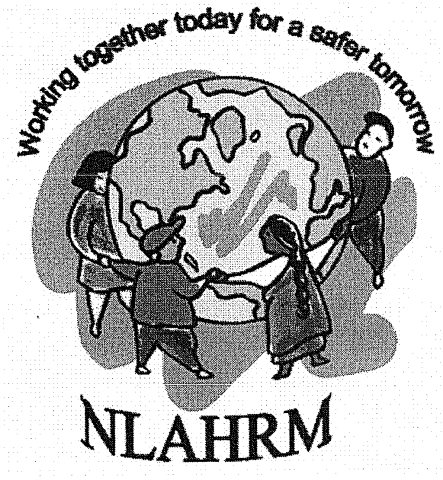
Submitted by

Newfoundland and Labrador Association
of Healthcare Risk Management



May 15, 2008

Mr. Robert Thompson
Chair
Task Force on Adverse Events
Government of Newfoundland and Labrador

Dear Mr.Thompson,

In response to your call for submissions to the Provincial Task Force on Adverse Events I am enclosing a copy of a Patient/Resident/Client Safety Manual that was completed by the Newfoundland and Labrador Association of Healthcare Risk Management in 2004.

The NL Association of Healthcare Risk Management is a Chapter of the American Society of Healthcare Risk Management and is currently comprised of clinical health professionals managing or coordinating patient safety/risk management programs and/or activities within the four provincial regional health authorities. Our association has been in existence for a number of years and began as an informal network to share ideas and develop common approaches to patient safety and risk management within the Province's health care boards. As our association predates the Canadian Patient Safety Institute and other provincial and national forums recently developed around patient safety, we formalized our network and obtained Chapter status with our American counterparts through ASHRM. We are pleased to note that our reliance on ASHRM has lessened in recent years with the establishment of the Canadian Patient Safety Institute.

2.

Using a template developed and shared by a chapter in the US, NLAHRM developed a manual that could assist organizations to move toward a culture of safety. The manual outlines the following tools and processes:

- incident/occurrence and adverse event data collection and reporting;
- hazard analysis and risk identification
- root cause analysis and failure modes and effects analysis
- disclosure
- fair and just reporting
- education and support

As frontline, clinical managers and coordinators, NLAHRM's goal was to provide a practical resource that risk management/patient safety health professionals and others could use (with their Board's approval) in the development of agency specific policies, procedures and programs. While we fully recognized that the document would need to be revised based on health systems research and new approaches, particularly relating to disclosure, it was a start. Our ultimate aim was that we would have a standardized approach to core patient safety principles within Newfoundland and Labrador's health organizations.

As an association we have long recognized that if we are to ***prevent*** adverse events and improve patient safety within health care, leaders and practitioners must have the necessary tools, resources, education and training. This continues to be our greatest challenge despite significant research which supports investments in patient safety initiatives, resources and technology to improve patient care.

I hope that this document and these comments will provide some assistance in achieving your mandate. On behalf of NLAHRM I wish you well and we look forward to attending the forum and the recommendations of the task force.

Sincerely,

Glenys P. Walsh

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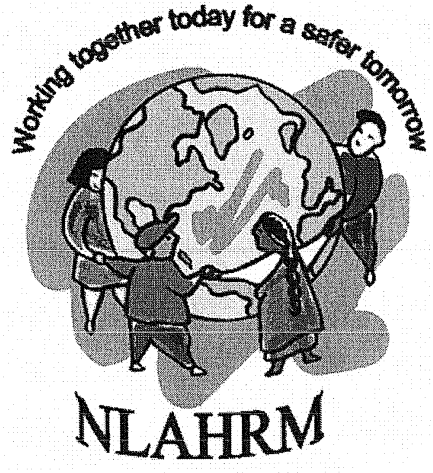

Newfoundland and Labrador Association of Healthcare Risk Management's
(NLAHRM)

PATIENT/RESIDENT/CLIENT SAFETY MANUAL

completed Nov. 2004

NLAHRM PATIENT/RESIDENT/CLIENT SAFETY MANUAL

Acknowledgement:

Thank you to the Pennsylvania Association of Health Care Risk Management (PAHCRM) which won an American Society for Healthcare Risk Management (ASHRM) Chapter Recognition Program Award in 2001; and who willingly shared their patient safety document.

The following document is the result of the combined efforts of the members of the Newfoundland and Labrador Association of Healthcare Risk Management (NLAHRM). Members of NLAHRM include:

Susan Sullivan – President
Glenys Walsh – Secretary
Elizabeth Michelin
Janice Sanger
Anne Lynch
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Jane McDonald
Judy Budgell – Treasurer
Heather Predham – Vice President
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PATIENT/RESIDENT/CLIENT/CLIENT SAFETY MANUAL

Table of Contents

PATIENT/RESIDENT/CLIENT SAFETY PROGRAM

Introduction:

The Board of Trustees of **(Title of your Board)** is committed to creating an environment that encourages occurrence identification, remediation, non-punitive reporting, and prevention of recurrences through education, systems redesign, and/or process improvement.

Additionally, a proactive assessment of high-risk activities, identified through aggregate data collection and utilizing knowledge-based information for risk reduction will be implemented.

Orientation Programs will emphasize job-related aspects of patient/resident/client safety, an interdisciplinary approach to patient/resident/client care and the requirement and mechanism to report adverse occurrences. Staff involved in serious/sentinel occurrences will have access to resources for debriefing and support.

Emphasis will also be placed upon patient/resident/client safety in areas such as patient/resident/clients' rights, patient/resident/client and family education, continuity of care and management of human resources.

Full disclosure of serious medical occurrences or unanticipated outcomes will be made to patients/residents/clients/families and to accrediting and licensing bodies as per Regional Policy.

Responsibility:

Although all members of the organization have responsibilities as specified in the Culture of Safety Policy, the **(Performance Improvement Committees, Safety Committee, Risk Management Committee or Individual or Committee identified in your organization)** shall continually monitor and evaluate the implementation and effectiveness of the Patient/Resident/Client Safety Program. This will permit oversight of all components of the organization and will generate appropriate feedback and follow-up. The **(Performance Improvement Committees, Safety Committee, Risk Management Committee or Individual or Committee identified in your organization)** shall prepare an annual report to the **(Board of Trustees or Title of your Governing Body)** indicating adverse occurrences, remediation activities and proactive efforts to prevent future occurrences.

Risk Identification:

Trending of adverse occurrences, environmental safety issues, aggregate data collection and review of sentinel occurrences in similar organizations are part of proactive identification and management of risks to patient/resident/client safety to prevent such occurrences.

Analysis:

As needed, a "failure mode," "effect" and "criticality" review shall be conducted on a high-risk process, selected in part through Critical Occurrence (Sentinel Event) summaries. The "failure mode" identifies step(s) where there is, or may be, an undesirable variation. The "effect" of each "failure mode" on a patient/resident/client is assessed as to the seriousness or "criticality" of such an occurrence. The most serious effects will require a root cause analysis to determine the cause of the variation and a redesign of the process or system to minimize or prevent the risk to the patient/resident/client. The redesigned process will be tested, implemented and monitored for on-going effectiveness or modification, if necessary.

In addition, error-prone or high-risk processes are measured and analyzed. Corrective action is taken to rectify significant deviations. At any given time, the critical steps of at least one high-risk process is the subject of measurement and analysis to determine degree of variation from intended performance.

Processes for failure mode, effect and criticality review or other error-prone/high risk processes may by identified by the Performance Improvement Department, Risk Management or the Patient/Resident/Client Safety Committee.

Finally, patient/resident/client/family and staff opinions, perceptions of risk and suggestions for improving safety will be solicited and aggregated to identify opportunities for improvement. These suggestions should be solicited in a separate process from the occurrence reporting process.

