



# الدليل السعودي للأحداث الجسيمة في القطاع الصحي

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## شكر وتقدير

يتقدم المركز السعودي لسلامة المرضى بالشكر والتقدير إلى جميع خبراء الرعاية الصحية الذين ساهموا في تطوير هذا الدليل. ثانيًا ، نود أن نتقدم بالشكر لكل المساهمين في مراجعة وتدقيق الدليل.

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## توجيه



تسعى وزارة الصحة دائماً إلى تقديم أفضل الخدمات الصحية للمواطنين الكرام مع الحرص على التحسين المستمر لجودة تقديم الرعاية الصحية بالإضافة إلى حماية صحة الفرد، حيث أولت هذه البلاد المباركة منذ تأسيسها " القطاع الصحي " جُلَّ رعايتها واهتمامها وأعطت ودعمت بسخاء للحفاظ على صحة وسلامة المواطن وبناء أجيال صحية سليمة تواصل مسيرة البناء والتطور في بلادنا الغالية.

وبفضل هذا الدعم والرؤية الثاقبة لجودة وملائمة خدمات الرعاية الصحية المقدمة في المملكة، تم إنشاء المركز السعودي لسلامة المرضى كمبادرة أساسية تتماشى مع التحول الوطني ورؤية مملكتنا الحبيبة 2030 .

ونتطلع إلى أن تدعم هذه المبادرة سلامة خدمات الرعاية الصحية المقدمة في المملكة وتعزز تمكين المرضى والعمل بشكل مكثف لتقليل الضرر الذي يمكن تجنبه.

د. توفيق بن فوزان الربيعية

وزير الصحة



## خلفية عن سلامة المرضى

كانت ولا زالت سلامة المرضى ضمن أولويات العمل الوطني في المملكة العربية السعودية ، وقد بذلت الجهات التنظيمية والجهات التنفيذية ممثلة بوزارة الصحة جهود كبيرة موجهة نحو تحقيق أفضل معايير سلامة المرضى وتعزيز الأنظمة الداعمة لها .

وباكورة هذه الإجراءات تمثلت في مبادرة برنامج جودة مكة المكرمة كأول برنامج إقليمي لاعتماد الجودة يتم تنفيذه في المنطقة الغربية من المملكة ، تلاها انشاء المركز السعودي لاعتماد المنشآت الصحية للتركيز على معايير خاصة بسلامة المرضى.

كما كان للجهود المبذولة أدناه اسهامات في تحقيق العديد من النتائج في مجال سلامة المرضى وذلك قبل صدور تنظيم المركز السعودي لسلامة المرضى.

### وزارة الصحة

كجزء من مراحل تطوير تحسين الخدمات الصحية ، الزمت وزارة الصحة جميع منشآت الرعاية الصحية (الحكومية والخاصة) الإبلاغ عن "الأحداث الجسيمة" عن طريق نظام الكتروني لرصدها وتحليلها .

### الهيئة العامة للغذاء والدواء

قدم نظام التيقظ الدوائي التابع للهيئة العامة للغذاء والدواء لمقدمي الرعاية الصحية ومنشآت الرعاية الصحية والأفراد نهجًا منظمًا للإبلاغ عن الآثار الجانبية والأخطاء الدوائية وأي خلل في جودة المستحضرات الصيدلانية والعيوب في الأجهزة والمستلزمات الطبية.

مع إطلاق رؤية المملكة العربية السعودية 2030 ، تم اعتماد العديد من تدابير سلامة المرضى لإعادة هيكلة وتعزيز سلامة المرضى .

في عام 2017 تم انشاء المركز السعودي لسلامة المرضى كمبادرة حكومية لضمان رعاية صحية آمنة لجميع افراد المجتمع وتوفير خدمات رعاية صحية خالية من الأضرار.



## 1. المقدمة

سلامة المرضى هي وقيمتهم من الضرر ولا شك أنه التزام مشترك لا يمكن تحقيقه إلا من خلال عمل جميع القطاعات معًا والبناء على خبرة مجموعة متنوعة من المنظمات والأفراد ، بما في ذلك المرضى وعائلاتهم. في هذا السياق، وفي عام 2017 تم إنشاء المركز السعودي لسلامة المرضى كأول مركز من نوعه في المنطقة لتحقيق أهداف وزارة الصحة ضمن رؤية التحول الوطني 2030.

يعمل المركز السعودي لسلامة المرضى على تعزيز أفضل الممارسات لجميع الممارسين الصحيين والمنشآت الصحية في المملكة ذات الصلة بهذا المجال وعليه فإن المركز بصدد تأسيس إستراتيجية لسلامة المرضى وتحفيز منظمي الرعاية الصحية ومموليها ومقدميها والمرضى بشأن سلامة المرضى وتقديم خدمات رعاية صحية أكثر اماناً للجميع .

وعلى الرغم من أن الخطر جزء لا يتجزأ من العلاج ، إلا أننا نعلم أنه يمكن وقاية المريض من الكثير من الأضرار وتجنب العديد من هذه الأحداث من خلال الإبلاغ عنها والتعرف على أسباب حدوثها لتفاديها في المستقبل.

سلامة المرضى والجودة أمران حيويان لأداء الرعاية الصحية الأمثل وتتمثل الخطوة الأولى في تحسين سلامة المرضى في التعرف على مدى وشدة الأوضاع الممارسات غير الآمنة.

