The Quality and Patient Safety Director should determine if the reported event is a Sentinel Event based on the below conditions:

5.2.2.1 Any event that falls under the below categories and match the definition outlined in the (**Annex.1**):

1. Abduction of any patient receiving care within a healthcare facility.
2. Discharge of an infant to the wrong family.
3. Discharge of a Minor or Incapacitated Patient to an unauthorized person.

4. Maternal death, permanent harm, or severe, temporary harm *
5. Suicide, attempted suicide, or self-harm that results in severe, temporary harm, permanent harm, or death while being cared for in a healthcare setting or within 72 hours of discharge, including the emergency department *
6. Surgery/invasive procedures performed at the wrong site, on the wrong patient, or the wrong procedure *
7. Administration of incompatible ABO, Non-ABO of blood/ blood products, or transplantation of incompatible organs *
8. Unintended retention of a foreign object in a patient after surgical/invasive procedure *
9. Neonatal death, permanent or sever temporary harm*
10. Rape of a patient, staff member, licensed independent practitioner, student and intern visitor, or vendor while on-site at the healthcare facility *
11. Assault leading to death, permanent harm, or severe, temporary harm, or homicide of a patient, staff member, licensed independent practitioner, student and intern visitor, or vendor while on-site at the healthcare facility *
12. Fire, flame, or unanticipated smoke, or flashes occurring during patient care within a healthcare facility *
13. Unauthorized departure of the patient (absconded) while on care from the healthcare facility that resulted in death, permanent harm, or severe temporary harm
14. Medication error leading to death, permanent, or severe temporary harm *
15. Patient death, permanent or severe temporary harm associated with venous thromboembolism (VTE) *
16. Patient death, permanent, or severe temporary harm as a result of medical device breakdown or failure when in use
17. The unexpected collapse of any building or malfunctioning structure within a healthcare facility *
18. Transfusing/transplantation of contaminated blood, blood products, organ or tissue
19. Death or serious disability associated with failure to manage/identify neonatal hyperbilirubinemia (bilirubin >30 milligrams/deciliter) *
20. Delivery of radiotherapy to the wrong body region or dose exceeds more than 25% of the total planned radiotherapy dose *
21. Any (stage 3, 4 or unstageable) healthcare facility- acquired pressure injury (ulcer)
22. Unexpected death, permanent or severe temporary harm associated with transport/transfer of patients
23. Patient death, permanent harm, or severe temporary harm as a result of patient fall *
24. Patient death, permanent harm, or severe temporary harm associated with wrong administration/connection of medical gas
25. Transmission of disease as a result of using contaminated instruments or equipment provided by the healthcare facility
26. Intraoperative or immediately postoperative/post-procedure death in an ASA Class I patient within the healthcare facility *
27. Accidental burn of second degree and above during patient care.

5.2.2.2 Any event that does not match the categories above but meets the sentinel event definition, where the event reaches the patient and results in death, severe, or permanent physical or psychological harm.

5.2.3 If the event is identified as Sentinel Event the Quality and Patient Safety Director should notify the facility's CEO or their designee within 24 hours to activate the Patient Safety Investigation Team.

5.2.4 The Quality and Patient Safety Director should report the Sentinel event through the SPSC platform within 48 hours of the Event Discovery Date and any other relevant authority.

5.2.4.1 If the event included two categories, they should be reported separately. (e.g. In the event where both the mother and neonate are affected, it is imperative to report their involvement separately under the respective categories: one under the maternal category and the other under the neonate category, respectively. This ensures proper documentation and analysis, supporting targeted actions to address maternal and neonatal care issues.

5.2.4.2 The Quality and Patient Safety Director should provide detailed information related to the event, such as: What happened, location, level of harm, who is affected, etc.

Categories marked with an asterisk (*) reflect changes to the description, inclusion, or exclusion criteria compared to the Saudi Healthcare Sentinel Event Manual.