See Appendix A – The American Society of Healthcare Risk Management (ASHRM) White Paper on Failure Mode & Effect Analysis (FMEA)

POLICIES

Policy on A Culture of Safety

(Use your own Organization's Policy here – or use this sample as a template for policy development)

It is the purpose of this policy to define the responsibilities of employees in relation to the culture of safety at all facilities of _____
Health Care Board Name

I. Policy

_____ is committed to providing a safe environment
Health Care Board Name
for all individuals. Promotion of safety and prevention of injury must be the first consideration in all actions, and is the responsibility of each employee, medical staff members, students and volunteers.

The culture of safety, and the ongoing promotion of a safe environment is achieved only through the capable, coordinated and efficient efforts of each individual's contribution toward these goals by promptly reporting errors/occurrences and "near misses" to enable identification and correction of system problems. To enhance increased reporting, this process de-emphasizes the "who" but focuses on the "how" of errors/occurrences, all the while underscoring individual accountability and responsibility.

II. Culture of Safety Philosophy

A. Individual employee responsibility
   1. Know and follow policies and procedures applicable to assigned duties.
   2. Use sound judgment and awareness of potential hazards before taking action.
   3. Promptly report errors/occurrences or situations of actual or potential occurrence or harm.

B. Management responsibility
   1. Educate staff regarding error/occurrence reporting and continuous safety improvement.
   2. Involve staff in identification of system flaws and potential corrective action required.
   3. Focus on the "how" of an error/occurrence – how did it occur, etc. – rather than "who" may have contributed to it.
   4. Maintain compliance with all licensing/regulatory bodies by appropriate actions taken for violations.
   5. Ensure that appropriate evaluation processes are implemented.
   6. Establish a culture that encourages error/occurrence reporting.
   7. Implement corrective measures and plans and educate all staff accordingly.

C. Administrative and medical staff responsibilities
   1. Promote improvements in safety by encouraging reporting, while avoiding "blaming," but emphasizing the "how" of errors/occurrences.
   2. Enlist assistance of persons in identifying real or potential hazards.
   3. Implement proven safety strategies throughout all areas of the facility.
   4. Provide for continual education of physicians and employees regarding safety issues and practices.
   5. Promptly reporting occurrences/errors or situations of actual or potential harm.

D. Governing Body
   1. Receive and monitor ongoing safety reports.
   2. Allocate adequate resources to support comprehensive patient/resident/client safety strategies.

Policy On Adverse Occurrences

(Use your own Organization's Policy here – or use this sample as a template for policy development)

These standards are intended as guidelines to assist in the delivery of patient/resident/client care or management of the organization's services. They are not intended to replace professional judgment in patient/resident/client care or administrative matters.

PATIENT/RESIDENT/CLIENT SAFETY:

_____ is committed to providing quality
Health Care Board Name
care to its patients/residents/clients and the communities it serves. Despite constant and committed efforts to provide and improve patient/resident/client care, it happens from time to time that patients/residents/clients are harmed rather than helped by the care they receive. While sometimes these outcomes of care are unavoidable, at other times they may result from errors in the provision of care.

_____analyzes such occurrences to prevent the recurrence of such
Health Care Board Name
events ("adverse occurrences", AOs). We are also committed to respecting the right of patients/residents/clients and their families to be informed about such occurrences.

POLICY:

_____ identifies and investigates all adverse
Health Care Board Name
occurrences and encourages the full and frank disclosure of adverse occurrences to patients/residents/clients.

PURPOSE:

- To address the issue of the disclosure of AO's to patients/residents/clients/families.
- To create a standardized mechanism for identifying, reporting, investigating, trending and resolving adverse occurrences
- To educate providers and patients/residents/clients/families concerning the many aspects of patient/resident/client safety.
- To provide a consistent mechanism for improving the patient/resident/client care process.

SCOPE:

This policy applies to all Patient/resident/clients cared for at any of the organizations of _____.
Health Care Board Name

DEFINITIONS:

Adverse Occurrence/Event (AO/AE) –
An unexpected and undesired incident/occurrence directly associated with the care or services provided to the patient/resident/client; or
An incident/occurrence that occurs during the process of providing health care and results in patient/resident/client injury or death; or
An adverse outcome for a patient/resident/client, including an injury or complication.
Based on the "Canadian Patient Safety Dictionary" Oct. 2003

Occurrences may result in or demonstrate a potential for an injury to an individual or damage to or loss of equipment or property. *(Canadian Council of Health Services Accreditation (CCHSA))*

Category of Adverse Occurrence/Event:
Error – The failure to complete a planned action as it was intended, or when an incorrect plan is used in an attempt to achieve a given aim. *"Canadian Patient Safety Dictionary" Oct. 2003*

Occurrence – Events, processes, practices or outcomes that are noteworthy by virtue of the hazards they create for, or the harms they cause, patients/residents/clients. *Based on the "Canadian Patient Safety Dictionary" Oct. 2003*

Critical Incident/Occurrence (Sentinel Event) – An occurrence resulting in serious harm (loss of life, limb, or vital organ) to the patient/resident/client or the significant risk thereof. Occurrences are considered critical when there is evident need for immediate investigation and response. *Based on the "Canadian Patient Safety Dictionary" Oct. 2003*

From the Joint Commission of Accreditation for Health Care Organizations (JCAHO)-USA: serious psychological injury would also be considered. Moreover, they state that the phrase "or risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.

From the Canadian Council of Health Services Accreditation – they add that the occurrence is unexpected, and related to system or process deficiencies – leading to death or major and enduring loss of function

Hazardous Condition – Any set of circumstances (exclusive of the disease or condition in which the Patient/resident/client is being treated), which significantly increases the likelihood of a serious adverse outcome.

Near Miss – Used to describe any process variation which did not affect the outcome, but for which a recurrence carries a chance of an adverse outcome.

Minimal Reporting Requirements Include: Refer to Aggregate data collection tools & definitions on pages 73-78 In order to compare like data, all participating organizations should report these occurrences as a minimum-reporting requirement.

SEVERITY OF ADVERSE OCCURRENCE:

MINOR:
Level 1: An event occurred but the patient/resident/client was not harmed; or

Level 2: An event occurred that resulted in the need for increased patient/resident/client assessments and there is no resultant patient/resident/client harm and no treatment/intervention is required.

MODERATE:
Level 3: An event occurred that resulted in the need for treatment and/or intervention and caused temporary patient/resident/client harm; or

Level 4: An event occurred that resulted in initial or prolonged hospitalization, and/or caused temporary patient/resident/client harm.

SERIOUS:
Level 5: An event occurred that resulted in permanent patient/resident/client harm or a near death occurrence, such as anaphylaxis; or

Level 6: An event occurred that resulted in patient/resident/client death.

* Levels 3 through 6 shall be discussed with patient/resident/client and or families. Discussion will be as per the organization's policy on disclosure.

Handling the Occurrence

The first priority upon discovering an adverse occurrence is to have the patient/resident/client evaluated, have the adverse occurrence remedied, if possible, insure that others are not at risk and obtain and sequester all relevant information, equipment, products, etc. for future analysis. (i.e. Loss Control)

REPORTING OF THE OCCURRENCE:

Internal Reporting:

(Your organization may wish to continue to use the Incident Report/Occurrence Report Policy and Procedure currently in place. Otherwise, you may use or adapt the sample policy contained in the patient/resident/client Safety Manual). ***Customize for your organization and list your policies.***

Reporting To Outside Agencies:

Examples include: *insurers, legal advisors, adverse drug reactions, hazardous equipment etc.*

DISCLOSURE:

1. What occurrences ought to be disclosed?

   Occurrences in which patients/residents/clients are harmed, including Severity Levels 3 through 6. For example: unexpected admission to intensive care, unexpected patient/resident/client death, unnecessary treatment with burdensome impact on the patient/resident/client, return to OR.

