RENFREW VICTORIA HOSPITAL

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ADMINISTRATIVE POLICY

Disclosure of Adverse Events and Adverse Outcomes

General Policy No.74

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DISCLOSURE OF ADVERSE EVENTS AND ADVERSE OUTCOMES

At the Renfrew Victoria Hospital we firmly believe that there are ethical, professional and legal imperatives for our physicians and other health practitioners to provide full and frank disclosure of all adverse outcomes and events to patients (or their surrogates) as soon as reasonably possible after they occur. In keeping with the Renfrew Victoria Hospital's non-blame, non-punitive philosophy, disclosure does not imply assignment or acceptance of fault.

The Renfrew Victoria Hospital requires that for all adverse outcomes and events, the disclosure should involve at a minimum a discussion between the attending practitioner and the patient (or their surrogate); and that this discussion should be documented in the health record. Consideration should be given to conducting a second meeting once the patient or their surrogate has had the opportunity to review the information provided as they may have additional questions or a need for clarification.

For the subset of adverse events that are preventable, or are critical incidents, the Renfrew Victoria Hospital requires a more formal disclosure process, which may include the involvement of the VP, Patient Care Services or V.P Corporate Services if the error occurs in pharmacy; if it occurs in lab or DI then the designated Medical Director may be involved. Critical incidents will be disclosed to the Medical Advisory Committee and the President & Chief Executive Officer.

This policy does not apply to errors that do not harm patients (i.e., near misses). These particular occurrences may not require disclosure to patients in all cases and should be left to the individual clinical judgement of the attending physician (or designate) and the clinical director/manager.

DEFINITIONS

An "adverse outcome" is any of the following:

- Development of a new temporary or permanent disability during therapy
- An unanticipated prolongation of hospitalization (where prolongation can refer to an entire admission or a readmission); or
- An unanticipated death.

A "preventable adverse event" is one that is felt to be due to an obvious error in management or a system design flaw.

A "critical incident", for the purposes of this policy, means any unintended event that occurs when a patient receives treatment in the hospital,

(a) That results in death, or serious disability, injury or harm to the patient, and

(b) Does not result primarily from the patient's underlying medical condition or from a known risk inherent in providing the treatment.

"Disclosure" refers to the communication of information regarding an adverse event, adverse outcome or critical incident.

A patient's "surrogate" includes any other person(s) as designated by the patient, or appropriate substitute decision-makers for patients who are incapable.

"Substitute decision maker" means a person who is authorized under the *Health Care Consent Act* to give or refuse consent to a treatment on behalf of a person who is incapable with respect to the treatment.

PROCEDURE

3.1 The responsibility for disclosing an adverse event, adverse outcome, or critical incident to a patient (or their surrogate) generally rests with the attending physician. See attached Appendix A – Disclosure of Adverse Events and Adverse Outcome & Appendix B – Disclosure Preparation Checklist.

3.1.1 There may be situations where the attending physician will not or cannot take the lead role in the disclosure discussions (i.e. physician unavailable, physician refuses to participate in disclosure discussions). In addition, there may be situations where the attending physician is not the appropriate person to participate in the discussions (i.e. physician feels he/she does not have the requisite communication skills; the relationship with the patient is seriously impaired/compromised). In such situations, the attending physician's designate (another physician) will conduct disclosure and any subsequent communications, if necessary, with the patient and/or their family.

3.1.2 A resident or a medical student is required to disclose to his or her supervising physician any adverse outcome or adverse event. The supervisor must bring the matter to the attention of the attending physician who is responsible for disclosing to the patient (or their) surrogate.

3.1.3 If the adverse event, adverse outcome or critical incident is not related to the care provided by a physician, then responsibility for disclosure will rest with the Clinical Manager or Vice President in disclosure will be deterred by the nature of the incident, in partnership with the attending physician or designate with CEO involvement

3.1.4 The Vice-President of Patient Care Services will determine the need for a Senior Quality Care Committee (Appendix C, D, E & F) and will arrange the meeting.

3.1.5 In the case of any disagreement regarding the responsible professional to lead the disclosure discussion (see above 3.1.1 – 3.1.3), the Chief of Staff and V.P. Patient Care Services will be consulted.