5.3 The investigation Process and Action Plan

5.3.1 The Patient Safety Investigation Team should be chaired by a designated leader with expertise in quality management or patient safety and consist of relevant stakeholders, comprising four to six professionals, ideally, the Patient Safety Investigation Team should include:

5.3.1.1 A Subject Matter Expert in the event under investigation.

5.3.1.2 A staff member who is not familiar with the incident under investigation

5.3.1.3 An experienced Root Cause Analysis (RCA) facilitator, preferably Quality and Patient Safety Personnel.

5.3.1.4 A frontline staff.

5.3.1.5 The RCA team may also include managers and supervisors, depending on the event's scope.

5.3.1.6 It is not advised to include any staff directly involved in the event or supervisors/managers of the department where the event has occurred in the RCA team to avoid any potential conflict of interest.

5.3.2 The Patient Safety Investigation Team should initiate the investigation process which include the following:

5.3.2.1 Provide support to the staff involved in the event.

5.3.2.2 Interview of patient/family, if applicable, and staff who were directly involved in the event.

5.3.2.3 Access to patient medical records and all documents related to patient care shall be provided to the committee/team.

5.3.2.4 Conduct a credible RCA for identifying the root causes and contributory factors, using the RCA and CAP template (**Annex.2**).

5.3.2.5 Apply Just Culture Principles and tool to determine staff behavior associated with the event.

5.3.3 The investigation process should aim to identify systematic factors that contributed to the occurrence of the event rather than concentrating solely on the performance of individual healthcare providers.

5.3.4 The identified causes and contributing factors in the RCA should be documented and written as causal statements (for example the causal statement can be written as: (cause) lead to (effect) which result in (event)).

5.3.5 The Patient Safety Investigation Team should develop at least one CAP to each cause and contributing factor (CF).

5.3.6 Each proposed corrective action should be strong or intermediate action as classified in the Action Hierarchy in the RCA and CAP template.

5.3.7 Each proposed corrective action should be assigned to a responsible individual with a target date for completion.

5.3.8 The RCA report and CAP should be reviewed and approved by all the Patient Safety Investigation Team members and leader/chairperson before they are approved by the facility's CEO or their designee.

5.3.9 Approved Sentinel Event RCA and CAP should be submitted to the SPSC platform within 30 working days from the Event Discovery Date.

5.3.10 During the submission process to SPSC platform, the Quality and Patient Safety Director must ensure that all fields are comprehensively filled.

5.4 Implementation of CAP and Monitoring

5.4.1 The facility's CEO should be responsible for implementing the corrective action plans.

5.4.2 The Quality and Patient Safety department is responsible for measuring and monitoring the effectiveness of the CAP in collaboration with relevant departments.

5.5 If SPSC team detects a sentinel event from any source (e.g., social media, direct patient complaints, or SPSC communication channels):

5.5.1 They will notify the facility by email to report the event on the SPSC platform. The facility is expected to report or respond to the email within two working days.

5.5.2 If the facility does not respond within the specified time, SPSC will escalate the matter in accordance with its escalation mechanism.

5.6 In cases where a sentinel event involves two or more facilities:

5.6.1 If both facilities are within the same governing body, the facility that discovered the event must follow the governing body's reporting policy.

5.6.2 The Quality and Patient Safety Director of the governing body is responsible to coordinate between these facilities and ensuring the event is reported to SPSC platform within the established time frame.

5.6.3 If the other facility is under a different governing body, the discovering facility must notify SPSC through the SE email: se@spsc.gov.sa. SPSC will then facilitate notification and coordination between the involved facilities to ensure the event is reported to SPSC platform within the established time frame.

6. Monitoring Performance Measurement

6.1 SPSC measures and monitors the adherence of the healthcare facility to this policy.

6.2 All healthcare facilities need to develop an internal performance improvement measure to monitor the implemented reporting mechanism.

7. Roles and Responsibilities

7.1 Healthcare Providers:

7.1.1 They are responsible for promptly reporting any identified Sentinel Event Immediately.

7.2 Quality and Patient Safety Directors:

7.2.1 They are responsible for determining if the reported event is a Sentinel Event or not.

7.2.2 They are responsible for notifying the facility's CEO or their designee about the Sentinel event within 24 hours.

7.2.3 They are responsible for ensuring the accurate submission of Sentinel Event reports to the SPSC platform within 48 hours of the event discovery date.

7.2.4 They are responsible for ensuring the quality, appropriateness, and timely submission of the Root Cause Analysis (RCA) and Corrective Action Plans (CAP) to the SPSC platform within the established 30-working-day timeline.