تم تصميم هذا الدليل وفق ما نص عليه تنظيم المركز الصادر بقرار مجلس الوزراء رقم 122 وتاريخ 1442/2/19 هـ وقرار المجلس الصحي السعودي (83/5) بتاريخ 1439/12/28 هـ

سيوفر هذا الدليل لمنشآت الرعاية الصحية في المملكة العربية السعودية قائمة بالأحداث الجسيمة التي يجب الإبلاغ عنها لتوجيه مرفق الرعاية الصحية حول أنواع الأحداث التي يتم إبلاغ المركز السعودي لسلامة المرضى بها.

كما أنه يوفر خطوات مفصلة لطريقة الإبلاغ وتحليل الأحداث الجسيمة مع تركيز انتباه المنشأة على فهم العوامل المساهمة في الحدث ، وتغيير مفهوم وثقافة الموظفين تجاه الإبلاغ عن الأحداث الجسيمة ، والتركيز على إخفاقات النظام والمتغيرات فيه لتقليل احتمال وقوع مثل هذا الحدث في المستقبل.

سيتم تحديث هذا الدليل بانتظام بعد رصد تقارير الأحداث الجسيمة وتخطيط هذه الأحداث على المستوى الوطني ومقارنتها بمعايير ومستويات دولية ومناقشة الأسباب الجذرية والعوامل المساهمة والدروس المستفادة والإجراءات التصحيحية للحد من حدوثها.



## II. تطوير الدليل السعودي للأحداث الجسيمة في القطاع الصحي

تم تطوير الدليل السعودي للأحداث الجسيمة في القطاع الصحي كجهد جماعي باستخدام المنهجيات التالية:

1. إنشاء فريق العمل.
2. رصد ومراجعة جميع القوائم الوطنية والدولية المتاحة للأحداث الجسيمة ،
3. تطوير قائمة مقترحة للأحداث الجسيمة، بما في ذلك منهجية الإبلاغ عن هذه الأحداث والتعامل معها ،
4. تمت استشارة الجهات الوطنية المعنية فيما يتعلق بالمعايير التالية:
  - 4.1 الاتفاق أو التحفظ مع التعليق على الأحداث الجسيمة التي تم اختيارها ،
  - 4.2 الاتفاق أو التحفظ مع التعليق على معايير التضمين والاستبعاد لكل نوع حدث ، و
  - 4.3 الاتفاق أو التحفظ مع التعليق على منهجية التبليغ عن الأحداث
5. تطوير مسودة أولية للدليل السعودي للأحداث الجسيمة في القطاع الصحي.
6. مشاركة المسودة الأولية للدليل مع خبراء متخصصين للمراجعة وابداء الملاحظات،
7. جمع الملاحظات على المسودة الأولية للدليل ،
8. مراجعة نتائج الملاحظات على المسودة الأولية للدليل

## III. معايير التضمين والاستبعاد للأحداث الجسيمة:

معايير التضمين والاستبعاد للأحداث الجسيمة في هذا الدليل تعتمد على الخواص التالية للأحداث:

- يُعرف الحدث عالمياً بأنه "يمكن منعه تماماً" ويجب ألا يحدث أبداً ،
  - الحدث يتضمن فشل الأنظمة أو الإجراءات ،
  - يمكن قياس الحدث وتحديد بوضوح
- غالبية الأحداث الجسيمة المدرجة في هذا الدليل تم تعديلها وتطويرها من قائمة الأحداث الجسيمة للجنة المشتركة الدولية ، قائمة الأحداث الجسيمة الأسترالية ، قائمة الأحداث الجسيمة في كندا ، قائمة الأحداث الجسيمة للمركز السعودي لاعتماد المنشآت الصحية ، ووزارة الصحة السعودية.

## IV. قائمة الأحداث الجسيمة الواجبة التبليغ

القائمة التالية للأحداث الجسيمة الواجب الإبلاغ عنها (راجع الملحق الأول).

## V. الإبلاغ عن الأحداث الجسيمة وإدارتها

يوضح هذا الدليل المبادئ التوجيهية العامة لتحديد الحدث الجسيم والإبلاغ عنه وإدارة الحدث داخل منشآت الرعاية الصحية وتقديم تحليل السبب الجذري (RCA) وخطة العمل التصحيحية (CAP) إلى القطاعات الصحية الحاكمة للمنشأة والمركز السعودي لسلامة المرضى. (راجع الملحق الثاني).



## أحكام سرية المعلومات:

جميع المعلومات الخاصة بالأحداث الجسيمة التي يتم الإبلاغ عنها على بوابة المركز السعودي لسلامة المرضى تعتبر خاصة و سرية، حيث سيقوم المركز بتحليل البيانات و إعداد التقارير بغرض التعلم من هذه الأحداث و نشر الدروس المستفادة، و لن يقوم المركز بالإفصاح عن هوية المنشآت الصحية التي قامت بالإبلاغ عن هذه الأحداث.

## 1. الإبلاغ عن الأحداث الجسيمة داخل منشآت الرعاية الصحية

### 1.1. الإبلاغ عن الأحداث الجسيمة

عند وقوع حادث يُشتبه في أنه حدث جسيم (حسب الفئات والتعاريف الواردة في هذا الدليل) ، يجب على الموظفين المشاركين بشكل مباشر في الحدث أو من قاموا باكتشافه الإبلاغ عنه وفقاً لسياسة منشأة الرعاية الصحية المعنية.