   Errors that do not harm patients/residents/clients and do not have the potential to do so (insignificant or minor occurrences) do not require disclosure to the patient/resident/client. If there is a question concerning disclosure, contact **(Risk Management, Quality Improvement or the responsible individual in your organization.)** After hours, inquiries should be directed to **(responsible party in your organization).**

2. To whom should the disclosure be made?

   Disclosure of AO's should be made to the affected patient/resident/client, and when appropriate, the patient/resident/client's family or designated decision-maker.

3. When should disclosure take place?

   Disclosure of the AO should take place as soon as practical after the AO has occurred or been identified. Disclosure to the Patient/resident/client should occur when the patient/resident/client is stable and/or able to comprehend the information. Disclosure to the patient/resident/client's family or decision-maker may occur sooner depending on the occurrence's severity and his/her need to know this information.

4. Who ought to disclose occurrences to patients/residents/clients?

   There are several ways in which an AO may be disclosed, depending upon the occurrence. The responsibility usually rests with the attending physician/most responsible party. In some circumstances further investigation will be required to determine which individual(s) should be involved. The attending physician/most responsible party and the **(risk manager –*customize for your organization*)** will consider involving representatives from nursing, allied health professionals, pastoral care, social workers or staff members known to and trusted by the patient/resident/client/family.

   If the attending physician/most responsible party is unwilling or unable to disclose the occurrence, or if investigation determines that his/her involvement could exacerbate the problem, the **(risk manager –*customize for your organization)*** will work with administration ***(customize)*** to identify the appropriate person to handle this responsibility.

5. How to disclose an occurrence

   The nature, severity and cause (if known) of the AO should be presented in a straightforward and non-judgmental fashion. An expression of sympathy is often appropriate and not an admission of guilt. Speculation should be avoided and focus should be placed on what is known at the time of discussion. Answer questions and provide assurance that unanswered questions will be investigated further. Describe what, if anything can be done to correct the consequences of the AO. Offer a second opinion, the involvement of outside assistance, or transfer of care to another practitioner if applicable.

6. How is disclosure documented:

   Relevant information and the medical/client record should be on hand. A summary of the disclosure should be noted in the medical/client record. A notation of attendees should also be retained.

TRENDING AND ACTION PLAN:

Trending:

Trending of occurrences is an interdisciplinary process, which may be done by **(Performance Improvement teams, Department Managers, Safety Officers, Risk Managers or various other hospital committees as established in your Performance Improvement Plan).** Whichever mechanism is used, a trending tool must be in place. **(You may use or adapt the form contained in the patient/resident/client Safety Manual).**

Action Plans:

These are examples of some of the actions that you might consider when developing your plan:

a. Organizational Processes

- Communication flow changes
- Consultant services – e.g. legal, insurer, ergonomic reviews
- Organization structure changes
- Inventory changes
- Staffing adjustments
- Revision of job descriptions
- New/revised policies and procedures
- Equipment changes
- Work flow/structure/ergonomic changes
- Business process redesign

- Establishment of a process improvement team
- Signage

b. Human Factors

- Staff meeting discussion
- Educational training programs
- Counseling/guidance
- Adjustment in clinical duties, clinical privileges or staff status
- Employee improvement plan

Policy on Occurrence Reporting

(Use your own Organization's Policy here – or use this sample as a template for policy development. ***Note*** *– consider using the definitions on Page 9)*

POLICY -

It is the policy of _____ to document and report immediately
Organization Name
all occurrences or unusual occurrences as defined in the guidelines set forth in this policy. This policy shall, at all times, comply with federal, provincial and local regulations in addition to those applicable standards set forth by the Canadian Council of Health Services of Accreditation or the Department of Health and Community Services.

PURPOSE

The purpose of occurrence reporting is to enhance the quality of patient/resident/client care, to assist in providing a safe (risk-reduced) environment for that care, and to allow prompt response by the Risk Management Department to potential liability exposure. It is not designed to place blame on individuals.

The interests of patients/residents/clients and staff are best served by the consistent and uniform utilization of a program designed to discover and report all unusual occurrences within the organization.

The Occurrence Report provides a uniform procedure of informing the Risk Management Department of relevant information surrounding an occurrence. The occurrence reporting policy should be followed with all incidents occurring at
_____. Depending on the type or severity of
List name(s) of your organization
Occurrence, the Risk Management Department should be notified immediately by telephone and then as a follow-up measure, by the submission of an Occurrence Report. Early and accurate reporting is the objective.

Other policy purposes are: to achieve consistency in the method of reporting; to serve as an information base for devising corrective measures to preclude reoccurrences; to target problem areas through effective trend analysis; and to promote open channels of communication throughout all levels within the organization on an as needed basis.

SCOPE

_____
List services in your organization

PROCEDURE

The procedure governing reporting of occurrences or unusual occurrences follows:

I. Guidelines – Occurrences may be those involving Patient/resident/client care or those involving the operation of a department/facility.

A. Patient/resident/client Care – Reported via the Occurrence Report.

1) Adverse Occurrence/Event (AO/AE) –
An unexpected and undesired incident/occurrence directly associated with the care or services provided to the patient/resident/client; or
An incident/occurrence that occurs during the process of providing health care and results in patient/resident/client injury or death; or
An adverse outcome for a patient/resident/client, including an injury or complication.
Based on the "Canadian Patient Safety Dictionary" Oct. 2003

2) Error –The failure to complete a planned action as it was intended, or when an incorrect plan is used in an attempt to achieve a given aim. *"Canadian Patient Safety Dictionary" Oct. 2003*

3) Critical Incident/Occurrence (Sentinel Event) – An occurrence resulting in serious harm (loss of life, limb, or vital organ) to the patient/resident/client or the significant risk thereof. Occurrences are considered critical when there is evident need for immediate investigation and response. *Based on the "Canadian Patient Safety Dictionary" Oct. 2003*

From the Joint Commission of Accreditation for Health Care Organizations (JCAHO)-USA: serious psychological injury would also be considered. Moreover, they state that the phrase "or risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.
From the Canadian Council of Health Services Accreditation (CCHSA) also describes the occurrence as unexpected and relating to system or process deficiencies leading to death or enduring loss of function.

4) Hazardous Condition – Any set of circumstances (exclusive of the disease or condition in which the Patient/resident/client is being treated) which significantly increases the likelihood of a serious adverse outcome.

5) Near Miss – Used to describe any process variation which did not affect the outcome, but for which a recurrence carries a chance of an adverse outcome.

B. Department/Facility/Organization – Reported via the Security Department Incident/Occurrence Report.

1. Damage or loss of property owned by either the facility/organization or patient/resident/client/visitor.

2. Visitor behavior problem.

3. Failure to follow hospital/organization policies (non-patient/resident/client care related).

4. Unsafe environment.

C. Employee injuries are reported in accordance with the facility's/organization's Workers' Compensation Program (**or specify your organization's procedure**)

D. Example of Reportable Incidents – The following examples are intended to illustrate types of reportable incidents:

1. Patient/resident/client Care

a. Bodily Injury – An inpatient/resident/client or outpatient/resident/client suffers an injury while on the hospital/organization's premises.

b. Violation of Rights – A patient/resident/client does not give informed consent before a procedure is performed; confidential patient/resident/client information is released to the public.

c. Blood wastage or infection control issues.

d. Unexplained or unexpected medical or surgical outcomes or mishaps.

e. Equipment problems related to a particular patient/resident/client.

2. Department/Facility/Organization

a. Visitor Fall

b. Theft

c. Assault

d. Confiscated weapon, illegal substance, etc.

e. Equipment problems not related to a particular patient/resident/client.

E. Objectives For Reporting – The report is a factual account of the details of an occurrence and provides a method for ensuring identification and for initiating an investigation of causes. The specific objectives are:

1. To improve the management of patient/resident/client care and treatment by assuring that appropriate and immediate intervention is done on the patient/resident/client's behalf and to prevent the possibility of a reoccurrence.