7.2.5 They are responsible for ensuring that timelines and responsibilities for implementing corrective actions are clearly outlined and communicated to all relevant parties.

7.2.6 They are responsible for measuring and monitoring the effectiveness of the CAP in collaboration with relevant parties.

7.2.7 They are responsible for ensuring the confidentiality and security of reported events by restricting access to authorized personnel only.

7.2.8 They are responsible for responding to SPSC notifications within two working days to avoid escalation of the matter.

7.3 Patient Safety Investigation Team:

7.3.1 They are responsible for conducting RCA and developing Corrective Action Plans (CAP).

7.3.2 They have the authority to conduct interviews with individuals at all levels of the organization who were involved in the event or possess knowledge related to the associated processes.

7.3.3 They are responsible for adhering to established timelines (30 working days) for completing the RCA and developing CAP.

7.4 The Healthcare Facility's Chief Executive Officer:

7.4.1 They are responsible for activating the Patient Safety Investigation Team upon confirmation of a Sentinel Event.

7.4.2 They are responsible for approving the Root Cause Analysis (RCA) and Corrective Action Plans (CAP).

7.4.3 They are responsible for implementing the corrective action plans.

7.5 The Saudi Patient Safety Center:

7.5.1 They are responsible for managing sentinel event data by ensuring all submitted information is kept private and confidential.

7.5.2 They are responsible for analyzing sentinel event data, trending it on a de-identified basis, and sharing lessons learned and recommendations to promote patient safety improvements.

7.5.3 They are responsible for responding to inquiries from healthcare facilities and, when necessary, coordinating between facilities related to sentinel events.

7.5.4 They are responsible for monitoring compliance with this policy to ensure adherence to the established guidelines and timelines by healthcare facilities.

7.5.5 They are responsible for conducting regular reviews and updates of the policy every three years or as needed to ensure alignment with changes in regulations or best practices.

8. Annexes

Annex.1: List of Reportable Sentinel Event

1. Abduction of any patient receiving care within a healthcare facility	
Event Description	This event is intended to capture all instances when patients of any age are abducted from a healthcare facility regardless of whether death, permanent harm or severe and temporary harm occurred or not (5).
Inclusion	• Abduction cases for any patients, whether under care or receiving care of any age group and health conditions (i.e., regardless of a patient's health condition) within a healthcare facility's premises/campus.
Exclusion	• Areas outside of the premises/campus of a healthcare facility. • Healthcare facility visitors and patients' companions. • Patients present within the premises/campus of a healthcare facility but not yet under care.

2. Discharge of an infant to the wrong family	
Event Description	This event is intended to capture all cases where an infant was discharged to the wrong parent/legal guardian regardless of whether death, permanent harm, or severe, temporary harm occurred or not (5).
Inclusion	• All incidents where an infant is discharged to the wrong parent/legal guardian.
Exclusion	• None

3. Discharge of a Minor or Incapacitated Patient to an unauthorized person	
Event Description	This event is intended to capture all cases where a minor or incapacitated patient was discharged to an unauthorized parent/legal guardian regardless of whether death, permanent harm, or severe, temporary harm has occurred or not (6). **Minor is defined as** a person whose cognition has not been completed and at the age of eighteen or less (7). **Incapacitated patient is defined as** an adult individual who lacks the ability to meet essential requirements for physical health, safety, or self-care and /or unable to receive/evaluate information or make/communicate decisions. Translated from (7).
Inclusion	• All incidents due to the failure to double-check and/or identify the correct family, parents, or legal guardian before discharge.
Exclusion	• None.

4. Maternal death, permanent harm, or severe, temporary harm *	
Event Description	This event is intended to capture death, permanent harm, or severe, temporary harm cases of women while pregnant or within 42 days of the termination of pregnancy (8).
Inclusion	• Any cause related to or aggravated by the pregnancy or its management (8).
Exclusion	• Accidental causes like motor vehicle collisions.