### 1.2. استجابة منشآت الرعاية الصحية بعد الحدث الجسيم

بمجرد أن يتلقى القسم المسؤول إخطاراً بأي حادث يشتبه في أنه حدث جسيم ، من المتوقع أن يقوم القسم المسؤول بالتعاون مع الفريق المعين داخل منشأة الرعاية الصحية بمراجعة الحدث والتحقق منه ومطابقته مع فئات الحدث الجسيم المحددة والمدرجة في هذا الدليل.

يجب على قائد / مدير المنشأة تعيين فريق تحليل السبب الجذري (RCA) ليكون مسؤولاً عن إدارة الحدث في غضون (24) ساعة من وقت الإبلاغ الداخلي عن الحدث. من الناحية المثالية ، يجب أن يضم فريق تحليل السبب الجذري خبيراً في موضوع الحدث قيد التحقيق ، وموظفاً ليس على دراية بالحدث قيد التحقيق ، وميسر لتحليل السبب الجذري (RCA) ، وموظفي الخطوط الأمامية. قد يشمل فريق تحليل السبب الجذري (RCA) أيضاً المديرين والمشرفين وفقاً لنطاق الحدث. لا يُنصح بإدراج أي من الموظفين المشاركين مباشرة في الحدث ، أو المشرفين / المديرين في القسم الذي وقع فيه الحدث في فريق تحليل السبب الجذري (RCA) ، لتجنب أي تضارب محتمل في المصالح.

فريق تحليل السبب الجذري (RCA) المعين مسؤول عما يلي:

- تقديم الدعم للموظفين المشاركين في الحدث ،
- بدء عملية التحقيق ،
- مقابلة المريض / العائلة ، إن أمكن ، والموظفين الذين شاركوا بشكل مباشر في الحدث ،
- إجراء تحليل للأسباب الجذرية (RCA) لتحديد الأسباب الجذرية والعوامل المساهمة ، باستخدام الأدوات المحددة في هذا الدليل ،
- التوصية بخطة عمل تصحيحية (CAP) ، مع تحديد المسؤوليات والجدول الزمني للتنفيذ ،
- تقديم تحليل السبب الجذري (RCA) وخطة العمل التصحيحية (CAP) ، إلى القطاع الحاكم للمنشأة.

نظراً لطبيعة هذه الأحداث وحساسيتها ، فإن كل منشأة رعاية صحية ملزمة بتحديد آلية للإفصاح عن أحداث سلامة المرضى للمرضى وعائلاتهم.

### 1.3. إجراء تحليل موثوق للسبب الجذري (RCA)

بعد الإبلاغ عن الحدث ، يكون فريق تحليل السبب الجذري (RCA) المعين مسؤولاً عن إكمال تحليل السبب الجذري.





## 1.4. خطة العمل التصحيحية (CAP)

يعد وضع خطة عمل تصحيحية (CAP) خطوة مهمة يجب أن يتخذها فريق تحليل السبب الجذري (RCA) بعد تحديد الأسباب الجذرية والعوامل المساهمة في الحدث. (راجع الملحق الثالث). يجب أن تحدد الخطة ما يجب القيام به لمنع حدوث أحداث مماثلة في المستقبل. قد تختلف الإجراءات في قوتها للحد من أخطار النظام أو القضاء عليها وفقاً لتصنيفها حسب التسلسل الهرمي للإجراءات (راجع الملحق الرابع) إلى إجراءات قوية أو إجراءات متوسطة أو إجراءات ضعيفة. قد يحدد الفريق أكثر من إجراء تصحيحي لكل سبب جذري وعامل مساهم ؛ يوصى بتحديد إجراء أقوى أو متوسط القوة واحد على الأقل لكل عامل مساهم في حدوث الحدث.

لضمان تنفيذ خطة العمل التصحيحية ، يجب على الفريق تعيين مسؤوليات الأفراد مع التاريخ (التواريخ) المستهدفة لانتهاؤهم. قبل تقديم الخطة التصحيحية (CAP) إلى القطاع الحاكم للمنشأة الصحية ، يجب على قائد / مدير المنشأة التأكد من أن الخطة تتضمن ما يلي:

- العوامل المساهمة محددة جيداً ،
- بيان سببي / سبب جذري لكل عامل مساهم ،
- الإجراءات (الإجراءات) التصحيحي لكل بيان سببي ، يتضمن على الأقل إجراء قوي واحد أو متوسط القوة ،
- الشخص المسؤول عن تنفيذ كل إجراء
- الموعد المستهدف لإتمام كل إجراء.

يعد مخطط جانث أحد الأدوات الفعالة التي يمكن استخدامها من قبل فريق إدارة وتحليل الأحداث الجسيمة لرصد ومراقبة توقيت تنفيذ خطة العمل. يوضح هذا المخطط مهمة (مهام) خطة العمل المعتمدة ، والمسؤول عن تنفيذ المهمة (المهام) ، ومتى يجب تنفيذ المهمة (المهام) ، والمدة التي ستستغرقها المهمة (المهام). مع تقدم خطة العمل ، يُظهر الرسم البياني المهام التي تم إكمالها ضمن الإطار الزمني المخصص لها من قبل الفرد / الفريق المعين.

