Saudi Healthcare Sentinel Event Manual

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Foreword

The Saudi Arabian healthcare industry is experiencing exponential growth associated with one of the world's highest growing population rates and remarkable economic prosperity.

These achievements were concurrent with the significant improvements in the healthcare sectors' overall performance, secondary to the unparalleled governmental support and the introduction of many quality and safety initiatives.

These elements, along with the deep understanding of the importance of the quality services provided, were integral behind the establishment of the Saudi Patient Safety Center (SPSC), as a key initiative in alignment with the national transformation and Vision 2030.

We look forward to supporting the safety of healthcare services provided in the Kingdom through this initiative and work diligently to foster patient empowerment and advocacy by minimizing the effects of avoidable hazards to all patients.

Dr. Tawfig bin Fawzan AlRabiah

Minister of Health, Kingdom of Saudi Arabia

Background

Patient safety has been on the national agenda of the Kingdom of Saudi Arabia, with considerable efforts directed towards measures and support systems developed by the Saudi Government and the Ministry of Health (MOH) that aim at reducing healthcare associated harm to patients. These measures are evident in the initiative of Makkah Region Quality Program (MRQP) as the 1st regional quality accreditation program implemented in the western region of the Kingdom, and the establishment of the Saudi Central Board of Accreditation for Healthcare Institutions (CBAHI) as a national accreditation body with a focus on patient safety standards in 2001. As part of the accreditation process for healthcare facilities, CBAHI stipulated that all accredited healthcare facilities must report all of "Sentinel Events" through filling and submitting the Sentinel Event Reporting Form (SERF).

These efforts are considered the early milestones in the reporting of sentinel events and paved the way to the recent National mandate of sentinel event reporting:

- **Ministry of Health (MOH):** As part of the developmental stages of improving health services, the MOH stipulated that all the healthcare facilities (MOH/Governmental and Private) are required to report on a list of "Sentinel Events" to monitor and control serious medical incidents using an electronic system.
- **Saudi Food and Drug Authority (SFDA):** The SFDA pharmacovigilance system provided healthcare professionals, healthcare facilities, and individuals with a structured approach for reporting side effects, pharmacological errors, cosmetic side effects, any quality defects in pharmaceuticals, food poisoning, and defects in medical devices and supplies.

With the launch of the Saudi Vision 2030, various patient safety measures have been adopted to reform and enhance patient safety. The Saudi Patient Safety Center (SPSC) was established as a government initiative in 2017 by the Minister of Health to assume a leading role in the journey towards the elimination of preventable harm to patients and to healthcare professionals.

I. Introduction

Patient safety is a joint obligation that can only be accomplished by working together and building on the experience of a variety of organizations and people, including patients and their families. In this context, the Saudi Patient Safety Center (SPSC) established in 2017 as the first of its kind in the region to fulfill one of the National Transformation Vision 2030. SPSC acts as the patient safety strategy custodian with a mandate to galvanize healthcare regulators, payers, providers, patients, families, and communities around patient safety and provide healthcare services free from harm. Although the risk is an inherent part of treatment, we know that many of these events can be avoided by identifying and learning about incidents. Safety and quality are vital to optimum healthcare performance. The first step in improving safety is to obtain insight into the extent and severity of unsafe conditions and practices.

This manual is designed to outline the Saudi Patient Safety Center (SPSC) responsibilities and mandates in setting the mechanism for reporting of sentinel events as described in the **Saudi Health Council resolution (5/83) dated 28/12/1439 H** that is based on the **Ministerial approval (64570) dated 1/12/1441 H**. This manual provides healthcare facilities and healthcare facility governing sectors in the Kingdom of Saudi Arabia with a list of reportable sentinel events. It also provides a step-by-step guide that standardize the process of reporting and investigation and with focus on the facility's understanding of contributing factors to the event, culture's change and perception of staff, system failures, and process variabilities to reduce the probability of such an event in the future.

II. Development of the Saudi Healthcare Sentinel Event Manual

The Saudi Healthcare Sentinel Event manual has been developed as a collective effort utilizing the following methodologies:

1. Establishment of the task force team,
2. Mapping exercise with the available national and international lists of sentinel events,
3. Development of a proposed list of sentinel events, including the methodology to report and handle these events,
4. Healthcare stakeholders consultation with regards to the following parameters:
   - 4.1.1. Agreement / Reservation / Comments on the identified sentinel events.
   - 4.1.2. Agreement / Reservation / Comments on the inclusion and exclusion criteria of each event type.
   - 4.1.3. Agreement / Reservation / Comments on the reporting methodology.
5. Development of an initial draft for the Saudi Healthcare Sentinel Event manual,
6. Sharing of the initial draft for the Saudi Healthcare Sentinel Event manual with subject matter experts for review and feedback,
7. Collection of the feedback on the initial draft for the Saudi Healthcare Sentinel Event manual,
8. Review of the feedback results on the initial draft for the Saudi Healthcare Sentinel Event manual.

III. Inclusion and Exclusion Criteria of a Sentinel Event

The inclusion and exclusion of sentinel events in the Saudi Healthcare Sentinel Event Manual are based on the following criteria:

- The event is globally recognized as "totally preventable'' and therefore never happen,
- The event includes the failure of systems or processes, and
- The event can be clearly measurable and identifiable.

Sentinel events listed in this manual adopted from the Joint Commission International sentinel event list 2020, Australian sentinel events list April 2020, Never Events for Hospital Care in Canada 2015, NHS England Never Event list 2018, CBAHI and Saudi MOH sentinel event lists.