3.1.6 Initial disclosure to the patient or family will occur as soon as is reasonably possible after the adverse outcome, adverse event or critical incident has occurred and the patient's immediate needs have been met.

3.1.7 Disclosure discussions should always take place in a location that guarantees privacy and confidentiality.

3.1.8 For a preventable adverse event or critical incident, the health care professional leading the disclosure discussion should ask another health care colleague or the V.P responsible for that area to be present for the discussions.

3.2 In the case of serious preventable adverse events or Critical Incidents, the VP Patient Care Services and/or Chief Executive Officer should be contacted as soon as is reasonably possible after gaining knowledge of the adverse event or critical incident.

3.2.1 The disclosure of every critical incident must be made:
(a) To the affected patient;
(b) If the affected patient is incapable, to the patient's substitute decision-maker OR
(c) If the affected patient has died,
(i) to the substitute decision-maker immediately prior to the patient's death, or who would have been so authorized if the patient had been incapable, OR
(ii) to the patient's estate trustee, or to the person who has assumed responsibility for the administration of the patient's estate, if the estate does not have an estate trustee

3.2.2 Depending on the severity of the event, the following tasks may involve the Vice-President of Patient Care Services:
- Guidance on the disclosure process (Appendix D)
- Guidance on documentation; and
- Facilitation for all "Critical Incident" reviews under Quality of Care information Protection Act. (QCIPA) (Appendix B).
- The Vice-President of Patient Care Services will determine the need for Senior Quality Care Information Protection Act Committee and attendance required.

3.2.3 Disclosure discussions concerning preventable adverse events and critical incidents must include:
- The material facts of the event,
- Impact and consequences for the patient of the occurrence, as they become known,
- The actions taken and recommended to be taken to address the consequences to the patient of the occurrence, including any health care or treatment that is advisable

The above disclosure, including date and time of disclosure, must be documented in the Health Record (in-patient and out-patient record, including those patients attending solely for diagnostic procedure).

Additional considerations for disclosure and documenting disclosure should include:
Offers of assistance, including support of Social Work or Pastoral Care
- Information that is objective and factual, free from speculation or blame, and presented in a caring and compassionate manner
- The cause of the event, if known
- Expression of regret that the adverse event or adverse outcome occurred, including providing an apology and saying "sorry", as appropriate
- Plans for a review to identify causal factors and prevent its recurrence
- Names of individuals present at the disclosure meeting and relationship to patient
- Discussion points including: reaction/questions of participants; a statement indicating that the patient (or the surrogates) will be kept informed of new information as it becomes available
- Whether the patient refuses to receive the disclosure information
- Any request to review the patient's health record

- See Checklist (Appendix A) regarding Documentation of Disclosure of Preventable Adverse Events or Critical Incidents.
- See respectful management of serious clinical adverse event checklists for additional guidance (Appendix G & H)

3.2.4 Subject to the *Quality of Care Information Protection Act, 2004* (QCIPA – see 3.2.6) at an appropriate time following a disclosure of a critical incident, the physician or responsible Director/designate shall further disclose any systemic steps that the hospital is taking or has taken in order to avoid or reduce the risk of further similar critical incidents. The content and

date of this further disclosure shall be recorded in the health record.

3.2.5 If the adverse event has been reviewed and the review is QCIPA-protected, only the following information may be disclosed:

- Fact that a quality of care review took place (without details)
- Additional facts disclosed by review
- Changes ("systemic steps") that have been made (without disclosing that quality of care review was reason for them)

3.2.6 The Privacy Officer/VP Patient Care Services should be consulted regarding requirements of QCIPA and disclosure restrictions.

After an adverse event, critical incident or serious adverse outcome, consideration should be given to waiving charges related to a patient's care (i.e. room charges), in consultation with Financial Services and VP Patient Care Services.

If a health care practitioner discovers that a preventable adverse event or critical incident which occurred at the Renfrew Victoria Hospital has not been disclosed to a patient (or their surrogate), then the practitioner should inform their Chief of Staff or VP, Patient Care Services as appropriate. The responsible person will look into the matter, as appropriate to the situation.