## 2. الإبلاغ عن الأحداث الجسيمة وعملية إدارتها من قبل القطاع الحاكم لمنشأة الرعاية الصحية

يجب على القطاع الحاكم تقديم نموذج الإبلاغ عن الأحداث الجسيمة والذي يتضمن (تحليل السبب الجذري) RCA و (الخطة التصحيحية) مكتمل ، على بوابة الإبلاغ عن الأحداث الجسيمة للمركز السعودي لسلامة المرضى، في غضون ثلاثين (30) يوم عمل من تاريخ الإبلاغ الداخلي عن الحدث.

## 3. الإبلاغ عن الأحداث الجسيمة إلى المركز السعودي لسلامة المرضى

بعد استلام المركز السعودي لسلامة المرضى للإبلاغ ، سيقوم موظف المركز المكلف بمراجعة الحدث بجميع المستندات ذات الصلة للتأكد من أن التقارير والتقديم يفيان بالجدول الزمني المحدد ، وأن تحليل السبب الجذري شامل ويركز على النظام ، وليس الأفراد ، وتواجد الخطة التصحيحية مع تحديد المسؤولية والجدول الزمنية في حال وجود أي استفسارات ، سيقوم الموظف المكلف من قبل المركز السعودي لسلامة المرضى التواصل مع القطاع الحاكم للمنشأة الصحية.

سيقوم الفريق المسؤول في المركز السعودي لسلامة المرضى بمراجعة وتحليل العوامل المساهمة والأسباب الجذرية لجميع الأحداث المبلغ عنها على البوابة. وبناءً على التحليل ، سيقوم المركز بإعداد تقرير ربع سنوي يحدد الاتجاهات والدروس المستفادة لتقديمها للمراجعة والموافقة عليها من قبل لجنة مكلفة ، ورفع تقرير سنوي للمجلس الصحي السعودي.



## الملحق الأول: قائمة الأحداث الجسيمة الواجبة التبليغ

### Reportable Sentinel Event List

#### 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 were 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]

(Ref. No.)**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, and
  - 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 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 hyperbilirubinemia. [6].

**Inclusion:**

- All death or disability cases (e.g., Kernicterus) resulted from failure to identify/re-assess or manage neonatal hyperbilirubinemia. [7]

**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. [6]

**Inclusion:**

- All stage 3, 4, or unstageable pressure injury cases acquired after patients' admission.
- This includes the following Stages [8]:
  - Stage 3 Pressure Injury: Full-thickness skin loss,
  - Stage 4 Pressure Injury: Full-thickness skin and tissue loss, and
  - 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 failure to assess/identify patients for fall risk.
- 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. [6]

**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. [9]

**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 [10]:
  - Second Degree (Partial Thickness): Skin may be red, blistered, swollen. Very painful.

- Third Degree (Full Thickness): Whitish, charred, or translucent, with no pin prick sensation in burned area.