5. Suicide, attempted suicide, or self-harm that results in severe, temporary harm, permanent harm, or death while being cared for in a healthcare setting or within 72 hours of discharge, including the emergency department *	
Event Description	This event is intended to capture all cases of suicide, attempted suicide, or self-harm while being under care in any healthcare facility (9).
Inclusion	• Any patient identified as “at risk of suicide” and/or discharged from a healthcare facility without proper assessment/family education. • Failure to assess and/or identify a patients’ risk of suicide. • Failure to manage/monitor patients “at risk of suicide” during an inpatient stay or failure to educate a patient’s family about the suicidal risk upon discharge.
Exclusion	• Patients present within a healthcare facility but not yet under care (prior to medical contact), e.g., attempts suicide in the healthcare facility restroom prior to registration (10).

6. Surgery/invasive procedures performed at the wrong site, on the wrong patient, or the wrong procedure *	
Event Description	This event is intended to capture all surgical/invasive procedures performed on the wrong patients, wrong site, wrong procedure, or wrong implant/ prosthesis regardless of whether death, permanent harm, or severe, temporary harm has occurred or not (5). **Invasive procedures defined as** one where purposeful/deliberate access to the body is gained via an incision, percutaneous puncture, where instrumentation is used in addition to the puncture needle, or instrumentation via a natural orifice (11).
Inclusion	• Any surgical/invasive procedure performed on the wrong patient, wrong site, wrong procedure, or wrong implant/ prosthesis. • Dental procedures involving teeth extraction.
Exclusion	• Dental procedures involving the extraction of a primary tooth.

7. Administration of incompatible ABO, Non-ABO of blood/ blood products, or transplantation of incompatible organs *	
Event Description	This event is intended to capture cases involving the unintentional administration of incompatible ABO, non-ABO of blood/blood products, or transplantation of incompatible organs regardless of whether death, permanent harm, or severe, temporary harm occurred or not.
Inclusion	• All cases involving the administration of incompatible blood/blood products or organs.
Exclusion	• Situation where solid organs that are clinically suitable but ABO incompatible are intentionally transplanted (12).

8. Unintended retention of a foreign object in a patient after surgical/invasive procedure *	
Event Description	This event is intended to capture all cases involving the unintended retention of a foreign object in a patient after surgery or other invasive procedure, regardless of whether death, permanent harm, or severe, temporary harm occurred or not (5).
Inclusion	• All cases involving the unintended retention of a foreign object in a patient, regardless of whether the retained object was discovered within a healthcare facility during hospitalization post-procedure or post-discharge. • Any item is subject to a formal counting/checking process at the start of a surgical/invasive procedure and before completing the procedure, such as swabs, needles, instruments, and guidewires. • Unintentional retention of the surgical (items, such as gauze, towels) in the patient's vagina during vaginal delivery.
Exclusion	• Any object left for medical reasons in a patient, e.g., sutures, stents, implants, and medical devices.

9. Neonatal death, permanent or sever temporary harm*	
Event Description	This event is intended to capture all unanticipated death, permanent or sever temporary harm cases of a "term" neonate during the birth process or neonatal period (0-28 days) while being cared within healthcare facility. All term pregnancies, according to the definition of the International Classification of Diseases, are delivered between 37 weeks 0 days and 41 weeks 6 days (13).
Inclusion	• All cases include the unanticipated death, permanent or severe temporary harm of a "term" neonate from the birth process till 28 days while being cared for within the healthcare facility. • Unanticipated intrauterine death more than 37 weeks.
Exclusion	• The death of a "term" infant was related to congenital abnormalities. • Pregnancies resulting in fetal demise before 37 weeks of gestation. • Terminations of pregnancy for life-limiting fetal anomalies, or inductions of labor for pre-viable premature rupture of membranes.

10. Rape of a patient, staff member, licensed dependent practitioner, student and intern visitor, or vendor while on-site at the healthcare facility *	
Event Description	This event is intended to capture all cases of rape that is not limited to patient, staff member, licensed independent practitioner, student, intern, visitor, or vendor within a healthcare facility (5) regardless of whether death, permanent harm, or severe, temporary harm occurred or not.
Inclusion	• All rape cases encountered within the premises/campus of a healthcare facility.
Exclusion	• None.

11. Assault leading to death, permanent harm, or severe, temporary harm, or homicide of a patient, staff member, licensed independent practitioner, student and intern visitor, or vendor while on-site at the healthcare facility *	
Event Description	This event is intended to capture all assault and homicide cases not limited to patient, staff member, student and medical interns, visitor, or vendor within the premises/campus of a healthcare facility that led to death, permanent harm, or severe temporary harm or homicide cases (5).
Inclusion	• All assault and homicide cases within the premises/campus of a healthcare facility.
Exclusion	• None.