2. To provide a factual record of the occurrence so that the care being given can be evaluated and adequate care standards developed.

3. To further staff education through case review and discussion.

4. To provide trend analysis for Department Heads with the goal of reducing the number of occurrences and improving patient/resident/client safety.

5. To provide a factual record of the occurrence as a basis for immediate notification to the Risk Management Department so that the occurrence can be evaluated for potential liability exposure.

An effective reporting process can impact favorably on the quality of patient/resident/client care through needed operational modification, intensification of inservice education and orientation programs and strengthening of the proactive function of Risk Management.

F. Procedure For Reporting

1. Any employee or physician who discovers, witnesses or to whom an occurrence is reported is responsible for documenting the occurrence immediately via the Occurrence Report. Any employee who requires assistance should contact his/her supervisor. Supervisors must review all reports.

2. A Occurrence Report must be completed for all unusual occurrences.

3. An occurrence that results in an injury or potential injury to a patient/resident/client requires that a patient/resident/client's attending physician be immediately notified. If the attending physician is not in-house at the time of the occurrence, a member of the house staff or covering physician must also be notified.

4. The Medical/Client Record must reflect the objective facts relating to the patient/resident/client occurrence. No references to a completed Occurrence Report should be made in the Medical/Client Record.

5. All sections of the Occurrence Report must be completed. Security personnel will complete the Security Incident/Occurrence Report.

6. Once completed, the Occurrence Report should go directly to the Department Manager who will forward it to the Risk Management Department within 48 hours. The Security Officer/Director will send a copy of the Security Incident/Occurrence Report to the Risk Management Department.

7. Occurrences occurring in ancillary departments must follow the protocol outlined above.

8. Occurrences resulting in serious injury to a patient/resident/client or visitor must be reported to the Risk Management Department immediately by telephone and followed-up with an Occurrence Report. At the same time Risk Management is notified of a serious incident, the appropriate Administrator on-call must be notified. Also see Policy on Sentinel/Serious Occurrence Reporting.

9. Occurrence Reports are not to be used for punitive reasons or as a means of documenting alleged misconduct on the part of employees of other staff.

10. Occurrence Reports should never become a part of the patient/resident/client's chart and may not be copied or reproduced.

SENTINEL EVENT POLICY

(Use your own Organization's Policy here – or use this sample as a template for policy development)

POLICY:

It is the policy of the _____ to conduct a full investigation of all occurrences
Organization Name
which seriously compromise the quality of patient/resident/client care as well as patient/resident/client safety.

DEFINITION:

A **Sentinel Occurrence** is defined as an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of serious adverse outcome.

At least two of the following criteria should be met in order for the occurrence to be defined as a Sentinel Occurrence:

1. The occurrence has resulted in an unanticipated death or major permanent loss of function.

2. The occurrence is associated with significant deviation from the usual processes for providing health care services or managing the organization.

3. The occurrence has undermined, or has significant potential for undermining, the public's confidence in

_____.
Organization Name

A **Serious Occurrence** is one, which could seriously compromise quality assurance or patient/resident/client safety – i.e.:

Level 5: An event occurred that resulted in permanent patient/resident/client harm or a near death occurrence, such as anaphylaxis; or

Level 6: An event occurred that resulted in patient/resident/client death.

DETERMINATION OF SENTINEL AND/OR SERIOUS OCCURRENCES: The determination of whether an adverse occurrence is to be classified as a Sentinel and/or Serious Occurrence shall be made by the **Risk Manager (or individual designated by your organization).** If it is determined that the occurrence rises to the level of "Sentinel" or "Serious", the following persons shall be convened: CEO, Administration, VP of Nursing Service, Director of Performance Improvement, Director of Risk Management, President of the Medical Staff, appropriate Clinical Chairman **(list your facility's designed representatives).** Other key individuals may be called upon as appropriate to the nature of

the occurrence. This group shall also determine who in the hospital/organization will be assigned to the investigation if the occurrence is classified as sentinel and/or serious.
It is recognized that when an occurrence results in an unfavorable outcome, consideration of known complications, and/or patient/resident/client information regarding the risk/complication through informed consent, will be utilized in determining if a Sentinel Occurrence has occurred.

SENTINEL OCCURRENCES: Include, but are not limited to the following examples:

- Infant discharged to the wrong family
- Inpatient/resident/client suicide
- Rape (by another Patient/resident/client or staff)
- Hemolytic transfusion reaction
- Surgery on the wrong Patient/resident/client or wrong body part

See the Canadian Council of Health Services Accreditation Website listing for Sentinel Events at www.cchsa.ca

PROCEDURE: When a Sentinel Occurrence has been determined to have occurred, a Root Cause Analysis (RCA) shall be completed within 45 days of the occurrence and will be performed as follows:

- The Director of Risk Management **(or designated individual in your facility)** will notify the physicians involved, including those who are to be part of the RCA Team, and will follow up with the physicians involved accordingly.

- The RCA Team assigned to assess the Sentinel Occurrence and chaired by the Director of Risk Management **(Director of Performance Improvement or individual assigned in your facility)** will include staff at all levels closest to the issues, **(CEO, Administrator, Vice President of Nursing, Director of Performance Improvement, President of Medical Staff, etc.)**

- The Team will confer as frequently as necessary.

- The Director of Risk Management or his/her designee will document the findings and recommendations of the group. No other written documentation will be made or maintained except for peer review purposes. Oral progress reports will be made to senior management by the Director of Risk Management **(or individual designated in your facility).**

- The RCA Team will be responsible for determining the common causes of the occurrence that lie in the larger organizational systems supporting the health care providers. These systems include but are not limited to: credentialing and privileging for physicians and other licensed independent practitioners; hiring and competency review for others; continuing education of staff; management of information, including facilitation of communication, accessibility of knowledge-based information, and linkage of information sources; work process design; and measurement of performance with respect to both processes and outcomes.

- The RCA Team will focus attention on systems that can be redesigned for improvement, rather than on processes and people who cannot control causes outside themselves and who have only limited control over their own ability to avoid human error.

- The RCA Team will use multiple techniques including brainstorming and flow charts. The question "Why" will form the basic structure of the inquiry and will be re-addressed until all causes have been determined.

- The RCA Team may have access to Personnel Files and Peer Review Files if necessary to complete the investigation.

- Recommendations for change in the health-care-delivery process will be communicated on an ongoing basis and at the end of the investigation.

All minutes, reports, recommendations, communications and actions made or taken pursuant to this policy are deemed to be covered by the provisions of any federal or provincial legislation providing protection to peer review for related activities. Furthermore, the department directors, committees and/or panels charged with making reports, findings, recommendations or investigations pursuant to this policy shall be considered to be acting on behalf of the hospital/organization and Board of Directors when engaged in such quality review activities and thus shall be deemed to be protected under Section 8.1 of the Evidence Act of Newfoundland & Labrador.

Policy on Just/Fair Reporting

(Use your own Organization's Policy here – or use this sample as a template for policy development. Consider involving Human Resources in development of this policy.)

POLICY:

It is the policy of _____ to support the Culture of Safety through a non-punitive approach to occurrence reporting.

PURPOSE:

- To encourage open and honest reporting of injuries or hazards to patients/residents, visitors and staff.
- To limit disciplinary action to only those that involved willful or malicious misconduct or those in which the employee did not report or follow remediation recommendations.
- To facilitate education and problem resolution through forthright disclosure of process failure and/or human error.

PROCEDURE:

1. All occurrences or unusual occurrences, as defined in the Policy on Occurrence Reporting, shall be reported immediately via the Occurrence Report form and processed in accordance with that policy.
2. Reports will be completed by the employee who is involved in, witnesses, or discovers an occurrence or unusual occurrence, particularly those which pose a safety hazard.
3. Employees are not subject to disciplinary action EXCEPT as follows:
   a. The occurrence involves sabotage, malicious behavior, chemical impairment or criminal activity.
   b. False information is provided on the Occurrence Report or in follow-up investigation.
   c. An employee fails to respond to educational efforts and/or fails to participate in the education or other preventive plan.
4. Employees who meet any of the "Exceptions" listed in #3 will be subject to progressive review/disciplinary action in accordance with Human Resources policy and procedure and/or work rules.