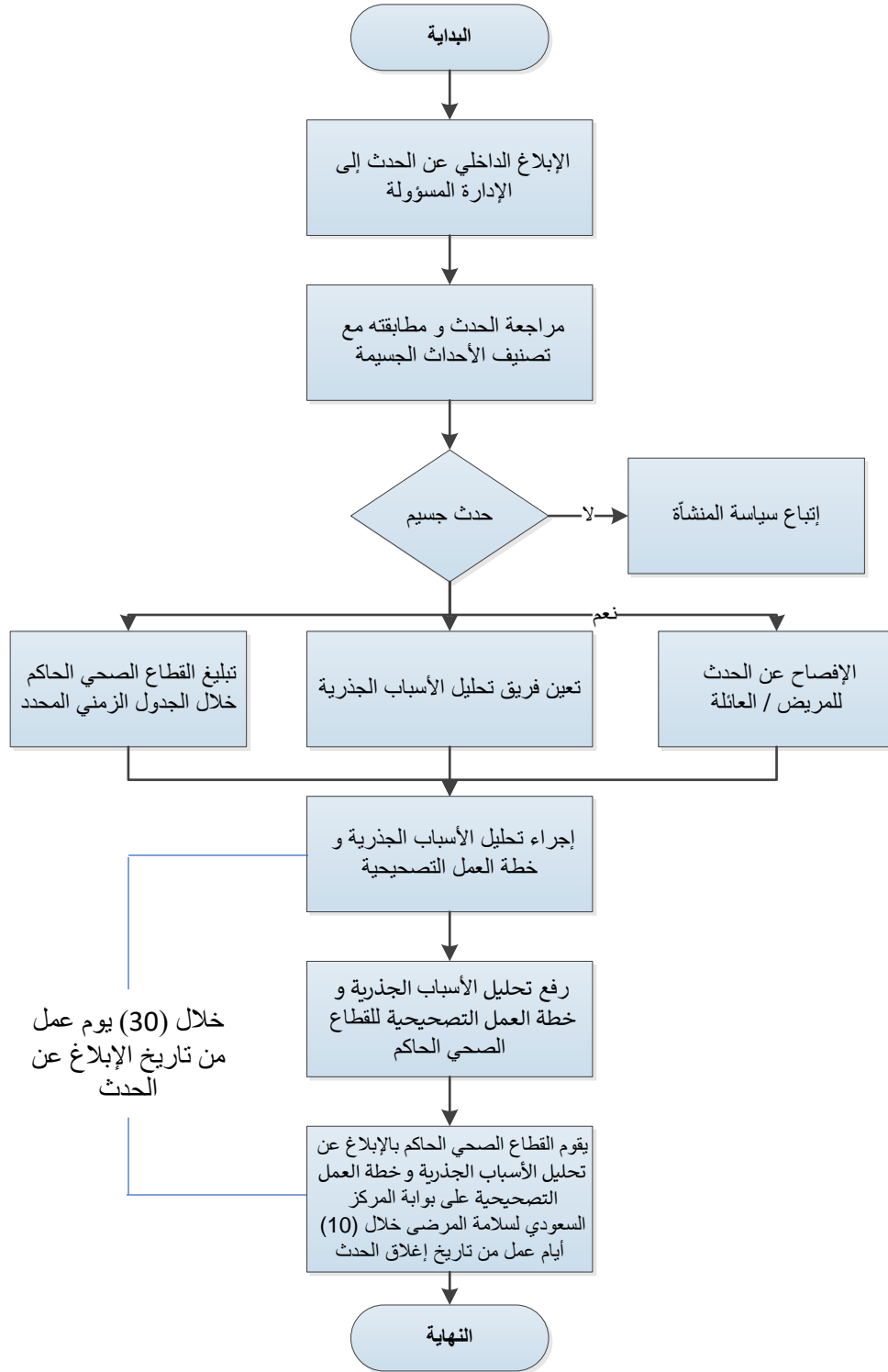
**Exclusion:**

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





## الملحق الثاني: الإبلاغ عن الأحداث الجسيمة وإدارتها



### الملحق الثالث: تحليل السبب الجذري والخطة التصحيحية

Category of Contributing Factor	Triggering Questions	Contributing factors	Causal Statement	Corrective Actions	Action Strength	Responsibility	Action Due Date
<b>Process Issues</b>	<p>1. What was the intended process flow? ----- ----- ----- -----</p> <p>2. Were there any steps in the process that did not occur as intended? <input type="checkbox"/>Yes      <input type="checkbox"/>No</p> <p>3. What were the steps in the process that did not occur as intended? ----- ----- ----- -----</p> <p>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? <input type="checkbox"/>Yes      <input type="checkbox"/>No</p>	<p><b>Check All that apply:</b></p> <p><input type="checkbox"/> Aids not available or not working (e.g., CTG machine; checklist; a risk assessment tool; fax machine to enable remote assessment of results)</p> <p><input type="checkbox"/> Difficulties in accessing senior/specialist advice</p> <p><input type="checkbox"/> Lack of prioritization of guidelines</p> <p><input type="checkbox"/> Poorly designed (i.e., Too complex; too much info.; difficult to conceive or remember)</p> <p><input type="checkbox"/> Too many tasks to perform at the same time</p> <p><input type="checkbox"/> Contradicting tasks</p> <p><input type="checkbox"/> Staff do not agree with the 'task/procedure design_</p> <p><input type="checkbox"/> Stages of the task not designed so that each step can realistically be carried out</p> <p><input type="checkbox"/> Inappropriate transfer of processes from other situations</p>	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
<b>Process Issues (continued)</b>	<p>5. Were there written up-to-date policies and procedures that addressed the work processes related to the event? <input type="checkbox"/>Yes      <input type="checkbox"/>No</p> <p>6. Were relevant policies/procedures clear, understandable, and readily available to all staff? <input type="checkbox"/>Yes      <input type="checkbox"/>No</p>	<p><b>Check All that apply:</b></p> <p><input type="checkbox"/> Insufficient opportunity to influence task/outcome where necessary</p> <p><input type="checkbox"/> Unreliable or ineffective general administrative systems (Please specify, e.g., Bookings, Patient identification, ordering, requests, referrals, appointments)</p> <p><input type="checkbox"/> Unreliable or ineffective admin infrastructure (e.g., Phones, bleep systems, etc.)</p> <p><input type="checkbox"/> Unreliable or ineffective administrative support</p> <p><input type="checkbox"/> Delays caused by system failure or design</p> <p><input type="checkbox"/> Time pressure</p> <p><input type="checkbox"/> Other: -----</p>	<p>Enter free text here (For Each Contributing factor, please write a causal statement)</p>	<p>Enter free text here (For Each Causal Statement, please write a no. of Actions)</p>	<p>For each action select (Drop Down List) Stronger/Intermediate/Weaker</p>	<p>For each action Enter free text here [Title/Position]</p>	<p>For each action [DATE]</p>
<b>Human Factors</b>	<p>1. What were staff-related human performance factors relevant to the outcome? ----- -----</p>	<p><b>Check All that apply:</b></p> <p><input type="checkbox"/> Stress (e.g., distraction / preoccupation)</p> <p><input type="checkbox"/> Lack of motivation (e.g., boredom, complacency, low job satisfaction)</p>	<p>Enter free text here (For Each Contributing factor, please write a causal statement)</p>	<p>Enter free text here (For Each Causal Statement, please write a no. of Actions)</p>	<p>For each action select (Drop Down List) Stronger/Intermediate/Weaker</p>	<p>For each action Enter free text here [Title/Position]</p>	<p>For each action [DATE]</p>