IV. Reportable Sentinel Event List

List of reportable sentinel events:

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 [1].

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 [1].

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 [2].

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 [3].

Inclusion:

- Any cause related to or aggravated by the pregnancy or its management [3].

Exclusion:

- Cases that were not related to the birth process or due to pre-existing conditions.
- Accidental or incidental causes.

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 [1].

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, e.g., attempts suicide in the healthcare facility restroom prior to checking in for care [4].

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, or wrong procedure regardless of whether death, permanent harm, or severe, temporary harm has occurred or not [1].

Inclusion:

- Any surgical/invasive procedure performed on the wrong patient, wrong site, or wrong procedure.
- 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.

Inclusion:

- All cases involving the administration of incompatible blood/blood products or organs.

Exclusion:

- None.

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 [1].

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.

Exclusion:

- Any object left for medical reasons in a patient, e.g., sutures, stents, implants, and medical devices.

9. Unanticipated death of a "term" infant

Event Description: This event is intended to capture all unanticipated death cases of a "term" infant during the birth process.

Inclusion:

- All cases include the unanticipated death of a "term" infant during the birth process.
- All term pregnancies, according to the definition of the International Classification of Diseases delivered between 37 weeks 0 days and 41 weeks 6 days [5].

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 previable premature rupture of membranes.

10. Rape leading to death, permanent harm, or severe, temporary harm of a patient, staff member, licensed independent practitioner, visitor, or vendor while on-site at the healthcare facility

Event Description: This event is intended to capture all cases of rape of a patient, staff member, licensed independent practitioner, visitor, or vendor within a healthcare facility that led to death, permanent harm, or severe, temporary harm or homicide cases [1].

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, visitor, or vendor while on-site at the healthcare facility

Event Description: This event is intended to capture all assault and homicide cases for patients, staff members, visitors, or vendors within the premises/campus of a healthcare facility that led to death, permanent harm, or severe temporary harm or homicide cases [1].

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 within a healthcare facility

Event Description: This event is intended to capture all fire, flame, unanticipated smoke, or flashes that occur 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 within a healthcare facility.

Exclusion:

- None.

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:

- All patients who leave a healthcare facility (including emergency care) while being cared for without the healthcare facility staff's knowledge/authorization.

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, or wrong route of administration [2].

Inclusion:

- Medication errors include, but are not limited to, death, permanent or severe temporary harm associated with:
  - 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 route of administration.

Exclusion:

- Medication errors related to unknown allergies.

15. Patient death, permanent, or severe temporary harm associated with intravascular air embolism

Event Description: This event is intended to capture all cases where patient death, permanent harm, or severe temporary harm was associated with air embolism [4].

Inclusion:

- High-risk procedures, including but not limited to procedures involving the head and neck, vaginal delivery and cesarean section, spinal instrumentation procedures, and liver transplantation.
- Low-risk procedures, including those related to the placement of infusion lines in a vascular space.

Exclusion:

- Neurosurgical procedures, where surgery was performed in a position that puts the head above the heart to reduce venous pressure, e.g., suboccipital craniotomy.

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 redult of medical devices failure within healthcare facilities.

Inclusion:

- All medical devices.

Exclusion:

- None.

17. The unexpected collapse of any building within a healthcare facility

Event Description: This event is intended to capture all cases of unexpected building or construction collapse within the premises/campus of a healthcare facility regardless of whether death, permanent or severe temporary harm occurred or not.

Inclusion:

- All buildings within the premises/campus of a healthcare facility, including structures under renovation or construction.

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.

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

Event Description: This event is intended to capture all cases when death or serious disability is associated with neonatal hyperbilirubinemia [5].

Inclusion:

- All death or disability cases (e.g., Kernicterus) resulted from failure to identify/re-assess or manage neonatal hyperbilirubinemia [6].

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 [1].

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 [5].

Inclusion:

- All stage 3, 4, or unstageable pressure injury cases acquired after patients' admission.

- This includes the following stages [7]:
  - 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.

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.
- Cases due to the failure of performing patient fall's risk assessment/identification.
- Failure to monitor/manage patients identified as "at fall risk."

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 [5].

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.

Inclusion:

- All cases of disease/infection transmission.
- Inpatients and Ambulatory care services.

Exclusion:

- None.

26. Death, permanent, or severe temporary harm associated with the use of incorrectly positioned Oro – or Nasogastric tube

Event Description: This event is intended to capture all instances of death, permanent harm, or severe temporary associated with the use of a misplaced naso- or orogastric tube [8].

Inclusion:

- All cases where a naso- or orogastric tube is accidentally inserted into the pleura or respiratory tract and not detected before starting a feed, flush, or medication administration.

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 [9]**:**
  - 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.

V. Sentinel Event Reporting and Management

This manual outlines the general guidelines for identifying, internal investigation, reporting, and managing of a sentinel event within a healthcare facility, Also a subsequent submission of Root Cause Analysis (RCA) and Corrective Action Plan (CAP) to the healthcare facility's governing sector and the Saudi Patient Safety Center (SPSC) **(refer to Annex I)**.

Confidentiality provisions:

All sentinel event information submitted to Saudi Patient Safety Centre is considered private and confidential. Sentinel events data will be trended and used on de-identified basis for the purpose of disseminating lessons learned. No information about the reporting healthcare facilities will be shared publicly.