12. Fire, flame, or unanticipated smoke, or flashes occurring during patient care within a healthcare facility *	
Event Description	This event is intended to capture all fire, flame, unanticipated smoke, or flashes that occur during patient care within a healthcare facility, regardless of whether death, permanent harm, or severe temporary harm occurred or not.
Inclusion	• All fire, flame, unanticipated smoke, or flashes that occur during patient care within a healthcare facility.
Exclusion	• Anticipated fire, flame, smoke, or flashes occurring within a healthcare facility. • Fire, flame, smoke, or flashes occurring outside the healthcare facility.

13. Unauthorized departure of the patient (absconded) while on care from the healthcare facility that resulted in death, permanent harm, or severe temporary harm	
Event Description	This event is intended to capture all death, permanent harm, or severe temporary harm cases associated with a patient leaving a healthcare facility without the knowledge/authorization of the healthcare facility staff.
Inclusion	• Patients departing form a healthcare facility, including those receiving emergency care, without the knowledge or authorization of the healthcare facility's staff.
Exclusion	• None.

14. Medication error leading to death, permanent, or severe temporary harm *	
Event Description	This event is intended to capture all medication error cases resulting in death, permanent harm, or severe temporary harm, such as errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong preparation, wrong rate, or wrong route of administration (6). **Medication error is defined as** any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer (14).
Inclusion	Any medication errors leading to death, permanent or severe temporary harm associated with but not limited to: • Administration of the wrong dose, including over or under-dosing. • Administration of a medication to a patient with a known allergy to the drug or one of its components, the failure to check/review the patient's allergies before administration, or the failure to record/retrieve a patient's allergy information before administration. • Drug interactions or contraindications with known potential risk. • Failure to administer prescribed medications, e.g., missed doses or missed medication. • Wrong rate of administration. • Wrong route of administration.
Exclusion	• Medication errors related to unknown allergies.

15. Patient death, permanent or severe temporary harm associated with venous thromboembolism (VTE) *	
Event Description	This event is intended to capture all cases associated with venous thromboembolism that resulted in patient death, permanent harm, or severe temporary harm.
Inclusion	• Patients admitted within a healthcare facility, including day surgery.
Exclusion	• None.

16. Patient death, permanent, or severe temporary harm as a result of medical device breakdown or failure when in use	
Event Description	This event is intended to capture all cases of death, permanent or severe temporary harm as result of medical devices failure within healthcare facilities. **Medical Device defined as** Any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar that Intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of: Diagnosis, prevention, monitoring, treatment or alleviation of disease, o Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, o Investigation, replacement, modification, or support of the anatomy or of a physiological process, o Supporting or sustaining life, o Control of conception, o Disinfection of medical devices, o Providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body and any device which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means (15).
Inclusion	• All medical devices.
Exclusion	• None.

17. The unexpected collapse of any building or malfunctioning structure within a healthcare facility *	
Event Description	This event is intended to capture all cases of unexpected building or construction collapse or malfunctioning structure (e.g. auto door, elevators, etc.) within the premises/campus of a healthcare facility regardless of whether death, permanent or severe temporary harm occurred or not.
Inclusion	• All buildings, including those under renovation or construction, as well as all structures within the premises or campus of a healthcare facility.
Exclusion	• None.

18. Transfusing/transplantation of contaminated blood, blood products, organ or tissue	
Event Description	This event is intended to capture all cases of disease transmission associated with the infusion of contaminated blood, blood products, organs, or tissues regardless of whether death, permanent or severe temporary harm occurred or not.
Inclusion	• All cases of transfusing/transplantation of contaminated blood, blood products, organs, or tissues.
Exclusion	• Any case of transfusion/transplantation related to emergency case/lifesaving circumstances.