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

Category of Contributing Factor	Triggering Questions	Contributing factors	Causal Statement	Corrective Actions	Action Strength	Responsibility	Action Due Date
<b>Human Factors (continued)</b>	6. What was the source of psychological stressors? ----- ----- ----- -----	<b>Check All that apply:</b> <input type="checkbox"/> Lack of complex critical thinking skills <input type="checkbox"/> Rushing to complete task <input type="checkbox"/> Substance abuse <input type="checkbox"/> Trust <input type="checkbox"/> 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]
<b>Equipment / Technology</b>	1. Was available equipment/technology used as intended? <input type="checkbox"/> Yes <input type="checkbox"/> No 2. How did the equipment/technology performance affect the outcome? ----- ----- 3. How was the equipment/technology designed to minimize errors or easy-to-catch mistakes? ----- ----- -----	<b>Check All that apply:</b> <input type="checkbox"/> Interference/unclear equipment display <input type="checkbox"/> Poor working order <input type="checkbox"/> Inappropriate size <input type="checkbox"/> Unreliable <input type="checkbox"/> Ineffective safety features/not designed to fail-safe <input type="checkbox"/> Poor maintenance program <input type="checkbox"/> Failure of general services (power supply, water, piped gases, etc.) <input type="checkbox"/> Correct equipment not available <input type="checkbox"/> Insufficient equipment / emergency backup equipment <input type="checkbox"/> Incorrectly placed for use <input type="checkbox"/> 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
	4. Was there a maintenance program in place to maintain the equipment involved? <input type="checkbox"/> Yes <input type="checkbox"/> No						
<b>Equipment / Technology (continued)</b>	5. Were personnel trained appropriately to operate the equipment involved in the event? <input type="checkbox"/> Yes <input type="checkbox"/> No	<b>Check All that apply:</b> <input type="checkbox"/> Unclear controls <input type="checkbox"/> Not intuitive in design <input type="checkbox"/> Confusing use of color or symbols <input type="checkbox"/> Lack of or poor-quality user manual <input type="checkbox"/> Not designed to make detection of problems obvious <input type="checkbox"/> Use of items that have similar names or packaging <input type="checkbox"/> Problems of compatibility <input type="checkbox"/> 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]
<b>Environmental Factors</b>	1. How was the work area/environment designed to support the function it was being used for? ----- ----- ----- -----	<b>Check All that apply:</b> <input type="checkbox"/> 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.)	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
	<p>2. Had there been an environmental risk assessment (i.e., safety audit) of the area?</p> <p><input type="checkbox"/>Yes      <input type="checkbox"/>No</p>	<p><input type="checkbox"/> Poor or inappropriate area design (length, shape, visibility, provision of space)</p> <p><input type="checkbox"/> Inadequate security provision</p>					
<b>Environmental Factors (continued)</b>	<p>3. How was the physical work environment designed to decrease stress levels?</p> <p>-----</p> <p>-----</p> <p>-----</p> <p>-----</p> <p>4. Were appropriate safety evaluations and disaster drills been conducted as scheduled?</p> <p><input type="checkbox"/>Yes      <input type="checkbox"/>No</p> <p>5. Did the work area/environment meet current codes, specifications, and regulations?</p> <p><input type="checkbox"/>Yes      <input type="checkbox"/>No</p>	<p><b>Check All that apply:</b></p> <p><input type="checkbox"/> Lack of secure outside space</p> <p><input type="checkbox"/> Temperature too high/low</p> <p><input type="checkbox"/> Noise levels too high or low</p> <p><input type="checkbox"/> Lighting too dim or bright, or lack of</p> <p><input type="checkbox"/> Inadequate lines of sight</p> <p><input type="checkbox"/> Inadequate/inappropriate use of color contrast/patterns (walls/doors/flooring etc.)</p> <p><input type="checkbox"/> Housekeeping issues – lack of cleanliness</p> <p><input type="checkbox"/> Inadequate maintenance</p> <p><input type="checkbox"/> Fixture or fitting not available (failure or lack of capacity)</p> <p><input type="checkbox"/> Ligature/anchor points</p> <p><input checked="" type="checkbox"/> Other: -----</p>	<p>Enter free text here (For Each Contributing factor, please write a causal statement)</p>	<p>Enter free text here (For Each Causal Statement, please write a no. of Actions)</p>	<p>For each action select (Drop Down List) Stronger/Intermediate/Weaker</p>	<p>For each action Enter free text here [Title/Position]</p>	<p>For each action [DATE]</p>

Category of Contributing Factor	Triggering Questions	Contributing factors	Causal Statement	Corrective Actions	Action Strength	Responsibility	Action Due Date
<b>Staff Competency and Performance</b>	<p>1. How was the staff involved in the event properly qualified and trained to perform their function/duties? ----- ----- -----</p> <p>2. 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? ----- ----- -----</p> <p>3. How was the staff training needs assessment conducted? ----- ----- -----</p>	<p><b>Check All that apply:</b></p> <p><input type="checkbox"/> Mental impairment (e.g., illness, drugs, alcohol, pain)</p> <p><input type="checkbox"/> Lack of knowledge</p> <p><input type="checkbox"/> Lack of skills</p> <p><input type="checkbox"/> Inexperience</p> <p><input type="checkbox"/> Inappropriate experience or lack of quality experience</p> <p><input type="checkbox"/> Unfamiliar task</p> <p><input type="checkbox"/> Lack of testing and assessment</p> <p><input type="checkbox"/> Inadequate supervision</p> <p><input type="checkbox"/> Lack of / inadequate mentorship</p> <p><input type="checkbox"/> Training results not monitored/acted upon</p> <p><input type="checkbox"/> Training needs analysis not conducted/acted upon</p> <p><input type="checkbox"/> On the job training unavailable or inaccessible</p> <p><input type="checkbox"/> Emergency Training unavailable or inaccessible</p> <p><input type="checkbox"/> Team training unavailable or inaccessible</p> <p><input type="checkbox"/> Core skills training unavailable or inaccessible</p> <p><input type="checkbox"/> Refresher courses unavailable or inaccessible</p>	<p>Enter free text here (For Each Contributing factor, please write a causal statement)</p>	<p>Enter free text here (For Each Causal Statement, please write a no. of Actions)</p>	<p>For each action select (Drop Down List) Stronger/Intermediate/Weaker</p>	<p>For each action Enter free text here [Title/Position]</p>	<p>For each action [DATE]</p>