1. Sentinel Event Reporting and Management within Healthcare Facilities:

1.1 Reporting of Sentinel Events

Upon the occurrence of an incident suspected to be a sentinel event (as per categories and definitions stated in this manual), the staff directly involved in or has discovered the event shall report it as per the respective healthcare facility's policy.

1.2 Healthcare facility response following a Sentinel Event

- As soon as the responsible department receives a notification of any adverse event or incident suspected to be a sentinel event, the responsible department in collaboration with the designated team within the healthcare facility is expected to review, validate and match the incident with the sentinel event category identified and listed in this manual.
- The healthcare facility leader/director shall appoint a Root Cause Analysis (RCA) team in charge of managing the event within (24) hours of the time of internal reporting of the event.
- Ideally, the RCA team shall include a Subject Matter Expert in the event under investigation, a staff who is not familiar with the incident under investigation, an experienced Root Cause Analysis (RCA) facilitator, and frontline staff.

- The RCA team may also include managers and supervisors as per the event scope.

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.

The assigned RCA team is responsible for the following:

- Provide support to the staff involved in the event.
- Initiate the investigation process.
- Interview of patient/family, if applicable, and staff who were directly involved in the event
- Conduct a credible Root Cause Analysis (RCA) for identifying the root causes and contributory factors, using the tools specified in this manual.
- Recommend a Corrective Action Plan (CAP), with assigned responsibilities and the timeline for implementation.
- Submit the Root Cause Analysis (RCA) and Corrective Action Plan (CAP), after review and approval of the healthcare facility leader/director, to the healthcare facility's governing sector.
- Because of the nature and sensitivity of these events, every healthcare facility is obliged to have a disclosure process of patient safety events to patients and their families.

1.3 Conducting a Root Cause Analysis (RCA)

Following the reporting of a sentinel event, the assigned RCA team is responsible for completing the RCA template **(Annex II)**.

1.4 Corrective Action Plan

Developing a Corrective Action Plan (CAP) is an important step to be taken by the RCA team after identifying the root causes and contributing factors to the event **(Annex II)**. The CAP should identify what needs to be done to prevent similar events from occurring in the future. Actions might differ in their strength to control or eliminate system hazards as classified by the Action Hierarchy **(Annex III)** into strong actions, intermediate actions, or weak actions.

The team may identify more than one corrective action for each root cause and contributing factor; it is recommended to identify at least one stronger or intermediate strength action for each contributing factor to the event occurrence. To assure the Corrective Action Plan's implementation, the team shall assign actions to the responsible individuals with target date(s) for completion.

Before submission of the CAP to the healthcare facility's governing sector, the healthcare facility leader/director must make sure that the plan includes the following:

- Well identified contributing factors.
- A Causal statement/root cause for each contributing factor.
- Corrective Action(s) for each causal statement, that includes at least one stronger or intermediate strength.
- Responsible person for the implementation of each action.
- The target date for completion of each action.

One of the effective tools that can be used by the sentinel event analysis and management team for monitoring and controlling the timeliness of the implementation of the action plan is the Gantt Chart. This chart shows the task(s) of an approved action plan in response to a sentinel event, who is responsible for task(s) execution, when the task(s) must take place, and how long the task(s) will take to be completed. As the action plan progresses, the chart shows which tasks have been completed within its allocated timeframe by the assigned individual/team.

2. Sentinel Event Reporting and Management Process for the Healthcare Facility's Governing Sector

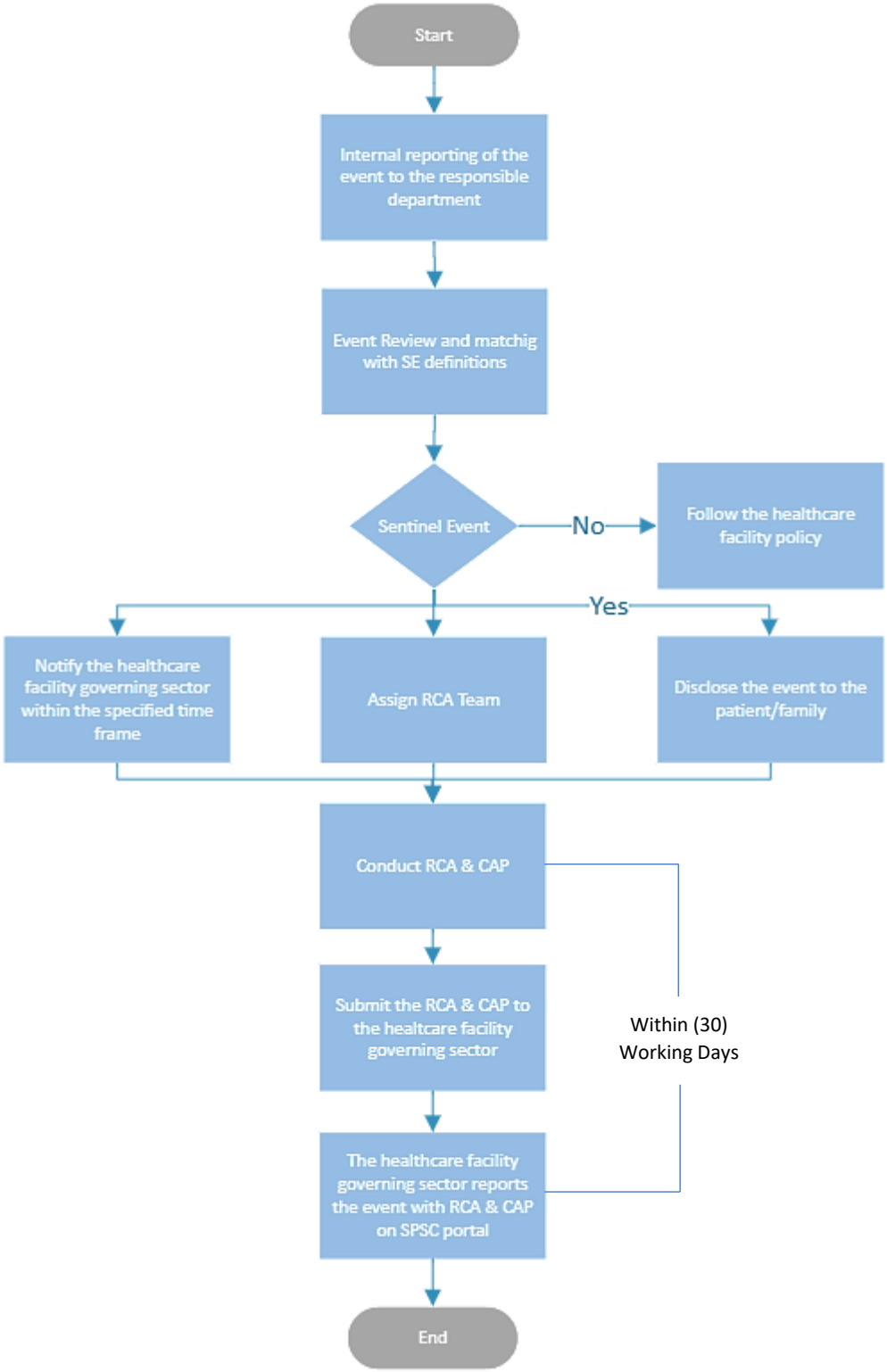
The governing sector shall submit the completed sentinel event reporting form with the RCA and CAP section **(Annex II)** on the SPSC sentinel events reporting portal within thirty (30) working days from the date of internal reporting of the event.