EDUCATION

EMPLOYEE ORIENTATION

PATIENT/RESIDENT/CLIENT SAFETY

(To Be Adapted For Your Own Organization)

How Did We Get Here?

According to the Canadian Adverse Events Study, 2000/01:

- **Adverse Events occurred in 7.5% of the hospital admissions studied**
- **If this rate was applied to the almost 2.5 million annual hospital admissions in Canada similar to the type studies – it would mean**
  - **185,000 of hospital admissions are associated with an adverse event**
  - **70,000 of those are potentially preventable.**
- **Adverse Events may cause between 9,250 – 23,750 deaths per year.**
- **More people die from adverse events than from breast cancer, HIV or MVAs combined.**
- **The two most common types of events were:**
  - **34% were related to surgical procedures**
  - **24% were related to drug or fluid related events.**

**** From the CIHI Document "Health Care in Canada" 2004***

According to the British National Health Service Report, *An Organization with a Memory(2000):*

- **Adverse events in which harm is caused, occur in approximately 10% of patient admissions (or about 850,000 times a year!)**

According to the *Quality in Australian Health Care Study* (Wilson et al, 1995):

- **16.6% of admissions were associated with an adverse event.**
- **Of those – 51% were considered highly preventable**

According to another Canadian study (Wanzel, Jamieson, et al, 2000):

On a general surgery service:

- **75 patients (39%) of 192 inpatients suffered a total of 144 complications. Of these:**
  - **29% were considered trivial**
  - **63% were considered of moderate severity**
  - **7% were considered life threatening**
  - **1% were fatal**
  - **18% were considered potentially attributable to error.**

Medical Error By The Numbers

- **Leape (1991) – medical errors caused 1 out of every 5 injuries or deaths**
- **Brennan (1991) – one out of every 25 hospitalized patients is injured by medical errors.**
- **Iatrogenic injuries occur in 3.7% of hospitalizations; 70% are preventable.**
  (Harvard Medical Practice Study, 1991)
- **How much is 1%? – In the airline industry, it would be 3 jumbo jet crashes every 2 days.**
- **Canadian Adverse Events Study – 1 in 13 hospital patients in Canada experience an adverse event as a result of their care.**

Why Isn't It Fixed Yet?

- **Provider barriers to progress**
- **Resistance to change.**
- **Fear of looking incompetent.**
- **Fear of discipline or retaliation.**
- **Failure to appreciate the complexity.**
- **No national strategies/consistencies to date– as discussed in " Building a Safer System" (2002) – however since then the issue has been targeted by new groups such as:**
    - **Provincial Safety Committees have been established ie The Provincial Adverse Event/Patient Safety Committee co chaired by Loretta Chard of the DOHCS & Jeannie House of the NLHBA**
    - **A National Body – the Canadian Patient Safety Institute was established in December 2003.**

Factors That Contribute To Error

- **Cognitive lapses:**
  - **Mental "slips"**
  - **tendency to over generalize**
  - **confirmation bias**
  - **overconfidence**
  - **reversion under stress**

Moving Beyond Blame

- **Errors do occur and will always occur.**
- **Employee accountabilities relating to occurrences include:**
    - **Duty to prevent occurrence/error when possible**
    - **Duty to report occurrence**
    - **Duty to remedy resultant injuries**

Goals of Patient/ Resident/Client Safety Program

- **Promote a culture of safety**
- **Promote "moving away from blame" reporting environment**
- **Reinforce communication amongst the healthcare team and with patients/residents/clients and families**
- **Engage patients/residents/clients in the safety of their care**

GOAL 1 – Promote A Culture Of Safety

- **Educate all staff about Culture of Safety Policy**
- **Incorporate "Patient/resident/client Safety" tenets in employee orientation and employee competencies**
- **Regular analysis of internal reporting to identify systems that could potentially cause harm**
- **Positive recognition for those reporting safety issues internally**

GOAL 2 – Promote Reporting Environment That De-emphasizes Blame

- **Develop Human Resource Policy to create a system of occurrence reporting that moves away from blame**

- **Regular reporting of trends and patient/resident/client safety issues in non identifiable aggregate format to the (Medical Executive Committee and Board – *use your organizations reporting mechanisms)***

GOAL 3 – Reinforce Communication Amongst The Healthcare Team And With Patients/Residents/Clients And Families

- **Identify for patients/residents/clients who is responsible for guiding their care.**
- **Ongoing education of physicians and employees on communication skills.**

GOAL 4 – Engage Patients/Residents/Clients In The Safety Of Their Care

- **Patients/residents/clients and families must be treated as partners in their care.**
- **Involve patients/residents/clients in all care decisions.**
- **Distribute brochures to encourage patients/residents/clients to be involved in their care.**
- **Involve patients/residents/clients in improving our processes.**
- **Making patients/residents/clients accountable for their care – e.g. if they do not understand about a medication, they need to ask.**

Culture of Safety Policy

- **Purpose:**
  - **It is the purpose of this policy to define the responsibilities of all employees in relation to the culture of safety.**
- **Policy:**
  - **Promotion of safety and prevention of injury must be the first consideration in all actions, and is the responsibility of each employee. Promoting safety is a condition of employment.**

Individual Employee Responsibility

- **Know and follow policies and procedures applicable to assigned duties.**
- **Use sound judgment and awareness of potential hazards before taking action.**
- **Promptly report occurrences or situations of actual or potential harm.**

Management Responsibility

- **Educate staff on:**
  - **Occurrence reporting**
  - **Continuous safety improvement**
  - **Identifying system flaws and potential corrective action required**
- **Focus on the "how" *not* the "who" of an occurrence while underscoring individual accountability and responsibility.**
- **Ensure safe practice by all individuals by appropriate evaluative processes.**

Administrative and Medical Staff Responsibilities

- **Promote / implement improvements in safety.**
- **Encourage reporting.**
- **Enlist assistance in identifying real or potential hazards.**
- **Provide continual education of physicians and employees regarding safety issues and practices.**
- **Promptly report occurrences/errors or situations of actual or potential harm.**

Governing Body Responsibilities

- **Receive and monitor on-going safety reports.**
- **Allocate adequate resources to support a comprehensive patient/resident/client safety program**

Policy On Adverse Occurrences

Purpose

- **Disclose to patients/residents / clients/ families**
- **Mechanism to identify, report, investigate and resolve adverse occurrences**
- **Educate providers and patients/residents / clients/ families on patient/resident/client safety**
- **Improve patient/resident/client care process**

Severity of Occurrence

MINOR:

- **Level 1: An event occurred but the Patient/resident/client was not harmed; or**

- **Level 2: An event occurred that resulted in the need for increased patient/resident/client assessments and there is no resultant patient/resident/client harm and no treatment/intervention is required.**

MODERATE:

- **Level 3: An occurrence occurred that resulted in the need for treatment and/or intervention and caused temporary patient/resident/client harm.**

- **Level 4: An occurrence occurred that resulted in initial or prolonged hospitalization, and caused temporary patient/resident/client harm.**

SEVERE:

- **Level 5: An occurrence occurred that resulted in permanent patient/resident/client harm or near death occurrence, such as anaphylaxis.**

- **Level 6: An occurrence occurred that resulted in patient/resident/client death.**

Handling the Occurrence

The first priority upon discovering an adverse occurrence is to have the patient/resident/client evaluated, have the adverse occurrence remedied, if possible, insure that others are not at risk and obtain and sequester all relevant information, equipment, products, etc. for future analysis.