Consideration should be given to the caregivers involved in adverse event, outcome or critical incident by consulting the Ethics Committee, ensuring an Employee Assistance program referral or professional support services for counselling, crisis intervention and support.

4. RELATED POLICIES AND / OR LEGISLATIONS:

- College of Physicians and Surgeons of Ontario (CPSO)
- Quality of Care Information Protection Act 2004
- Public Hospitals Act RSO 1990, Regulation 965 (updated May 2010)
- Canadian Patient Safety Dictionary, October 2003
- Quality of Care Information Protection Act Tool Kit, 2004
- Respectful Management of Adverse Events, 2nd Edition, 2011, Institute for Healthcare Improvement

RESOLUTION

THIS POLICY IS ESTABLISHED BY THE MANAGEMENT COMMITTEE OCTOBER 2, 2005; REVIEWED OCT. 2011; REVISED JUNE 2009, SEPT. 2010 & OCT. 30, 2012;

Randy Penney, President & CEO

APPENDIX A

DISCLOSURE OF ADVERSE EVENTS AND ADVERSE OUTCOME

DOCUMENTATION OF DISCLOSURE OF PREVENTABLE ADVERSE EVENTS OR CRITICAL INCIDENTS

Items in italics are required by legislation

This completed checklist will be part of the clinical record.

- ☐ Date time and place of disclosure meeting
- ☐ Names of those present
- ☐ Facts of what occurred – "the material facts of what occurred with respect to the critical incident"
- ☐ Actions taken (or to be taken to understand how the event occurred)
- ☐ The impact and consequences for the patient of the critical incident, as they become known
- ☐ The actions taken and recommended to be taken to address the consequences to the patient of the critical incident, including any health care or treatment that is advisable
- ☐ Disclosure of any systemic steps that the hospital has taken in order to avoid or reduce the risk of further similar critical incidents. Consult VP Patient Care Services when the incident was Critical or falls under the Quality of Care Information Protection Act. This further disclosure shall be recorded.
- ☐ Responses to questions answered
- ☐ Transfer of care to another physician/Involvement of other health care professional
  - ☐ Considered
  - ☐ Discussed
  - ☐ Planned
  - ☐ Completed
- ☐ Offers of assistance made (as appropriate)
  - ☐ Social Work
  - ☐ Spiritual Care
- ☐ Name of individual who will follow up with patient/surrogate where appropriate
  - ☐ Contact number
- ☐ Other Issues
- ☐ Patient/surrogate requested chart – Yes ☐ / No ☐
- ☐ Signature of health care practitioner

APPENDIX B

Disclosure Preparation Check List – A Quick Reference Tool

For consideration following an adverse event and prior to disclosure a discussion with patient:

Have you:

- ☐ Reviewed Disclosure Policy
- ☐ Determined disclosure is necessary
- ☐ Considered involving the Senior Management Team
- ☐ Considered reporting to your Insurer
- ☐ Determined that you are the right person to do the disclosure
- ☐ Acquired the necessary communication skills to lead the disclosure discussion
- ☐ Considered the "W"s (when, where, and with whom)
- ☐ Prepared what you are going to say
- ☐ Anticipated questions (know the facts)
- ☐ Considered apologizing or expressing regret
- ☐ Obtained a copy of the Disclosure documentation tool

Refer to Disclosure Policy

We would like to acknowledge the work of The Ottawa Hospital for their assistance in the content of this policy.

APPENDIX C

SENIOR QUALITY OF CARE COMMITTEE

The Senior Quality of Care Committee (SQCC) has been officially designated as a Committee by the Renfrew Victoria Hospital Board of Directors and Senior Management Team to comply with the Quality of Care Information and Protection Act, 2004 (QCIPA), which came into effect on November 1, 2004. Other existing Quality of Care Committees will be delegated specific reviews by the Senior Quality of Care Committee.

Purpose/Function of the Committee

The purpose of the Quality of Care Committee is to carry on activities for the purpose of studying, assessing or evaluating the provision of health care with a view to improving or maintaining the quality of the health care or the level of skill, knowledge, and competence of those who provide the health care.