3. Process Post Submission of the Sentinel Event, RCA and CAP to SPSC

Upon submission of the Sentinel Event, RCA and CAP to SPSC, the assigned SPSC employee will review the event with all its related documents to ensure that the RCA is comprehensive and focuses on the system, not individuals, and the CAP has assigned responsibility with timelines. In case of any inquiries, the assigned SPSC employee shall communicate with the healthcare facility's governing sector.

The responsible team in SPSC shall review and analyze the contributing factors and the root causes of all reported events on the portal. Based on the analysis, SPSC shall prepare a quarterly report that identifies trends and lessons learned to be presented for review and approval by a designated committee. An annual report shall be submitted to the Saudi Health Council.

Annex I. Sentinel Event Reporting and Management Process



Annex II. RCA & CAP

Category of Contributing Factor	Triggering Questions	Contributing factors	Causal Statement	Corrective Actions	Action Strength	Responsibility	Action Due Date
Process Issues	1. What was the intended process flow? ---------- ---------- ---------- ---------- 2. Were there any steps in the process that did not occur as intended? ☐Yes ☐No 3. What were the steps in the process that did not occur as intended? ---------- ---------- ---------- ---------- 4. Had a previous investigation been done for a similar event, were the causes identified, and were effective interventions developed and implemented on a timely basis? ☐Yes ☐No	**Check All that apply:** ☐ Aids not available or not working (e.g., CTG machine; checklist; a risk assessment tool; fax machine to enable remote assessment of results) ☐ Difficulties in accessing senior/specialist advice ☐ Lack of prioritization of guidelines ☐ Poorly designed (i.e., Too complex; too much info.; difficult to conceive or remember) ☐ Too many tasks to perform at the same time ☐ Contradicting tasks ☐ Staff do not agree with the 'task/procedure design_ ☐ Stages of the task not designed so that each step can realistically be carried out ☐ Inappropriate transfer of processes from other situations	Enter free text here (For Each Contributing factor, please write a causal statement)	Enter free text here (For Each Causal Statement, please write a no. of Actions)	For each action select (Drop Down List) Stronger/Intermediate/ Weaker	For each action Enter free text here [Title/Position]	For each action [DATE]

Category of Contributing Factor	Triggering Questions	Contributing factors	Causal Statement	Corrective Actions	Action Strength	Responsibility	Action Due Date
Process Issues (continued)	5. Were there written up-to-date policies and procedures that addressed the work processes related to the event? ☐Yes ☐No 6. Were relevant policies/procedures clear, understandable, and readily available to all staff? ☐Yes ☐No	**Check All that apply:** ☐ Insufficient opportunity to influence task/outcome where necessary ☐ Unreliable or ineffective general administrative systems (Please specify, e.g., Bookings, Patient identification, ordering, requests, referrals, appointments) ☐ Unreliable or ineffective admin infrastructure (e.g., Phones, bleep systems, etc.) ☐ Unreliable or ineffective administrative support ☐ Delays caused by system failure or design ☐ Time pressure ☐ Other: _____	Enter free text here (For Each Contributing factor, please write a causal statement)	Enter free text here (For Each Causal Statement, please write a no. of Actions)	For each action select (Drop Down List) Stronger/Intermediate/ Weaker	For each action Enter free text here [Title/Position]	For each action [DATE]
Human Factors	1. What were staff-related human performance factors relevant to the outcome? ----------	**Check All that apply:** ☐ Stress (e.g., distraction / preoccupation) ☐ Lack of motivation (e.g., boredom, complacency, low job satisfaction)	Enter free text here (For Each Contributing factor, please write a causal statement)	Enter free text here (For Each Causal Statement, please write a no. of Actions)	For each action select (Drop Down List) Stronger/Intermediate/ Weaker	For each action Enter free text here [Title/Position]	For each action [DATE]