19. Death or serious disability associated with failure to manage/identify neonatal hyperbilirubinemia (bilirubin >30 milligrams/deciliter) *	
Event Description	This event is intended to capture all cases when death or serious disability is associated with neonatal hyperbilirubinemia (bilirubin >30 milligrams/deciliter) (5). **Kernicterus is** a type of brain damage that can result from high levels of bilirubin in a baby's blood (16).
Inclusion	• All death or disability cases (e.g., Kernicterus) resulted from failure to identify/re-assess or manage neonatal hyperbilirubinemia (16).
Exclusion	• None.

20. Delivery of radiotherapy to the wrong body region or dose exceeds more than 25% of the total planned radiotherapy dose *	
Event Description	This event is intended to capture all cases where radiotherapy dose was delivered to the wrong body region or when the dose exceeds more than 25% of the total planned dose (5) regardless of whether death, permanent harm, or severe, temporary harm occurred or not.
Inclusion	• This event includes radioisotope therapy and radiation producing machines.
Exclusion	• None.

21. Any (stage 3, 4 or unstageable) healthcare facility- acquired pressure injury (ulcer)	
Event Description	This event is intended to capture any stage 3, 4, or unstageable pressure injury acquired after patient admission (13).
Inclusion	All pressure injury cases acquired after patients' admission that include the following stages (17): • Stage 3 Pressure Injury: Full-thickness skin loss. • Stage 4 Pressure Injury: Full-thickness skin and tissue loss. • Unstageable Pressure Injury: Obscured full-thickness skin and tissue loss.
Exclusion	• Progression from stage 2 to stage 3, if stage 2 was recognized upon admission. • When the injury was unstageable upon admission.

22. Unexpected death, permanent or severe temporary harm associated with transport/transfer of patients	
Event Description	This event is intended to capture all death, permanent, or severe temporary harm associated with the transport or transfer of patients.
Inclusion	• All cases of transport or transfer inside or outside the healthcare facility premises, where protocols were not followed.
Exclusion	• None.

23. Patient death, permanent harm, or severe temporary harm as a result of patient fall *	
Event Description	This event is intended to capture patient death, permanent harm, or severe temporary harm associated with patient falls while being cared for within a healthcare facility.
Inclusion	• Patients admitted within a healthcare facility, including day surgery and emergency department.
Exclusion	• None.

24. Patient death, permanent harm, or severe temporary harm associated with wrong administration/connection of medical gas	
Event Description	This event is intended to capture all death, permanent harm, or severe temporary harm cases associated with the administration/connection of the wrong medical gas (13).
Inclusion	• Incidents where systems designated to deliver medical gas to a patient contain no gas or the wrong gas.
Exclusion	• None.

25. Transmission of disease as a result of using contaminated instruments or equipment provided by the healthcare facility	
Event Description	This event is intended to capture all cases of disease transmission after using contaminated devices, instruments, or equipment regardless of the source of contamination regardless of whether death, permanent harm, or severe, temporary harm occurred or not.
Inclusion	• All cases of disease/infection transmission.
Exclusion	• None.

26. Intraoperative or immediately postoperative/postprocedure death in an ASA Class I patient within the healthcare facility *	
Event Description	This event is intended to capture ASA Class I patient death associated with the administration of anesthesia whether or not the planned surgical procedure was carried out within the healthcare facility (10).
Inclusion	• All ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out. • Immediately post-operative means within 24 hours after surgery or other invasive procedure was completed or after administration of anesthesia (if surgery/procedure not completed).
Exclusion	• None.