Category of Contributing Factor	Triggering Questions	Contributing factors	Causal Statement	Corrective Actions	Action Strength	Responsibility	Action Due Date
	4. Was training provided prior to the start of the work process? <input type="checkbox"/> Yes <input type="checkbox"/> No						
<b>Staff Competency and Performance (continued)</b>	5. How were the results of training monitored over time? <input type="checkbox"/> Yes <input type="checkbox"/> No 6. How were all staff trained in the use of relevant barriers and controls? ----- ----- -----	<b>Check All that apply:</b> <input type="checkbox"/> Poor rule compliance Routine violation of rules/regulations <input type="checkbox"/> 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]
<b>Manpower Planning Issues</b>	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). <input type="checkbox"/> Yes <input type="checkbox"/> No 2. How did actual staffing compare with the ideal level? -----	<b>Check All that apply:</b> <input type="checkbox"/> Overload <input type="checkbox"/> Inappropriate skill mix (e.g., Lack of senior staff; Trained staff; etc.) <input type="checkbox"/> Low staff to patient ratio <input type="checkbox"/> Use of temporary staff <input type="checkbox"/> High staff turnover <input type="checkbox"/> Shift related fatigue <input type="checkbox"/> Excessive working hours <input type="checkbox"/> Lack of breaks during work hours	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
	<p>----- ----- 3. What was the plan for dealing with staffing contingencies? ----- ----- ----- ----- 4. Were such contingencies a factor in this event? <input type="checkbox"/>Yes      <input type="checkbox"/>No</p>	<p><input type="checkbox"/> Excessive extraneous tasks <input type="checkbox"/> Failure to address/manage issues of competence <input type="checkbox"/> Other: ----- -</p>					
<b>Leadership and Safety Culture</b>	<p>1. How does leadership address the continuum of patient safety events, including close calls, adverse events, and unsafe, hazardous conditions? ----- ----- ----- 2. How does the healthcare facility's culture support risk reduction? -----</p>	<p><b>Check All that apply:</b> <input type="checkbox"/> Inadequate decision/action caused by Group influence <input type="checkbox"/> Hierarchical structure/Governance structure not conducive to discussion, problem sharing, etc. <input type="checkbox"/> Tight boundaries for accountability and responsibility <input type="checkbox"/> Professional isolation <input type="checkbox"/> Clinical versus the managerial model</p>	<p>Enter free text here (For Each Contributing factor, please write a causal statement)</p>	<p>Enter free text here (For Each Causal Statement, please write a no. of Actions)</p>	<p>For each action select (Drop Down List) Stronger/Intermediate/Weaker</p>	<p>For each action Enter free text here [Title/Position]</p>	<p>For each action [DATE]</p>



Category of Contributing Factor	Triggering Questions	Contributing factors	Causal Statement	Corrective Actions	Action Strength	Responsibility	Action Due Date
	<p>-----</p> <p>-----</p> <p>3. How does leadership demonstrate accountability for implementing measures to reduce the risk of patient harm?</p> <p>-----</p> <p>-----</p> <p>-----</p> <p>4. How does leadership communicate corrective actions stemming from any analysis following reported risks?</p> <p>-----</p> <p>-----</p> <p>-----</p>	<p><input type="checkbox"/> Lack of robust Service level agreements/contractual arrangements</p> <p><input type="checkbox"/> Inadequate safety terms and conditions of contracts</p> <p><input type="checkbox"/> Contractors related problem</p> <p><input type="checkbox"/> Inappropriate safety/efficiency balance</p> <p><input type="checkbox"/> Lack of risk management plans</p> <p><input type="checkbox"/> Inadequate leadership example (e.g., visible evidence of commitment to safety)</p>					
<b>Leadership and Safety Culture (continued)</b>	<p>5. How does the overall culture encourage change, suggestions, and warnings from staff regarding risky situations or problem areas?</p>	<p><b>Check All that apply:</b></p> <p><input type="checkbox"/> Inadequately open culture to allow appropriate communication</p> <p><input type="checkbox"/> Inadequate learning from past incidents</p>	<p>Enter free text here (For Each Contributing factor, please write a causal statement)</p>	<p>Enter free text here (For Each Causal Statement, please write a no. of Actions)</p>	<p>For each action select (Drop Down List) Stronger/Intermediate/Weaker</p>	<p>For each action Enter free text here [Title/Position]</p>	<p>For each action [DATE]</p>