Membership

- Vice President, Patient Care Services – Chair
- Chief of Medical Staff
- President of Medical Staff
- Vice President, Corporate Services (responsible for clinical areas)
- Medical Directors of Medical/Surgical Departments
- Nurse Manager (Acute, ER, OR, OBS, Complex Continuing Care, Dialysis)
- Nursing Staff representatives
- Pharmacist
- Department Managers of other clinical areas as needed i.e. radiology

Matters Reviewed by Committee

- The Committee shall review matters which may give rise to significant quality of care concerns, specifically:
- Ann occurrence involving an unexpected death or serious bodily harm.
- An occurrence or series of occurrences that have the potential to result in death or serious bodily harm
- An occurrence or series of occurrences that have the potential to result in harm to a number of patients.

See Quick Reference Disclosure/QCIPA Review Process, Appendix I.

Information on the Committee

Depending on the matter to be reviewed, the Committee may seek or receive information/report from any hospital staff member, committee and/or external person/entity.

All incidents are reported first to the Senior Quality of Care Committee through the Vice-President of Patient Care Services, for the Quality of Care Committee to decide whether the incident would best be reviewed by another committee or individual and then delegate to the another committee or individual to carry out the particular review.

Committees being delegated specific reviews/recommendations by the QCIPA include:

- Medical Advisory Committee
- Obstetrical Liaison Committee
- Operating Room Committee
- Infection Control Committee
- Pharmacy and Therapeutics Committee
- Continuous Quality Improvement Committee
- Ethics Committee

Review/Follow-Up

The Committee may disclose information pertaining to reviews (may include recommendations and any other information):

- To Management* (see below) if the committee considers that it is necessary for the purpose of improving or maintaining the quality of health care provided at the hospital.
- For the purpose of eliminating or reducing a significant risk of serious bodily harm to a person or group of persons.

(*Management is defined in the QCIPA as including President and CEO, members of the Senior Management Staff, and Board of Directors.)

Frequency of Meetings

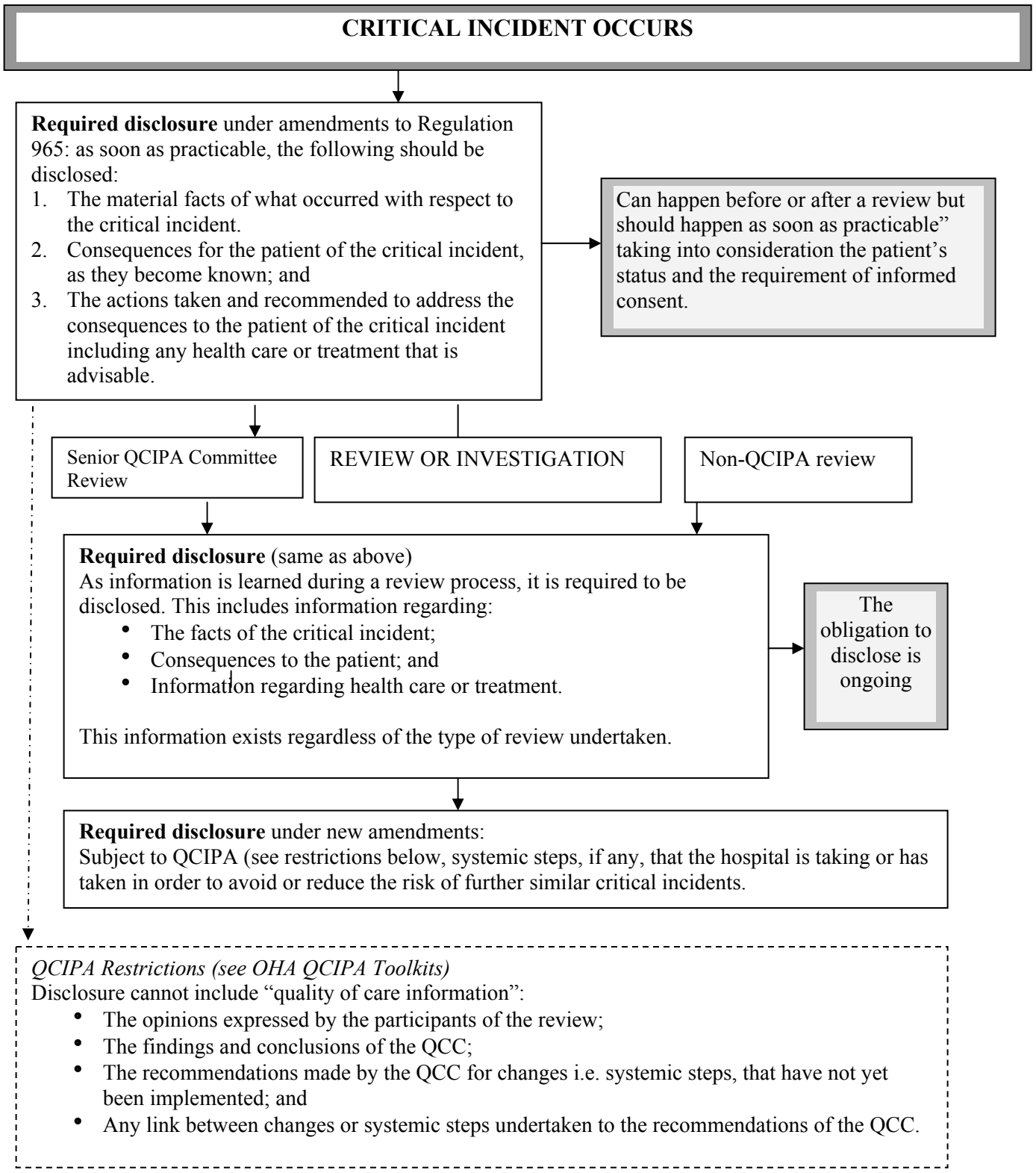
Members of the Committee shall meet at the call of the chair related to any incident which requires review.

