**SCOPE:**

This policy and procedure applies to all employees of the Royal Victoria Regional Health Centre (RVH) as well as professional staff with RVH privileges (i.e., medical, dental, midwifery, and extended class nurses), volunteers, students, and contractors. These individuals shall be referred to collectively as *workers* herein. The requirements apply whether working on RVH property or working on behalf of or representing RVH elsewhere.

**POLICY STATEMENT:**

It is the policy of RVH to report and investigate all patient safety incidents in order to promote a culture of safety and to create learning opportunities for quality improvement. This document provides the steps to be followed when any patient safety incident occurs at RVH.

**DEFINITIONS:**

**Patient Safety Incident (PSI):** An event or circumstance which could have resulted or did result in harm to a patient. The continuum of PSI types is based on increasing levels of harm, as follows:

1. **Near Miss**: A patient safety incident that did not reach the patient. Near misses have the potential to cause varying degrees of harm from none to critical.
2. **No Harm Patient Safety Incident**: A patient safety incident that reached a patient but no harm resulted.
3. **Harmful Patient Safety Incident**: A patient safety incident that resulted in harm to the patient.
4. **Critical Patient Safety Incident**:

Any unintentional event that occurs when a patient receives treatment in the hospital;

1. that results in death, or serious disability, injury or harm to the patient, and,
2. does not result primarily from the patient’s underlying medical condition or from a known risk inherent in providing treatment.

Examples of critical patient safety incidents include but are not limited to:

* unexpected death, including suicides or attempted suicides within the organization.
* medication error resulting in patient dying.
* foreign object retained in patient during surgery resulting in additional surgeries/ complications.
* any patient death, paralysis, coma or other major loss of function associated with an adverse drug event or adverse transfusion reaction.
* patient outcome is symptomatic, requiring life-saving intervention or major surgical/medical intervention, shortening life expectancy or causing major permanent or long term harm or loss of function.

**Initial Understanding of Facts document**: The manager or Hospital Service Leader (HSL) is responsible for gathering information pertaining to a critical patient safety incident or near miss critical patient safety incident within the first four (4) hours of the incident. This document will be provided to the manager or HSL by the Quality and Risk Coordinator. The information required to complete this document can be gathered from multiple sources (example: SLS, Electronic Medication Record, speaking to staff, etc.) and includes, but not limited to:

* location of patient safety incident
* patient identifiers (i.e., patient name and V#)
* workers involved in incident
* brief factual description of incident
* initial interview of patient and workers involved

**National System for Incident Reporting (NSIR):** An anonymous database through Canadian Institute for Health Information designed to capture a subset (i.e., intravenous medications or fluids) of all critical patient safety incident reporting.

**Quality of Care Committee (QCC):** A group of stakeholders governed by the provisions of the *Quality of Care Information and Protection Act* (QCIPA) who review matters that may give rise to significant quality of care concerns, including but not limited to patient safety incidents such as:

* an incident involving unexpected death or serious bodily harm;
* an incident or series of incidents that have the potential to result in death or serious bodily harm;
* an incident or series of incidents that have the potential to result in harm to a number of patients.

**Safety Learning System (SLS):** The electronic incident management system adopted by RVH to capture all patient and worker incidents. Specific roles are assigned within the SLS as follows:

**Reviewer**: The person who is responsible for the management of the incident within the SLS.

**Investigator(s)**: The person or people invited by the person initiating the incident to participate in the review and document on a specific incident.

**Substitute Decision Maker (SDM):** Isa person who is authorized to give or refuse consent for treatment on behalf of a person who has been deemed incapable of making personal health care decisions.  A patient’s SDM will be the person or persons who meet the requirements to be a SDM and who are ranked highest on the hierarchy of SDMs listed in the legislation.

**PROCEDURE:**

Immediate Response for person discovering patient safety incident

1. Immediately provide appropriate patient care and implement corrective actions to prevent harm to the patient or anyone else. If required, seek assistance from Resource/Charge Nurse, Most Responsible Provider (MRP) and Interprofessional team.
2. Preserve evidence related to the patient safety/critical incident. Example: IV pump, medication packaging, etc.
3. Document facts pertaining to the patient safety incident, immediate actions taken, and any other pertinent information in the patients’ health record.
4. Notify appropriate leader/manager. Verbal communication is required if there is harm to the patient.
	1. Resource Nurse/Charge Nurse/Team Leader/Supervisor
	2. Unit Manager/Hospital Service Leader (HSL)
	3. Attending or MRP, when applicable
	4. Pharmacist, when applicable
5. For all patient safety incidents, the person who discovers the incident is to document the facts in the Safety Learning System (SLS). Automatic notification will be sent to the manager.
6. Disclose patient safety incident (or critical patient safety incident) to the patient and/or patient’s substitute decision maker (SDM) utilizing the Corporate Clinical Policy and Procedure *Disclosure of Harm* and document disclosure.
	1. In the event of a critical patient safety incident, obtain and utilize the Disclosure of Harm Checklist. This checklist can be found within the Disclosure of Harm policy as an appendix.