Category of Contributing Factor	Triggering Questions	Contributing factors	Causal Statement	Corrective Actions	Action Strength	Responsibility	Action Due Date
Human Factors (continued)	2. Did personnel have an adequate sleep? ☐Yes ☐No 3. Was fatigue properly anticipated? ☐Yes ☐No 4. What was the reason for fatigue? ---------- ---------- ---------- ---------- 5. Were there phycological stressors? ☐Yes ☐No	**Check All that apply:** ☐ Domestic problems (e.g., family related issues) ☐ Lifestyle problems (e.g., financial/housing issues) ☐ Cultural beliefs ☐ Low self-confidence/over confidence (e.g., Gregarious, reclusive, interactive) ☐ Risk averse/risk taker ☐ Preoccupation/narrowed focus (Situational awareness problems) ☐ Perception/viewpoint affected by info. or mindset (Expectation/Confirmation bias) ☐ Distraction/Attention deficit ☐ Failure to follow established policies/procedures ☐ Inability to focus on the task ☐ Inattentional blindness/confirmation bias ☐ Personal problems	Enter free text here (For Each Contributing factor, please write a causal statement)	Enter free text here (For Each Causal Statement, please write a no. of Actions)	For each action select (Drop Down List) Stronger/Intermediate/ Weaker	For each action Enter free text here [Title/Position]	For each action [DATE]

Category of Contributing Factor	Triggering Questions	Contributing factors	Causal Statement	Corrective Actions	Action Strength	Responsibility	Action Due Date
Human Factors (continued)	6. What was the source of phycological stressors? --- --- --- ---	**Check All that apply:** ☐ Lack of complex critical thinking skills ☐ Rushing to complete task ☐ Substance abuse ☐ Trust ☐ Other: _____	Enter free text here (For Each Contributing factor, please write a causal statement)	Enter free text here (For Each Causal Statement, please write a no. of Actions)	For each action select (Drop Down List) Stronger/Intermediate/ Weaker	For each action Enter free text here [Title/Position]	For each action [DATE]
Equipment / Technology	1. Was available equipment/technology used as intended? ☐Yes ☐No 2. How did the equipment/technology performance affect the outcome? 3. --- --- 3. How was the equipment/technology designed to minimize errors or easy-to-catch mistakes? 4. --- --- 5. Was there a maintenance program	**Check All that apply:** ☐ Interference/unclear equipment display ☐ Poor working order ☐ Inappropriate size ☐ Unreliable ☐ Ineffective safety features/not designed to fail-safe ☐ Poor maintenance program ☐ Failure of general services (power supply, water, piped gases, etc.) ☐ Correct equipment not available ☐ Insufficient equipment / emergency backup equipment ☐ Incorrectly placed for use ☐ Incorrectly stored	Enter free text here (For Each Contributing factor, please write a causal statement)	Enter free text here (For Each Causal Statement, please write a no. of Actions)	For each action select (Drop Down List) Stronger/Intermediate/ Weaker	For each action Enter free text here [Title/Position]	For each action [DATE]

Category of Contributing Factor	Triggering Questions	Contributing factors	Causal Statement	Corrective Actions	Action Strength	Responsibility	Action Due Date
	in place to maintain the equipment involved? ☐Yes ☐No						
Equipment / Technology (continued)	6. Were personnel trained appropriately to operate the equipment involved in the event? ☐Yes ☐No	**Check All that apply:** ☐ Unclear controls ☐ Not intuitive in design ☐ Confusing use of color or symbols ☐ Lack of or poor-quality user manual ☐ Not designed to make detection of problems obvious ☐ Use of items that have similar names or packaging ☐ Problems of compatibility ☐ Other: _____	Enter free text here (For Each Contributing factor, please write a causal statement)	Enter free text here (For Each Causal Statement, please write a no. of Actions)	For each action select (Drop Down List) Stronger/Intermediate/ Weaker	For each action Enter free text here [Title/Position]	For each action [DATE]
Environmental Factors	1. How was the work area/environment designed to support the function it was being used for? 2. ---------- 3. Had there been an environmental risk	**Check All that apply:** ☐ Poor or inappropriate office design (computer chairs, the height of tables, anti-glare screens, security screens, panic buttons, placing of filing cabinets, storage facilities, etc.) ☐ Poor or inappropriate area design (length, shape, visibility, provision of space)	Enter free text here (For Each Contributing factor, please write a causal statement)	Enter free text here (For Each Causal Statement, please write a no. of Actions)	For each action select (Drop Down List) Stronger/Intermediate/ Weaker	For each action Enter free text here [Title/Position]	For each action [DATE]