Continuous Quality Improvement Committee Documentation

The Committee will use the quality of care working document (Appendix B) and committee report sheet (Appendix C) for documentation of meetings and follow-up required.

Appendix D – Quick Reference Disclosure Process

(What to disclose and when to disclose it)



APPENDIX E

RVH SENIOR QUALITY OF CARE COMMITTEE

WORKING DOCUMENT

PRIVILEGED AND CONDIFENTIAL

QUALITY OF CARE COMMITTEE

Date of Incident: _____Incident #:_____

Subject:_____
(what this particular document is about)

_____ _____

Date **Completed by:**

APPENDIX F

RVH SENIOR QUALITY OF CARE COMMITTEE

PRIVILEGED AND CONDIFENTIAL

QUALITY OF CARE COMMITTEE
Report, Recommendations and Follow-Up

Note: The information contained in this document is privileged and confidential. This document is not to be released and when completed, the original and all supporting documentation will be kept in the office of the Quality/Risk Manager. No other copies are to be kept. Do not file or refer to this document in any client/patient chart.

Please Print

Date of Incident:	**Incident #**
Date of Committee Meeting:	**Date Report Complete:**
Chairperson:	**Signature:**

Participants:

Synopsis of Event

Findings of Investigation:

Recommendations:
Shaded "Response", Date Completed and "Responsible Person" to be completed by person/team responding to recommendations of the Quality of Care Committee.

Recommendation	Response	Date Completed	**Responsible Person**

APPENDIX G

RESPECTFUL MANAGEMENT OF SERIOUS CLINICAL ADVERSE EVENTS

Overview
Everyday, clinical adverse events occur causing physical and psychological harm to one or more patients, their families, staff and the hospital. Averse events must be responded to in a timely and effective manner. The attached checklists are to guide senior management in required steps to be taken following an adverse event.

A QCIPA review team can be initiated to review and create a plan for follow-up. The attached guidelines are a reference for senior management team members to ensure respective management of serious clinical adverse events.