Unit Manager/HSL or delegate (SLS Reviewer role)

1. Acknowledge receipt of all patient safety incidents within 48 hours in SLS by changing Approval Status to “Being Reviewed”.
2. Ensure disclosure process has occurred to patient and family and is documented within SLS.
3. In the event of a critical patient safety incident immediately notify:
	* **Business Hours**: Program Operations Director and Manager Quality & Risk
	* **Weekends/Nights/Holidays**: MRP, Leader (Operations Director, Director) and Senior Leader on call and Chief Quality and Privacy Officer.
4. Support staff following critical patient safety incident.
5. Complete the Initial Understanding of Facts document (Appendix I), provided by Quality and Risk, and forward to Quality and Risk Office in preparation for the Urgent Teleconference / Meeting.
6. Complete a comprehensive Chart Review (Appendix II) in preparation for a review, if Quality Care Committee (QCC) delegates a Quality of Care Review or Incident Analysis. Once complete please forward the original and all supporting documentation to Quality and Risk Office. No copies are to be made or kept.
7. Where a critical patient safety incident results from a physical hazard on RVH premises (e.g., slippery or uneven surface, etc.) to which workers are also vulnerable, please refer to Occupational Health and Safety policy 11.5, *Critical Injury and Fatality Reporting and Investigation*.
8. Complete all documentation in the progress notes of the SLS and change Approval Status to “Final Approval” within 20 days of the incident.

In the event of a critical patient safety incident, the following additional actions shall be taken:

Operations Director/Director

1. Immediately notify the appropriate Program Vice President (VP) and Chief Quality and Privacy Officer.
2. Ensure appropriate follow up has occurred including notification to MRP.
3. Participate in Quality of Care Review or Incident Analysis, as appropriate.

Quality and Risk Office

Within 48 hours of critical patient safety incident (during regular business hours):

1. Provide appropriate Manager with Initial Understanding of Facts document in preparation for Urgent Teleconference / Meeting.
2. Support appropriate manager and staff through the process.
3. Schedule Urgent Teleconference / Meeting (Appendix III) within 48 hours of incident with Quality of Care Committee (QCC) and most appropriate leaders.

In the event that a Quality of Care Review or Incident Analysis has been delegated by the QCC:

1. Provide appropriate manager with chart review document for completion.
2. Investigate and interview staff to understand what happened, how and why?
3. Review documentation and develop sequence of events/timelines.
4. Schedule and facilitate review within 30-45 days of incident.
5. Finalize recommendation and assign timelines/accountabilities and continuous follow up to ensure recommendations are implemented/completed.

Chief Quality and Privacy Officer

Within 48 hours of critical patient safety incident (during regular business hours):

1. Ensure notification has occurred to the following: Executive Vice President (EVP), Chief Nursing Executive (CNE) and Chief of Staff within 48 hours.
2. Participate in the Patient Safety Incident Urgent Teleconference / Meeting.
3. Support the follow through with the RVH Disclosure of Harm Policy.
4. Work with the EVP, Chief of Staff and Chair of Medical Advisory Committee (MAC) to ensure the critical patient safety incident is appropriately reported to the Administrator and MAC.

Downtime Procedure

In the event the SLS becomes unavailable, paper-based forms are available throughout the facility, located in the downtime binder on each unit. Once complete, the form shall be provided to immediate supervisor. The supervisor shall proceed with his or her normal follow-up process and forward a photocopy of the signed form to the Quality and Risk office within 10 days. The Quality and Risk office will enter the incidents and outcome of investigation into the Safety Learning System once the downtime process is no longer in effect.

**CROSS REFERENCES:**

Corporate Clinical Policy and Procedure *Disclosure of Harm* (2018).

Corporate Clinical Policy and Procedure *Critical Patient Safety Incident Reporting and*

*Investigation* (2015).

Occupational Health and Safety 11.5, *Critical Injury and Fatality Reporting and*

*Investigation* (2014).