Category of Contributing Factor	Triggering Questions	Contributing factors	Causal Statement	Corrective Actions	Action Strength	Responsibility	Action Due Date
	assessment (i.e., safety audit) of the area? ☐Yes ☐No	☐ Inadequate security provision					
Environmental Factors (continued)	3. How was the physical work environment designed to decrease stress levels? 4. ---------- 4. Were appropriate safety evaluations and disaster drills been conducted as scheduled? ☐Yes ☐No 5. Did the work area/environment meet current codes, specifications, and regulations? ☐Yes ☐No	**Check All that apply:** ☐ Lack of secure outside space ☐ Temperature too high/low ☐ Noise levels too high or low ☐ Lighting too dim or bright, or lack of ☐ Inadequate lines of sight ☐ Inadequate/inappropriate use of color contrast/patterns (walls/doors/flooring etc.) ☐ Housekeeping issues – lack of cleanliness ☐ Inadequate maintenance ☐ Fixture or fitting not available (failure or lack of capacity) ☐ Ligature/anchor points ☒ Other: _____	Enter free text here (For Each Contributing factor, please write a causal statement)	Enter free text here (For Each Causal Statement, please write a no. of Actions)	For each action select (Drop Down List) Stronger/Intermediate/ Weaker	For each action Enter free text here [Title/Position]	For each action [DATE]
Staff Competency and Performance	1. How was the staff involved in the event properly qualified and	**Check All that apply:**	Enter free text here	Enter free text here	For each action select	For each action Enter free text here	For each action [DATE]

Category of Contributing Factor	Triggering Questions	Contributing factors	Causal Statement	Corrective Actions	Action Strength	Responsibility	Action Due Date
	trained to perform their function/duties? 2. ---------- 3. How were all staff oriented to the job, department, and facility policies regarding safety, security, hazardous material management, emergency preparedness, life safety management, medical equipment, and utility management? 4. ---------- 5. How was the staff training needs assessment conducted? 6. ---------- 7. Was training provided prior to the start of the work process?	☐ Mental impairment (e.g., illness, drugs, alcohol, pain) ☐ Lack of knowledge ☐ Lack of skills ☐ Inexperience ☐ Inappropriate experience or lack of quality experience ☐ Unfamiliar task ☐ Lack of testing and assessment ☐ Inadequate supervision ☐ Lack of / inadequate mentorship ☐ Training results not monitored/acted upon ☐ Training needs analysis not conducted/acted upon ☐ On the job training unavailable or inaccessible ☐ Emergency Training unavailable or inaccessible ☐ Team training unavailable or inaccessible ☐ Core skills training unavailable or inaccessible ☐ Refresher courses unavailable or inaccessible	(For Each Contributing factor, please write a causal statement)	(For Each Causal Statement, please write a no. of Actions)	(Drop Down List) Stronger/Intermediate/ Weaker	[Title/Position]	

Category of Contributing Factor	Triggering Questions	Contributing factors	Causal Statement	Corrective Actions	Action Strength	Responsibility	Action Due Date
	☐Yes ☐No						
Staff Competency and Performance (continued)	8. How were the results of training monitored over time? ☐Yes ☐No 6. How were all staff trained in the use of relevant barriers and controls? 7. ----------	**Check All that apply:** ☐ Poor rule compliance Routine violation of rules/regulations ☐ Other:_____	Enter free text here (For Each Contributing factor, please write a causal statement)	Enter free text here (For Each Causal Statement, please write a no. of Actions)	For each action select (Drop Down List) Stronger/Intermediate/ Weaker	For each action Enter free text here [Title/Position]	For each action [DATE]
Manpower Planning Issues	1. Was there sufficient staff on-hand for the workload at the time? (i.e., Workload too high, too low, or wrong mix of staff). ☐Yes ☐No 2. How did actual staffing compare with the ideal level? 3. ---------- 4. What was the plan for dealing with staffing contingencies?	**Check All that apply:** ☐ Overload ☐ Inappropriate skill mix (e.g., Lack of senior staff; Trained staff; etc.) ☐ Low staff to patient ratio ☐ Use of temporary staff ☐ High staff turnover ☐ Shift related fatigue ☐ Excessive working hours ☐ Lack of breaks during work hours ☐ Excessive extraneous tasks ☐ Failure to address/manage issues of competence	Enter free text here (For Each Contributing factor, please write a causal statement)	Enter free text here (For Each Causal Statement, please write a no. of Actions)	For each action select (Drop Down List) Stronger/Intermediate/ Weaker	For each action Enter free text here [Title/Position]	For each action [DATE]

Category of Contributing Factor	Triggering Questions	Contributing factors	Causal Statement	Corrective Actions	Action Strength	Responsibility	Action Due Date
	5. ---------- ---------- -------- 6. Were such contingencies a factor in this event? ☐Yes ☐No	☐ Other: _____ __					
Leadership and Safety Culture	1. How does leadership address the continuum of patient safety events, including close calls, adverse events, and unsafe, hazardous conditions? 2. ---------- ---------- -------- 3. How does the healthcare facility's culture support risk reduction? 4. ---------- ---------- -------- 5. How does leadership demonstrate accountability for implementing	**Check All that apply:** ☐ Inadequate decision/action caused by Group influence ☐ Hierarchical structure/Governance structure not conducive to discussion, problem sharing, etc. ☐ Tight boundaries for accountability and responsibility ☐ Professional isolation ☐ Clinical versus the managerial model ☐ Lack of robust Service level agreements/contractual arrangements ☐ Inadequate safety terms and conditions of contracts ☐ Contractors related problem ☐ Inappropriate safety/efficiency balance	Enter free text here (For Each Contributing factor, please write a causal statement)	Enter free text here (For Each Causal Statement, please write a no. of Actions)	For each action select (Drop Down List) Stronger/Intermediate/ Weaker	For each action Enter free text here [Title/Position]	For each action [DATE]