RESPECTFUL MANAGEMENT OF SERIOUS CLINICAL ADVERSE EVENTS CHECKLIST

ELEMENT	DIMENSIONS	STARTED ☑	COMPLETED ☑
Organizational Culture of Safety	Have expectations been set? Are board and leadership accountable		
	Are there established systems, policies, and a crisis management plan?		
Internal Notification	Have the CEO, Executive Leaders, Risk Management, CQI and Patient Safety, PR, Legal Counsel and other relevant leaders been notified of the event? Has the Board of Directors been notified?		
Senior Quality Care Committee	Has the threshold been met for activation of Senior Quality of Care Committee?		
	Is the team membership in place?		
	What executive leadership will chair the team?		
	Is there a need for an independent facilitator?		
Priority 1: The Patient and Family			
	Who is RVH 24/7 contact person for the patient and family?		
	Has RVH acknowledged the pain, expressed empathy and regret?		
	Are the immediate needs of the patient and family met?		
	Has the patient had a full clinical assessment?		

ELEMENT	DIMENSIONS	STARTED ☑	COMPLETED ☑
Priority 1: The Patient and Family **Continued…**			
	Has RVH assessed the personal safety of the patient and family?		
	Has the patient's primary care physician and extended care team been notified?		
	What is being heard from the patient and family?		
	Has RVH apologized, as appropriate?		
	Does RVH understand what the patient and family want said to others about the event?		
	Is RVH providing ongoing support to the patient and family, including reimbursement of out-of pocket expenses?		
	Is RVH prepared to have an open discussion about compensation, if deemed appropriate?		
	Has the family been engaged in the immediate investigation and then invited to participate in the root cause analysis (RCA) of the event?		
	Has RVH suppressed all normal PR and other communications to the patient or family that could inflict further pain?		
Priority 2: The Frontline Staff			
	Who is RVH's 24/7 contact person for staff involved in the event?		
	Has the personal safety of frontline staff been assessed?		
	What is being heard from the frontline staff?		
	Has RVH expressed empathy and been visible?		
	Have frontline staff been invited to participate in any investigation and the RCA?		
Priority 3: The Organization	**The Event**		
	Has an overall RVH point person been established?		
	What is known about what happened? What is the system for updates?		

ELEMENT	DIMENSIONS	STARTED ☑	COMPLETED ☑
Priority 3: The Organization continued…	**The Event continued…**		
	Is there clear and present danger to other patients, given what we know?		
	Has the root cause analysis been initiated? Is there an executive sponsor?		
	What about the event is known internally and externally?		
	What is being heard internally and externally in response?		
	What are the priorities to be addressed and who is the point person?		
	Are there materials that need to be sequestered?		
	What is the system to be used for urgent updates?		
	Has billing stopped per hospital-acquired condition policy?		
	Internal and External Communications		
	What is RVH prepared to say internally and externally?		
	Who are on point for communications?		
	Is there clarity on what the patient and family want said to others? Have they had input into all communications to the media, the community?		
	Has a press release been prepared in case it is needed?		
	Have there been communications to Directors, patients, families, staff, and internal/external members of the patient's extended care team?		
	Have there been external communications to the media, the community?		
	Are there "friendly" experts available?		
	Should outside media help be obtained?		

ELEMENT	DIMENSIONS	STARTED ☑	COMPLETED ☑
Priority 3: The Organization Continued …	**External Notifications and unannounced Visits**		
	Are there required notifications to public health, OHIP, etc.		
	Is this event being reported to the Joint Commission, others?		
	Have risk insurers/outside legal counsel been notified?		
	Are there provincial/federal agencies to be notified? (i.e. Food and Drug Administration, Family Services, etc?		
	Do law enforcement agencies need to be notified?		
	Are there others that would benefit from learning from this event (i.e. Institute for Safe Medication Practices?		