Category of Contributing Factor	Triggering Questions	Contributing factors	Causal Statement	Corrective Actions	Action Strength	Responsibility	Action Due Date
	----- ----- -----	<input type="checkbox"/> Incentives for 'at risk'/'risk taking' behaviors <input type="checkbox"/> Acceptance/toleration of inadequate adherence to current practice <input type="checkbox"/> Ignorance/poor awareness of inadequate adherence to current practice <input type="checkbox"/> Disempowerment of staff to escalate issues or take action <input type="checkbox"/> Ineffective leadership – clinically <input type="checkbox"/> Ineffective leadership – managerially <input type="checkbox"/> Lack of decision making <input type="checkbox"/> Inappropriate decision making <input type="checkbox"/> Untimely decision making (delayed) <input type="checkbox"/> Leader poorly respected					
<b>Leadership and Safety Culture (continued)</b>	6. How does leadership address disruptive behaviors? ----- ----- -----	<b>Check All that apply:</b> <input type="checkbox"/> Lack of support networks for staff <input type="checkbox"/> Inappropriate level of assertiveness <input type="checkbox"/> Inadequate inter-professional challenge	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
		<input type="checkbox"/> Bed Availability <input type="checkbox"/> Other: -----					
<b>Communication and Information</b>	1. Was the patient correctly identified? <input type="checkbox"/> Yes <input type="checkbox"/> No  2. How was information from various patient assessments shared and used by the treatment team members on a timely basis? ----- ----- ----- -----	<b>Check All that apply:</b> <input type="checkbox"/> Language <input type="checkbox"/> Incomplete information (test results, patient history) <input type="checkbox"/> Misrepresentation of information <input type="checkbox"/> The inappropriate tone of voice and style of delivery for the situation <input type="checkbox"/> Ambiguous verbal commands/directions <input type="checkbox"/> Incorrect use of language <input type="checkbox"/> Made to inappropriate person(s) <input type="checkbox"/> Incorrect communication channels used	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]
<b>Communication and Information (continued)</b>	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,	<b>Check All that apply:</b> <input type="checkbox"/> Inadequate patient identification <input type="checkbox"/> Records difficult to read <input type="checkbox"/> All relevant records not stored together and accessible when required	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
	<p>progress notes, medication administration record, x-ray, labs, etc.)? -----</p> <p>-----</p> <p>4. Was communication between management/supervisors and front-line staff adequate? (i.e., Accurate, complete, unambiguous, using standard vocabulary and no jargon)</p> <p><input type="checkbox"/>Yes      <input type="checkbox"/>No</p> <p>5. Was communication between front line team members adequate?</p> <p><input type="checkbox"/>Yes      <input type="checkbox"/>No</p>	<p><input type="checkbox"/> Records incomplete or not contemporaneous (e.g., unavailability of patient management plans, patient risk assessments, etc.)</p> <p><input type="checkbox"/> Written information not circulated to all team members</p> <p><input type="checkbox"/> Communication not received</p> <p><input type="checkbox"/> Communications directed to the wrong people</p> <p><input type="checkbox"/> Lack of information to patients</p> <p><input type="checkbox"/> Lack of effective communication to staff of risks (Alerts systems etc.)</p> <p><input type="checkbox"/> Body Language issues (closed, open, body movement, gestures, facial expression)</p>					
<b>Communication and Information (continued)</b>	<p>6. Was communication across patient care areas adequate (e.g., transfers, consults)</p> <p><input type="checkbox"/>Yes      <input type="checkbox"/>No</p>		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
	7. How were policies and procedures communicated adequately? ----- ----- ----- -----		write a causal statement)	please write a no. of Actions)			
<b>Communication and Information (continued)</b>	8. How was the endorsement of patient information communicated adequately? ----- ----- ----- -----	<b>Check All that apply:</b> <input type="checkbox"/> Negative team reaction to conflict <input type="checkbox"/> Negative team reaction to newcomers <input type="checkbox"/> Lack of team openness/communication with colleagues <input type="checkbox"/> Failure to seek support <input type="checkbox"/> Lack of easy access to technical information, flow charts and diagrams <input type="checkbox"/> Lack of direct or understandable feedback from the task <input type="checkbox"/> 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]
<b>Others</b>	Are there any other any unasked questions?	Enter free text here	Enter free text here (For Each Contributing	Enter free text here (For Each Causal	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
			factor please write a causal statement)	Statement please write a no. of Actions)			



## الملحق الرابع : التسلسل الهرمي للإجراءات

Action Strength	Action Category	Example
<b>Stronger Actions</b> (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.
<b>Intermediate Actions</b>	Tangible involvement by leadership	Participate in unit patient safety evaluations and interact with staff; support the RCA <sup>2</sup> process (root cause analysis and action); purchase needed equipment; ensure staffing and workload are balanced.
	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.
<b>Intermediate Actions</b> (continued)	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.
	Checklist/cognitive aids	Use pre-induction and pre-incision checklists in operating rooms. Use a checklist when reprocessing flexible fiber optic endoscopes.



Action Strength	Action Category	Example
	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.
	Enhanced documentation, communication	Highlight medication name and dose on IV bags.
<b>Weaker Actions (these tasks require more reliance on humans to remember to perform the task correctly)</b>	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.





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# المركز السعودي لسلامة المرضى SAUDI PATIENT SAFETY CENTER



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