Reporting

- **Internal reporting to track and trend – as per policy #**

- **Outside agency reports. For Example:**
    - **insurers,**
    - **legal advisors,**
    - **adverse drug reactions,**
    - **hazardous equipment, etc.**

What Occurrences Should Be Disclosed?

Severity levels 3-6, for example, unexpected admission to ICU, return to OR, unexpected death. Levels 1 and 2 occurrences need not be disclosed, unless there was a variance in the expected outcome.

To Whom Should Disclosure Be Made?

To the affected patient/resident/client and, when appropriate, patient/resident/client's family or designated decision maker.

When Should Disclosure Take Place?

As soon as practical when patient/resident/client is stable and able to comprehend. Disclosure to family may occur sooner depending on severity of occurrence and need to know this information.

Who Should Disclose?

Usually the attending physician/most responsible party.
Sometimes investigation will be needed to determine which individual(s) should be involved.
Also, nursing, social workers, pastoral care, or staff known to the family may be asked to participate.

If the attending physician/most responsible party is unwilling or unable to disclose the occurrence, of if investigation determines that this could exacerbate the problem, Senior Administration will identify an appropriate individual.

How To Disclose An Occurrence

- **Straight-forward and non-judgmental.**
- **Expression of sorrow is often appropriate and not an admission of guilt.**
- **Avoid speculation and focus only on what is known at the time.**
- **Answer questions and offer assurance that unanswered questions will be investigated further.**
- **Describe what, if anything, can be done to correct the consequences of error.**
- **Offer a second opinion, involvement of outside assistance, or transfer of case to another person.**

Physician Education

Reasons to Disclose

- **Golden rule**
- **Supports patient/resident/client autonomy / ability to provide informed consent**
- **May relieve patient/resident/client distress**
- **Could facilitate compensation process and mitigate loss**
- **Can increase trust**
- **"It's the right thing to do"**

Deciding Whether to Disclose

- **In general, obligation to disclose a clear mistake that causes significant harm that is able to be remedied, mitigated or compensated.**
- **In controversial cases, get a second opinion from risk management.**
- **Consider notification of insurer, in a timely manner.**

What to Say

- **Convene all affected parties who would benefit by the disclosure (patient/resident/client, family, significant others)**
- **Treat it as an instance of "breaking bad news"**
- **Begin by stating that you regret this has occurred.**
- **Describe the decisions that were made, including those in which the patient/resident/client participated.**
- **Describe the course of occurrences, using non-technical language.**
- **State the nature of the mistake, consequences and corrective action, including what is being done to prevent future occurrences.**
- **Elicit questions or concerns and address them.**
- **Express personal regret, again.**

Conclusion

- **Human beings will always make mistakes**
- **How will we handle them?**
- **Patient/resident/client safety and physician welfare will be well served if we can be more honest about our mistakes to our patients/residents/clients, our colleagues and ourselves.**

Documentation of Disclosure

- **Relevant information and the medical record should be on hand.**
- **Summary of disclosure and attendees documented in medical record.**

POLICY ON OCCURRENCE REPORTING

Occurrence Reports are used to:

- **Enhance quality of patient/resident/client care**
- **Assist in providing safe (risk-reduced) environment**
- **Allow prompt response to potential liability exposure**
- **Achieve consistency in reporting**
- **Serve as information base for devising corrective measures**
- **Target problem areas through trend analysis**
- **Promote open channels of communication**

Occurrences may involve patient/resident/client care or operation of department / organization.

Patient/resident/client Care Occurrences reported via Occurrence Reports

1. **Adverse Occurrence/Event (AO/AE)** –
   An unexpected and undesired incident/occurrence directly associated with the care or services provided to the patient/resident/client; or
   An incident/occurrence that occurs during the process of providing health care and results in patient/resident/client injury or death; or
   An adverse outcome for a patient/resident/client, including an injury or complication.
   Based on the "Canadian Patient Safety Dictionary" Oct. 2003

2. **Error** –The failure to complete a planned action as it was intended, or when an incorrect plan is used in an attempt to achieve a given aim. *"Canadian Patient Safety Dictionary" Oct. 2003*

3. **Critical Incident/Occurrence (Sentinel Event)** – An occurrence resulting in serious harm (loss of life, limb, or vital organ) to the patient/resident/client or the significant risk thereof. Occurrences are considered critical when there is evident need for immediate investigation and response. *Based on the "Canadian Patient Safety Dictionary" Oct. 2003*

   From the Joint Commission of Accreditation for Health Care Organizations (JCAHO)-USA: serious psychological injury would also be considered. Moreover, they state that the phrase "or risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.

   From the Canadian Council of Health Services Accreditation – they add that the occurrence is unexpected, and related to system or process deficiencies – leading to death or major and enduring loss of function

4. **Hazardous Condition – Any set of circumstances (exclusive of the disease or condition in which the patient/resident/client is being treated), which significantly increases the likelihood of a serious adverse outcome.**

5. **Near Miss – Used to describe any process variation which did not affect the outcome, but for which a recurrence carries a chance of an adverse outcome.**

Department/Facility /Organization– Reported via Occurrence Reports

1. **Damage or loss of property owned by either the organization or patient/resident/client/visitor.**

2. **Visitor behavior problem.**

3. **Failure to follow organization policies (non-patient/resident/client care related).**

4. **Unsafe environment.**

Employee injuries are reported on a (*Workers' Compensation Incident Report)*
insert the name of your organizations form

Examples of Reportable Occurrences:

Patient/resident/client Care

- **Inpatient/outpatient/resident/client injury on hospital/organization premises**
- **Violation of Rights – patient/resident/client does not give consent; patient/resident/client information is released**
- **Blood wastage or infection control issues.**
- **Unexplained or unexpected medical/surgical outcome or mishap**
- **Equipment problems related to a particular patient/resident/client**

Department/Organization

- **Visitor injury or fall**
- **Theft or assault**
- **Confiscated weapon, illegal substance, etc.**
- **Equipment problems not related to a particular patient/resident/client**

Procedure: (*adapt to your organization's policy*)

1. **Any employee or physician who discovers, witnesses or to whom an occurrence is reported is responsible for documenting the occurrence immediately via the Occurrence Report. Any employee who requires assistance should contact his/her supervisor. Supervisors must review all reports.**

2. **An Occurrence Report must be completed for all unusual occurrences.**

3. **An occurrence that results in an injury or potential injury to a patient/resident/client requires that a patient/resident/client's attending physician be immediately notified. If the attending physician is not in-house at the time of the occurrence, a member of the house staff or covering physician must also be notified.**

4. **The Medical/Client Record must reflect the objective facts relating to the patient/resident/client incident. No references to a completed occurrence report should be made in the Medical/Client Record.**

5. **All sections of the occurrence report must be completed. Security personnel will complete the Security Incident/Occurrence Report.**

6. **Once completed, the occurrence report should go directly to the Department Manager who will forward it to the Risk Management Department within 48 hours.**

7. **A copy of the Security Incident/Occurrence Report will be sent to the Risk Management Department by the Security Officer/Director.**

8. **Occurrences occurring in ancillary departments must follow the protocol outlined above.**

9. **Occurrences resulting in serious injury to a patient/resident/client or visitor must be reported to the Risk Management Department immediately by telephone and followed-up with a Occurrence Report. A member of the Risk Management Department is available 24 hours per day, seven days per week, via beeper. At the same time Risk Management is notified of a serious incident, the appropriate Administrator on-call must be notified.**

10. **Occurrence reports are not to be used for punitive reasons or as a means of documenting alleged misconduct on the part of employees or other staff.**

11. **Occurrence reports should never become a part of the patient/resident/client's chart and may not be copied or reproduced.**

POLICY ON SENTINEL / SERIOUS OCCURRENCES

Sentinel Occurrence Definition:

A Sentinel Occurrence is defined as an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of serious adverse outcome.