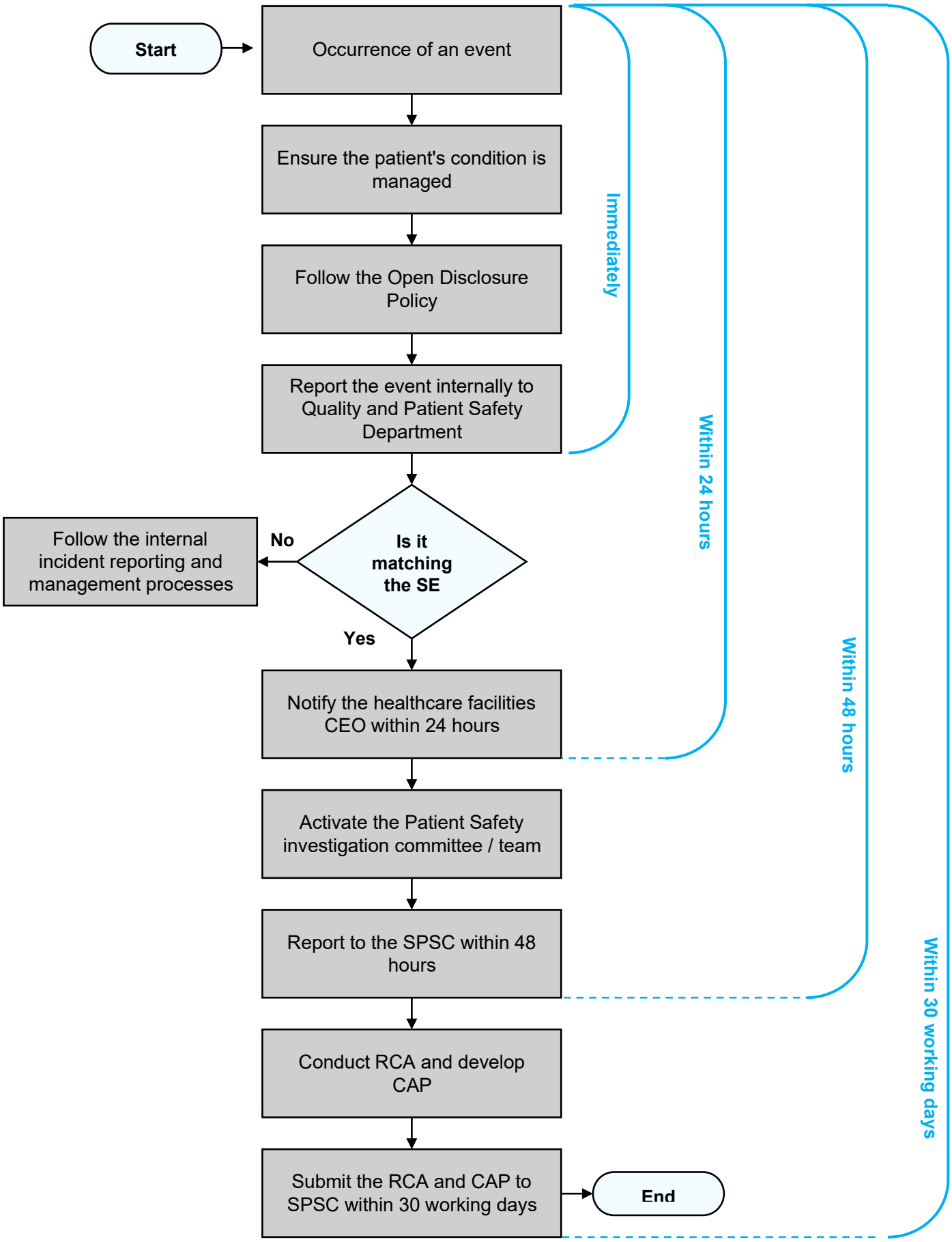
27. Accidental burn of second degree and above during patient care	
Event Description	This event is intended to capture all cases of second-degree burns or above that occur during patient care.

Inclusion	• Inpatient and ambulatory care accidental burn due to, but not limited to, heat, electrical discharge, friction, chemicals, and radiation.
	• The following classification of burns based on the American Burn Association (18):
	  ○ Second Degree (Partial Thickness): Skin may be red, blistered, swollen. Very painful.
	  ○ Third Degree (Full Thickness): Whitish, charred, or translucent, with no pinprick sensation in a burned area.

Exclusion	• This event does not include burns due to a patients' personal use of room facilities/equipment such as the kitchen and shower.

Annex .2: RCA and CAP template

Annex .3: Flowchart of Procedures



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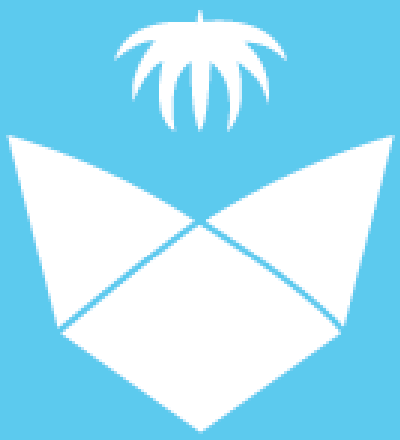

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