Category of Contributing Factor	Triggering Questions	Contributing factors	Causal Statement	Corrective Actions	Action Strength	Responsibility	Action Due Date
	measures to reduce the risk of patient harm? 6. ---------- 7. How does leadership communicate corrective actions stemming from any analysis following reported risks? 8. ----------	☐ Lack of risk management plans ☐ Inadequate leadership example (e.g., visible evidence of commitment to safety)					
Leadership and Safety Culture (continued)	5. How does the overall culture encourage change, suggestions, and warnings from staff regarding risky situations or problem areas? ----------	**Check All that apply:** ☐ Inadequately open culture to allow appropriate communication ☐ Inadequate learning from past incidents ☐ Incentives for 'at risk'/'risk taking' behaviors ☐ Acceptance/toleration of inadequate adherence to current practice ☐ Ignorance/poor awareness of inadequate adherence to current practice	Enter free text here (For Each Contributing factor, please write a causal statement)	Enter free text here (For Each Causal Statement, please write a no. of Actions)	For each action select (Drop Down List) Stronger/Intermediate/ Weaker	For each action Enter free text here [Title/Position]	For each action [DATE]

Category of Contributing Factor	Triggering Questions	Contributing factors	Causal Statement	Corrective Actions	Action Strength	Responsibility	Action Due Date
		☐ Disempowerment of staff to escalate issues or take action ☐ Ineffective leadership – clinically ☐ Ineffective leadership – managerially ☐ Lack of decision making ☐ Inappropriate decision making ☐ Untimely decision making (delayed) ☐ Leader poorly respected					
Leadership and Safety Culture (continued)	6. How does leadership address disruptive behaviors? ----------	**Check All that apply:** ☐ Lack of support networks for staff ☐ Inappropriate level of assertiveness ☐ Inadequate inter-professional challenge ☐ Bed Availability ☐ Other: _____	Enter free text here (For Each Contributing factor, please write a causal statement)	Enter free text here (For Each Causal Statement, please write a no. of Actions)	For each action select (Drop Down List) Stronger/Intermediate/ Weaker	For each action Enter free text here [Title/Position]	For each action [DATE]
Communication and Information	1. Was the patient correctly identified? ☐Yes ☐No 2. How was information from various patient	**Check All that apply:** ☐ Language ☐ Incomplete information (test results, patient history)	Enter free text here (For Each Contributing factor, please	Enter free text here (For Each Causal Statement,	For each action select (Drop Down List) Stronger/Intermediate/ Weaker	For each action Enter free text here [Title/Position]	For each action [DATE]

Category of Contributing Factor	Triggering Questions	Contributing factors	Causal Statement	Corrective Actions	Action Strength	Responsibility	Action Due Date
	assessments shared and used by the treatment team members on a timely basis? --- --------------------------	☐ Misrepresentation of information ☐ The inappropriate tone of voice and style of delivery for the situation ☐ Ambiguous verbal commands/directions ☐ Incorrect use of language ☐ Made to inappropriate person(s) ☐ Incorrect communication channels used	write a causal statement)	please write a no. of Actions)			
Communication and Information (continued)	3. How did existing documentation provide a clear picture of the work-up, the treatment plan, and the patient's response to treatment? (e.g., Assessments, consultations, orders, progress notes, medication administration record, x-ray, labs, etc.)? 4. --	**Check All that apply:** ☐ Inadequate patient identification ☐ Records difficult to read ☐ All relevant records not stored together and accessible when required ☐ Records incomplete or not contemporaneous (e.g., unavailability of patient management plans, patient risk assessments, etc.) ☐ Written information not circulated to all team members ☐ Communication not received	Enter free text here (For Each Contributing factor, please write a causal statement)	Enter free text here (For Each Causal Statement, please write a no. of Actions)	For each action select (Drop Down List) Stronger/Intermediate/ Weaker	For each action Enter free text here [Title/Position]	For each action [DATE]

Category of Contributing Factor	Triggering Questions	Contributing factors	Causal Statement	Corrective Actions	Action Strength	Responsibility	Action Due Date
	4. Was communication between management/supervisors and frontline staff adequate? (i.e., Accurate, complete, unambiguous, using standard vocabulary and no jargon) ☐Yes ☐No 5. Was communication between front line team members adequate? ☐Yes ☐No	☐ Communications directed to the wrong people ☐ Lack of information to patients ☐ Lack of effective communication to staff of risks (Alerts systems etc.) ☐ Body Language issues (closed, open, body movement, gestures, facial expression)					
Communication and Information (continued)	6. Was communication across patient care areas adequate (e.g., transfers, consults) ☐Yes ☐No 7. How were policies and procedures communicated adequately? 8. ----------		Enter free text here (For Each Contributing factor, please write a causal statement)	Enter free text here (For Each Causal Statement, please write a no. of Actions)	For each action select (Drop Down List) Stronger/Intermediate/ Weaker	For each action Enter free text here [Title/Position]	For each action [DATE]

Category of Contributing Factor	Triggering Questions	Contributing factors	Causal Statement	Corrective Actions	Action Strength	Responsibility	Action Due Date
Communication and Information (continued)	8. How was the endorsement of patient information communicated adequately? --- --- --- ---	**Check All that apply:** ☐ Negative team reaction to conflict ☐ Negative team reaction to newcomers ☐ Lack of team openness/communication with colleagues ☐ Failure to seek support ☐ Lack of easy access to technical information, flow charts and diagrams ☐ Lack of direct or understandable feedback from the task ☐ Other:	Enter free text here (For Each Contributing factor, please write a causal statement)	Enter free text here (For Each Causal Statement, please write a no. of Actions)	For each action select (Drop Down List) Stronger/Intermediate/ Weaker	For each action Enter free text here [Title/Position]	For each action [DATE]
Others	Are there any other any unasked questions?	Enter free text here	Enter free text here (For Each Contributing factor please write a causal statement)	Enter free text here (For Each Causal Statement please write a no. of Actions)	For each action select (Drop Down List) Stronger/Intermediate/ Weaker	For each action Enter free text here [Title/Position]	For each action [DATE]