At least two of the following criteria should be met in order for the occurrence to be defined as a Sentinel Occurrence:

1. **The occurrence has resulted in an unanticipated death or major permanent loss of function.**

2. **The occurrence is associated with significant deviation from the usual processes for providing health care services or managing the organization.**

3. **The occurrence has undermined, or has significant potential for undermining, the public's confidence in the Hospital/Organization.**

Sentinel Occurrences (in addition to major permanent injury or unanticipated death)

- **Infant abduction**
- **Infant discharged to wrong family**
- **Inpatient/resident/client suicide**
- **Rape (by another patient/resident/client or staff)**
- **Hemolytic transfusion reaction**
- **Surgery on wrong patient/resident/client or wrong body part**

Requires Root Cause Analysis

Serious Occurrence Definition:

A Serious Occurrence is one, which could seriously compromise quality assurance or patient/resident/client safety.

Serious Occurrence Examples:

- **Deaths due to injuries, suicide or unusual circumstances**
- **Deaths due to malnutrition, dehydration or sepsis**
- **Deaths or serious injuries due to a medication error**
- **Elopements**
- **Transfers to another hospital/organization as a result of injuries or accidents**
- **Complaints of patient/resident/client abuse, whether or not confirmed by the facility/organization**
- **Rape**
- **Surgery performed on the wrong patient/resident/client or on the wrong body part**
- **Hemolytic transfusion reaction**
- **Infant abduction or infant discharged to the wrong family**
- **Significant disruption of services due to disaster such as fire, storm, flood or other occurrence**
- **Notification of termination of any services vital to the continued safe operation of the facility/organization or the health and safety of its patients/residents/clients and personnel, including, but not limited to, the anticipated or actual termination of electric, gas, steam heat, water, sewer and local exchange telephone service.**
- **Unlicensed practice of a regulated profession**

The individual responsible for Risk Management in your organization determines if an adverse occurrence rises to the level of sentinel and/or serious occurrence.
If so, a Root Cause Analysis will be conducted

NLAHRM PATIENT/RESIDENT/CLIENT SAFETY MANUAL

Guidelines To Prevent Falls In The Hospital

1. Always follow your physician's orders and the nurses' instructions regarding whether you must stay in bed or if you require assistance to go to the bathroom.

2. When you need assistance, use your call light or bell by your bed or in the bathroom and wait for the nurse/assistant to arrive to help you.

3. Ask the nurse for help if you feel dizzy or weak getting out of bed. Remember you are more likely to faint or feel dizzy after sitting or lying for a long time. If you must get up without waiting for help, sit in bed awhile before standing. Then rise carefully and slowly begin to walk.

4. Wear non-skid slipper socks whenever you walk in the hospital. If you don't have any, ask your nurse.

5. Remain lying or seated while waiting for assistance. Please be patient someone will answer your call as promptly as possible.

6. Do not tamper with side rails that may be in use. Side rails are reminders to stay in bed and are designed to ensure your safety.

7. Walk slowly and carefully when out of bed. Do not lean or support yourself on rolling objects such as IV poles or your bedside table.

8. Do not use furniture to assist youself.

How Can I Prevent Problems?

If you were injured, wish to report an adverse occurrence, want to discuss concerns you have with the quality of care you received, or an unanticipated outcome, or even wish to offer suggestions for Patient/resident/client safety, please contact:

_____

insert name & phone number of contact person in your facility

"Your well-being is our primary concern"

List Facilities :

_____

Hospital Name or Logo

A Culture of Safety

Our first priority is promotion of safety and prevention of injury.

Despite constant and committed efforts, it happens from time to time, that patients/residents are harmed rather than helped by healthcare. While these outcomes are often unavoidable, at other times, they result from preventable mistakes or errors in the provision of care.

To assist you in managing your care, we are providing information on medical errors, falls and reporting safety issues.

What Are Medical Errors?

Medical errors happen when something that was planned as a part of medical care doesn't work out, or when the wrong plan was used in the first place. Medical errors can occur anywhere in the health care system:

What Can You Do?

1. The single most important way you can help to prevent errors is to be an active member of your health care team.

2. Make sure that all of your doctors know about everything your are taking. This includes prescription and over-the-counter medicines, and dietary supplements such as vitamins and herbs.

3. Make sure your doctor knows about any allergies and adverse reactions you have had to medicines.

4. When your doctor writes you a prescription, make sure you can read it.

5. Ask for information about your medicines in terms you can understand both when your medicines are prescribed and when you receive them.

6. When you pick up your medicine from the pharmacy, ask: Is this the medicine that my doctor prescribed?

7. If you have any questions about the directions on your medicine labels, ask.

hospital, clinics, outPatient/resident/client surgery centers, doctors' offices, nursing homes, pharmacies, patients/residents' homes. Errors can involve: medicines, surgery, diagnosis, equipment, lab reports. They can happen during even the most routine tasks, such as when a hospital Patient/resident/client on a salt-free diet is given a high-salt meal.

8. Ask your pharmacist for the best device to measure your liquid medicine. Also, ask questions if you're not sure how to use it.

9. Ask for written information about the side effects your medicine could cause.

10. If you have a choice, choose a hospital at which many patients/residents have the procedure or surgery you need.

11. If you are in a hospital, consider asking all health care workers who have direct contact with you whether they have washed their hands.

12. When you are being discharged from the hospital, ask your doctor to explain the treatment plan you will use at home.

13. If you are having surgery, make sure that you, your doctor, and your surgeon all agree and are clear on exactly what will be done.

14. Speak up if you have questions or concerns.

15. Make sure that someone, such as your personal doctor, is in charge of your care.

16. Make sure that all health professionals involved in your care have important health information about you.

17. Ask a family member or friend to be there with you and to be your advocate (someone who can help get things done and speak up for you if you can't).

18. Know that "more" is not always better.

19. If you have a test, don't assume that no news is good news.

20. Learn about your condition and treatments by asking your doctor and nurse and by using other reliable sources.

Falls - - Are You At Risk?

Certain conditions make us more prone to falls and other accidental injuries. Here are just a few:

- **Multiple medications**
  The more medications you take, the more likely you are to experience dizziness or other risky side effects. Tell all of your health care providers about all of the drugs you take. Ask them about any side effects that might place you at risk for falls.

- **Walking difficulties**
  Shuffling, weakness, stooped over posture, inability to walk a straight line, numbness or tingling of toes can make falls more likely. Ask your doctor about assistive devices such as a cane or walker and learn how to use them correctly.

- **Chronic conditions that interfere with thinking, such as Alzheimer's Disease**

- **Impaired vision or hearing**

- **Two or more falls in the past 6 months**

  If you are falling frequently, see your doctor. It's important to find out why.

- **Fear of Falling**
  Do not cut back on your normal activities. Inactivity can actually lead to more falls because of lost muscle strength. Your doctor can also recommend an exercise program to increase muscle strength and coordination, which can help to reduce the risk of falling. If you feel unsteady on your feet, talk to your doctor. You may benefit from a cane or walker.