**REFERENCES:**

*Excellent Care for All Act* (2010, 2011)

*Quality of Care Information and Protection Act* (2016)

Canadian Incident Analysis Framework. (2012) Canadian Patient Safety Institute

Davies, J.M., Hebert, P., Hoffman, C*.* (October 2003). *Canadian Patient Safety*

*Dictionary*.

Royal College of Physicians and Surgeons of Canada, Canadian Medical Protective

Association, (2012). Improving patient safety through disclosure and quality improvement reviews

World Health Organization. (2009). WHO Patient Safety Research: Patient Safety A

World Alliance for Safer Healthcare.

**Incident Analysis – Initial Understanding of Facts**

Privileged and Confidential

Prepared for the Quality of Care Purposes

To better assist you please complete the chart below. Our team is happy to assist once you have an initial understanding of the facts. With this information, we will be able to assess the appropriate next steps. Once completed, please forward the original and all supporting documentation to the Patient Safety, Quality and Risk Management Office. No other copies are to be made or kept. Do not file or refer to this document in any patient record.

Please ensure the incident has been entered into the Safety Learning System.

|  |
| --- |
| **Initial Understanding of Facts** |
| V# |  |
| Patient Name |  |
| Incident # |  |
| Safety Learning System # |  |
| Date of Birth |  |
| Patient’s age |  |
| Diagnosis |  |
| Date of incident |  |
| Location of patient at time of incident |  |
| Location of patient at time of discovery of incident (if different) |  |
| Contributing factors  |  |
| Status of patient before the incident |  |
| Status of patient after the incident |  |
| If this was a fall, was falls protocol in place? |  |
| **Interview the staff who were on shift working with the patient to understand the details of the incident.** |
| When did the incident happen? |  |
| How did the incident happen? |  |
| When did staff respond? |  |
| How did staff respond? |  |
| Describe patient current status |  |
| Relevant diagnosis? |  |
| Review nursing documentation to ensure it meets all applicable standards |  |
| Ensure physician review has occurred |  |
| Has disclosure occurred and by who? |  |
| If this case meets the criteria of a Coroner’s Case, has the Coroner been notified of this case?  |  |

**Chart Review**

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Prepared for Quality of Care Purposes

To better understand the incident, we ask that you kindly complete the table below based on your findings from your Chart Review. This information will help to develop a chronological list of events to be discussed at the Review. Our team is happy to assist if you have any questions, concerns or difficulties completing.

Once completed, please forward the original and all supporting documentation to the Patient Safety, Quality and Risk Management Office. No other copies are to be made or kept. Do not file or refer to this document in any patient record.

**Date of Meeting:**
**V #:**
**Incident #:**

|  |  |  |
| --- | --- | --- |
| **Date****(and time if relevant)** | **Fact** | **Source** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
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|  |  |  |

**Date Completed:**

 **Patient Safety Incident Urgent Teleconference / Meeting**

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Prepared for Quality of Care Purposes

The Patient Safety Incident Urgent Teleconference / Meeting should be held as soon as possible (within one business day) following the potential critical incident. The Patient Safety, Quality & Risk Management Office (PSQRM) is required to coordinate the teleconference.

**Date of Potential Critical Incident**: Click here to enter text. **SLS#**:Click here to enter text.

**Date of Teleconference Meeting**: Click here to enter text. **V#**, if applicable Click here to enter text.

**Facilitator**: Click here to enter text.

 **Participants (or delegates) to include:**

|  |  |
| --- | --- |
| [ ]  **VP(s) of involved area(s):**Click here to enter text. | [ ]  **Chief Quality & Privacy** **Officer:**Click here to enter text. |
| [ ]  **Director(s) of involved area(s):**Click here to enter text. | [ ]  **Quality & Risk Manager:** Click here to enter text.  |
| [ ]  **EVP Patient & Family Experience:** Click here to enter text. | [ ]  **Manager/Supervisor of Areas:**Click here to enter text.  |
| [ ]  **VP Patient Programs & Chief Nursing Executive:**Click here to enter text.  | [ ]  **Director Interprofessional Practice:** Click here to enter text. |
| [ ]  **Chief of Department(s) involved:**Click here to enter text. | [ ]  **Others as required:**Click here to enter text. |

**Agenda of Teleconference / Meeting:**
(*check as completed*)

[ ]  Review the details of the occurrence (synopsis):
Click here to enter text.