APPENDIX H

RESPECTFUL MANAGEMENT OF SERIOUS CLINICAL ADVERSE EVENTS WORK PLAN: ELEMENTS, DIMENSIONS AND MILESTONES

Element	Dimension	Pre-Event	First Hour	First Day	First Week	First Month	Activities after First Month
Organizational Culture of Safety	Board and Leadership	Trust, Respect, Human Rights, Forgiveness, Repentance					Learning and improvement
	Systems, Policies, Procedures, Guidelines are followed?	Approve	Assemble	Annotate	Annotate	Annotate	Revise
Notification	CEO, Senior Management	Learning System	Activated	Engaged and visible	Engaged and visible	Engaged and visible	Learning & improvement
	Board		Pending	Activated	Updated	Updated	Learning & improvement
Senior Quality Care Committee	Threshold met for activation	Plan	Activated	Meeting	Schedule	Schedule	Stand down with plan
	Membership	Plan	Activated	Refine	Refine	Updated	Formal Debrief
	Chair	Plan	Activated	Refine	Ongoing	Ongoing	
	Facilitator	Plan	Activated	Ongoing	Ongoing	Ongoing	Revise Plan
Priority 1: The Patient and Family	Who's on Point			Establish	Report	Report	To resolution and learning, including any external professional or judicial actions.
	Acknowledged Pain, Expressed Regret			Acknowledged	Ongoing	Ongoing	
	Patient/Family Needs Met			Established	Update	Update	
	Patient Fully Assessed			Assessed	Update	Update	
	Personal Safety			Assess	Update	Update	
	Primary Physician Notified			Notified	Report	Update	
	Hearing What			Report	Report	Report	

Element	Dimension	Pre-Event	First Hour	First Day	First Week	First Month	Activities after First Month
Priority 1: The Patient and Family	Apology Extended			Assessment	Assessment	Assessment	
	What do they want said			Establish	Update	Update	
	Provide ongoing support, reimbursements			Offer	Update	Update	
	Compensation approach			Review	Review	Establish	
	Mailings suppressed			Activated	Updated	Updated	
	Root cause Analysis (RCA) participant			Activated	Invited	Updated & reported	
Priority 2: The Frontline Staff	Who's on Point			Establish	Report	Report	To resolution and learning, including recognition of the efforts of staff, resolution of any external professional or judicial actions.
	Personal Safety			Assess	Update	Update	
	Hearing What			Report	Report	Report	
	Ongoing Support and Visibility			Offer	Report	Report	
	RCA Participants			Activated	Invited	Complete	
	THE EVENT						
Priority 3: The Organization	Who's on Point			Establish	Update	Update	Revise plan
	What Happened			Report	Report	Report	Learning & improvement
	Patient Clear and Present Danger			Assess & Report	Update	Update	Learning & improvement
	RCA and Executive Sponsor			Activated	Progress	Complete	Closed all risk reduction items
	Who Knows What			Report	Report	Report	Learning & improvement

Element	Dimension	Pre-Event	First Hour	First Day	First Week	First Month	Activities after First Month
Priority 3: The Organization continued …	Hearing What			Report	Report	Report	Learning & improvement
	Priorities: What, Who Is on Point			Set	Report	Update	All items addressed
	Materials to be sequestered			Immediate	Update	Update	Ultimate disposition
	System for urgent news			Set	Update	Update	Revise plan
	Billing Stopped (Hospital Acquired Condition, etc.)			Stop	Update	Update	Per statute/patient & family understanding
	INTERNAL AND EXTERNAL COMMUNICATIONS						
Priority 3: The Organization continued …	What prepared to say			Establish	Update	Update	Learning & improvement
	Who is/are on point			Establish	Update	Update	Learning & improvement
	What patient/family want said			Establish	Update	Update	Learning & improvement
	Press release/talking points			Prepare	Update	Update	Learning & improvement
	Internal communications: Patients, families, staff			Prepare	Update	Update	Learning & improvement
	External Communications: Media, Community, etc.			Prepare	Update	Update	Learning & improvement
	"Friendly" Experts on call			Consider	Update	Update	Learning & improvement
	Outside media help			Consider	Consider	Consider	Learning & improvement

Element	Dimension	Pre-Event	First Hour	First Day	First Week	First Month	Activities after First Month
	EXTERNAL NOTIFICATIONS AND UNANNOUNCED VISITS						
Priority 3: The Organization continued	Public Health			Consider	Update	Update	All requirements and conditions met. Demonstrated learning and improvement Learning shared externally
	Others			Consider	Update	Update	
	Risk Insurer			Notify	Update	Update	
	Other Provincial Agencies			Consider	Update	Update	
	Other Associations (ISMP)			Consider	Update	Update	