Adapted from the following sources:

- Joint Commission International (JCI). (2017). *Root Cause Analysis in Health Care: Tools and Techniques (Sixth Edition).* Oak Brook: Department of Publications and Education.
- U.S. Department of Veterans Affairs. (2015). *Root Cause Analysis Tools.* Durham: VA National Center for Patient Safety

Annex III. Action Hierarchy

Action Strength	Action Category	Example
Stronger Actions (These tasks require less reliance on humans to remember to perform the task correctly)	Architectural/physical plant changes	Replace revolving doors at the main patient entrance into the building with powered sliding or swinging doors to reduce patient falls.
	New devices with usability testing	Perform heuristic tests of outpatient blood glucose meters and test strips and select the most appropriate for the patient population being served.
	Engineering control (forcing function)	Eliminate the use of universal adaptors and peripheral devices for medical equipment and use tubing/fittings that can only be connected the correct way (e.g., IV tubing and connectors that cannot physically be connected to sequential compression devices [SCDs]).
	Simplify process	Remove unnecessary steps in a process.
	Standardize on equipment or process	Standardize the make and model of medication pumps used throughout the institution. Use bar coding for medication administration.
	Tangible involvement by leadership	Participate in unit patient safety evaluations and interact with staff; support the RCA[2] process (root cause analysis and action); purchase needed equipment; ensure staffing and workload are balanced.
Intermediate Actions	Redundancy	Use two RNs to independently calculate high-risk medication dosages.
	Increase in staffing/decrease in workload	Make float staff available to assist when workloads peak during the day.
	Software enhancements, modifications	Use computer alerts for drug-drug interactions.
	Eliminate/reduce distractions	Provide quiet rooms for programming PCA pumps; remove distractions for nurses when programming medication pumps.
	Education using simulation-based training, with periodic refresher sessions and observations	Conduct patient handoffs in a simulation lab/environment, with after action critiques and debriefing.
Intermediate Actions (continued)	Checklist/cognitive aids	Use pre-induction and pre-incision checklists in operating rooms. Use a checklist when reprocessing flexible fiber optic endoscopes.
	Eliminate look- and sound-alikes	Do not store look-alikes next to one another in the unit medication room.
	Standardized communication tools	Use read-back for all critical lab values. Use read-back or repeat-back for all verbal medication orders. Use a standardized patient handoff format.

Action Strength	Action Category	Example
	Enhanced documentation, communication	Highlight medication name and dose on IV bags.
Weaker Actions (these tasks require more reliance on humans to remember to perform the task correctly)	Double checks	One person calculates dosage, another person reviews their calculation.
	Warnings	Add audible alarms or caution labels.
	New procedure/ memorandum/policy	Remember to check IV sites every 2 hours.
	Training	Demonstrate correct usage of hard-to-use medical equipment.

Source: Action Hierarchy levels and categories are based on Root Cause Analysis Tools, VA National Center for Patient Safety, http://www.patientsafety.va.gov/docs/joe/rca_tools_2_15.pdf. Examples are provided here. Reproduced with permission.

Glossary

Adverse event:

An injury caused by medical management, rather than by the underlying disease, which prolongs hospitalization, produces a disability at the time of discharge, or both.

Authorized person:

The guardian or other individual(s) having the legally recognized ability to consent on behalf of the child [4] as per kingdom laws and regulation [10].

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.

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.

Healthcare facility's governing sector: In healthcare, it represents the individual(s), group, or agency that has ultimate authority, responsibility, and accountability for the overall strategic direction, methods of operations (management and planning), establishment of policies, maintenance of safety and quality of care provided by the hospital [11].

Healthcare facility leader/director:

The designated individual who has the responsibility to oversee effective functioning of processes within a defined scope of services [11].

Incapacitated patient:

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 [10].

Invasive procedure:

Includes but not limited to all interventional radiology, cardiology, interventions related to vaginal birth and interventions performed outside the surgical environment – for example, central line placement in ward areas [8].

Kernicterus:

"Kernicterus" refers to the neurologic consequences of the deposition of unconjugated bilirubin in brain tissue. Subsequent damage and scarring of the basal ganglia and brainstem nuclei may occur [6].

Medication error:

"A medication error is 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 [12].

Minor:

A person whose cognition has not been completed and at the age of eighteen or less. Translated from [10].

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.

Sentinel event:

An adverse event in health care delivery or other services, which either leads to or has potential to lead to catastrophic outcomes, thereby often mandating initiation of emergency intervention or of preventive measures.

Severe temporary harm:

Defined as critical, potentially life-threatening harm lasting for a limited time with no permanent residual but requires transfer to a higher level of care/monitoring for a prolonged period, transfer to a higher level of care for a life-threatening condition, or additional major surgery, procedure, or treatment to resolve the condition [1].

***Vascular air embolism*:**

The entrainment of air (or exogenously delivered gas) from the operative field or other communication with the environment into the venous or arterial vasculature, producing systemic effects [13].

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