To determine if this is a “Critical Incident”, as defined above, the following questions must be answered:

1. Is the incident a result of the patient’s primary underlying medical condition? [ ]  Yes [ ]  No
2. Is the incident a result from a known risk inherent in providing the treatment? [ ]  Yes [ ]  No

***If the answer to either of the above questions is YES, this incident would NOT be a “Critical Incident”.***

Determination of Critical Incident [ ]  Yes [ ]  No

Confirm Severity of Harm (see page 2 for definitions): [ ]  Near Miss [ ]  No Harm [ ]  Harmful [ ]  Critical Incident

[ ]  Confirm Most Responsible Leader for Critical Incident Click here to enter text.

[ ]  Confirm if Initial Disclosure has occurred [ ]  Yes [ ]  No

* Consider timing of disclosure, status of patient, presence of patient supports, most appropriate person to disclose

[ ]  Assign Patient Rep for communication with patient / POA / Legal SDM

Patient Rep Lead: Click here to enter text.

[ ]  Establish review method: [ ]  RVH Incident Analysis

[ ]  Root Cause Analysis (requires a minimum 2-hour meeting) or

[ ]  Quality of Care Review (QCR)

[ ]  Performance Review (to be conducted by manager or appropriate chief)

Is it recommended this review be conducted under QCIPA? [ ]  Yes [ ]  No

[ ]  Determine participants for review meeting (discuss who needs to be involved, maximum 10-12 participants)

Click here to enter text.

[ ]  Determine MRP(s) responsible for:

 [ ]  Documentation of sequence of events (name) Click here to enter text.

 [ ]  Discuss initial steps of investigation (which may include):

* Staff interviews (by PSQRM team)
* Chart review (by Professional Practice and/or Clinical Director)
* Policy / procedure review

[ ]  If medication / IV fluid administration incident, then discuss reporting to the National System of Incident Reporting (NSIR) (required to be done within 30 days following disclosure of the CI to MAC, CEO and/or patient) [ ]  Yes [ ]  No

[ ]  CEO / Chair of MAC notified? [ ]  Yes [ ]  No

Definition: Under the *Public Hospitals Act*, Critical Incident (CI) is “an unintended event that occurs when a patient receives treatment in the hospital; that results in death, serious disability, injury or harm to the patient, and does not result primarily from the patient’s underlying medical condition or from a known risk inherent in providing treatment.”

|  |
| --- |
| **Severity of Harm** |
| **Near Miss**A patient safety incident that did not reach the patient. Near misses have the potential to cause varying degrees of harm from none to critical. |
| **No Harm Patient Safety Incident**A patient safety incident that reached a patient but no harm resulted. |
| **Harmful Patient Safety Incident**A patient safety incident that resulted in harm to the patient. |
| **Critical Patient Safety Incident** Any unintentional event that occurs when a patient receives treatment in the hospital.1. That results in death, or serious disability, injury or harm to the patient, and,

Does not result primarily from the patient’s underlying medical condition or from a known risk inherent in providing treatment. |

**Print Name**:
 *(Name)*

**Signature**: **Date**: *(DD/MM/YY)*

During non-business hours including:

Nights, weekends, holidays

During Business Hours

(0800 – 1700)

Within 1 business day

Manager Quality & Risk schedule Urgent Teleconference to determine if incident review is QCIPA. Ensure incident is appropriately reported to Administrator and MAC and refer to the process within the Quality of Care committee Terms of Reference. Delegate appropriate staff to lead review. Prepare communication plan.

Immediately

Immediately

As soon as possible

Immediately

Immediately

Immediately

As soon as possible

Staff member: Safeguard patient and alerts charge nurse or supervisor. Documents into inpatient chart and Safety Learning System

Charge Nurse/Supervisor ensures patient’s safety, validates incident is critical and ensures MRP and Manager have been notified and incident documented

Manager obtains an initial understanding of facts, advises Operational Director, Manager Quality & Risk and others as necessary. Documents in Safety Learning System

Disclosure of the incident to patient and/or family by MRP and/or Manager (preferably both)

Staff member: Safeguard patient and alerts HSL immediately. Documents into inpatient chart and Safety Learning System

HSL ensures patient’s safety, validates incident is critical, obtains an initial understanding of the incident and notifies MRP, VP and Operations Director on call and Chief Quality & Privacy Officer. Ensures incident has been entered in Safety Learning System and documents their fact finding investigation in the appropriate section

Disclosure of the incident to patient and/or family by MRP and or/ HSL (preferably both)

Operations Director advises appropriate VP and Chief Quality & Privacy Officer. Ensure proper follow up has occurred and correct Physician(s) notified.

Critical Patient Safety Incident Occurs

As soon as possible