FORMS

_____
Hospital Name

PATIENT/RESIDENT/CLIENT SAFETY TRACKING TOOL

(Use Additional Sheet If Necessary) **Addressograph**

Occurrence Date _____ Time _____
Day of Week _____ Shift _____
Unit/Location of Occurrence _____

REPLACE WITH YOUR ORGANIZATION'S OCCURRENCE REPORT FORM

NLAHRM PATIENT/RESIDENT/CLIENT SAFETY MANUAL

REPLACE WITH YOUR ORGANIZATION'S CRITICAL/SENTINEL OCCURRENCE REPORT FORM

_____
Hospital Name

SAFETY ASSURANCE PEER REVIEW PROCESS

OCCURRENCE REPORT FOLLOW-UP REPORT FORM PROTECTED BY PA PEER REVIEW PROTECTION ACT

Patient/resident/client Name _____ Date of Follow-Up Report _____

Date of Occurrence/Potential Occurrence _____ Unit _____

FALL
Was foreign substance on floor? _____
Was patient medicated? _____
What medication? _____
Other environmental hazards? _____
Was pt. identified as high risk for falls? _____
Were restraints being used? _____
Patient's Footwear? _____

EQUIPMENT/DEVICE INFORMATION:
Name of Equipment _____
Manufacturer _____
Model No. _____
Serial No. _____
Lot No. _____
Equipment Sent To _____

1. List contributing factors, cause or reason for occurrence if known:

   _____

2. In your opinion, was the standard of care/practice upheld in this situation?
   ☐ Yes ☐ No ☐ Not Sure

3. What was the immediate treatment and/or corrective action taken: _____

   _____

4. What are results of x-ray or other diagnostic tests, if appropriate to occurrence: _____

   _____

   If results positive, were they reported to attending physician? _____
   What is Patient/resident/client's status/condition after occurrence and/or treatment:
   ☐ Unchanged
   ☐ Other: Specify _____

5. Evaluation:
   ☐ Isolated or single occurrence; no-trend noted. ☐ Recurring occurrence; trend/pattern noted. Systems Issue Identified
   Specify: _____

6. Follow-up: Check all that apply:
   ☐ A thorough investigation has been initiated/completed. Indicate by whom and outcome.
   _____
   ☐ A staff development plan will be initiated to address identified issues, e.g. educational session/inservice.
   ☐ Referred to _____
   ☐ Reviewed at staff meeting as a teaching opportunity.
   ☐ Other action

Note Occurrence Severity Index _____. (Level 3-6 must be discussed with Patient/resident/client by physician)

Signatures:
Employee/Staff Member _____ Date: _____
Department Head: _____ Date: _____
Administration: _____ Date: _____

Directions: This form is to be filled out completely. It is used exclusively for evaluation of the quality and efficiency of services provided by professional healthcare workers. This applies to all occurrences that are unusual occurrences, accidents or any situation where there is an actual or potential adverse (undesirable) outcome for a Patient/resident/client, visitor, staff member or volunteer. Please do not duplicate the completed form.

NLAHRM PATIENT/RESIDENT/CLIENT SAFETY MANUAL

AGGREGATE DATA COLLECTION PER 1000 PATIENT/RESIDENT/CLIENT DAYS

(Divide # of Patient/resident/client days for the month into the # of occurrences & multiple by 1000)

Aspect of Care & Indicators	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Medication Related												
Blood/Blood Products Related												
Treatment /Test												
Falls Related												
Theft												
Property Damage												
Equipment Related												
Smoking Related												
Missing Acute Care Client/Elopement												
Missing LTC Client/Elopement												
Discharged Against Medical Advice												
Unplanned Return to OR												
Unplanned return to ER												
Breach of Confidentiality												
Restraints Related												
Consent Related												
Suicide Attempt												
Assault/Abuse/ Harassment												
Anaesthesia Related												
OB Related												
Complaint												

Severity Codes:	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
Level 1													
Level 2													
Level 3													
Level 4													
Level 5													
Level 6													

Level 1 □ An occurrence occurred but the Patient/resident/client was not harmed
Level 2 □ An occurrence occurred that resulted in the need for increased Patient/resident/client assessments but no change in vital signs and no Patient/resident/client harm
Level 3 □ An occurrence occurred that resulted in the need for treatment and/or intervention and caused temporary Patient/resident/client harm
Level 4 □ An occurrence occurred that resulted in initial or prolonged hospitalization, and caused temporary Patient/resident/client harm
Level 5 □ An occurrence occurred that resulted in permanent Patient/resident/client harm or near death occurrence, such as anaphylaxis
Level 6 □ An occurrence occurred that resulted in Patient/resident/client death

NLAHRM PATIENT/RESIDENT/CLIENT SAFETY MANUAL

AGGREGATE DATA COLLECTION PER 1000 PATIENT/RESIDENT/CLIENT DAYS
(WHOLE NUMBER)

Aspect of Care & Indicators	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
Medication Related													
Blood/Blood Products Related													
Treatment /Test													
Falls Related													
Theft													
Property Damage													
Equipment Related													
Smoking Related													
Missing Acute Care Client/Elopement													
Missing LTC Client/Elopement													
Discharged Against Medical Advice													
Unplanned Return to OR													
Unplanned return to ER													
Breach of Confidentiality													
Restraints Related													
Consent Related													
Suicide Attempt													
Assault/Abuse/ Harassment													
Anaesthesia Related													
OB Related													
Complaint													
TOTALS													

Severity Codes:	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
Level 1													
Level 2													
Level 3													
Level 4													
Level 5													
Level 6													

Level 1 ☐ An occurrence occurred but the Patient/resident/client was not harmed
Level 2 ☐ An occurrence occurred that resulted in the need for increased Patient/resident/client assessments but no change in vital signs and no Patient/resident/client harm
Level 3 ☐ An occurrence occurred that resulted in the need for treatment and/or intervention and caused temporary Patient/resident/client harm
Level 4 ☐ An occurrence occurred that resulted in initial or prolonged hospitalization, and caused temporary Patient/resident/client harm
Level 5 ☐ An occurrence occurred that resulted in permanent Patient/resident/client harm or near death occurrence, such as anaphylaxis
Level 6 ☐ An occurrence occurred that resulted in Patient/resident/client death

DEFINITIONS for Aggregate Data Collection:

Where applicable, all occurrences should include the "near misses", in other words occurrences that were caught before the error could be made.

Medication related – preventable events in the medication use process. Any occurrence involving the medications, this includes ordering, transcription, administration, reactions etc.

Examples include, but are not limited to occurrences involving:

- Incorrect date/time
- Failure to instruct patient/family
- Incorrect dosage
- Incorrect route/site
- Omitted dose(s)
- Unordered medication given
- Improper medication regime ordered
- Improper preparation of medication
- Wrong medication administered
- Outdated drug or solution
- Wrong patient
- Improper IV rate
- Significant Extravasations
- Order expired
- Adverse Drug Reactions – previously known or newly detected side effects of drugs that may occur in the course of error free medication use. This includes Contrast Media reactions.

Blood Product Related – any occurrence, other than consent, related to the process of blood or blood product administration. This includes, but is not limited to ordering, delivering, reactions, monitoring. Examples include:

- Delay in administration
- Failure to insure contamination free
- Infiltration
- Transfusion problem
- Wrong additive
- Wrong flow rate
- Wrong patient
- Wrong solution
- Wrong type of blood or product
- Needle stick injury

Test/ Treatment Related: This refers to any diagnostic or treatment procedure or test performed anywhere in the health care organization– including inpatient, outpatient and community services. Laboratory and diagnostic imaging and operating room procedures are included in this category. Examples include but are not limited to:

- complications
- delayed or omitted treatment procedures
- delays, omitted or incorrect results or reports
- failure/delay in referral/consultation
- improper or omitted monitoring
- improper performance of treatment/procedure
- improper treatment/course
- omitted history/physical

- incorrect client
- equipment failure
- defective medical device
- specimens (lost, mislabeled, transport, etc)
- Retained foreign body
- Improper sponge and needle count

Falls Related-

A witnessed or unwitnessed event that results in a person coming to rest on the ground or floor or other lower level. (RNAO) All repeat falls should be reported on occurrence reports.

Theft/Suspected Theft: Missing patient/resident/client articles of any value that are suspected of being stolen, whether or not the occurrence is reported to the police.

Property Damage: Any occurrence resulting in damage to the patient/resident/client's personal property. This includes but is not limited to examples such as:

- Motor vehicle damage in parking lot
- Water damage
- Aggressive behavior leading to property damage.
- Break and enter.

Equipment/Product Related: refers to any occurrence that involves equipment related to client use. Examples include, but are not limited to:

- Equipment malfunction/failure
- Improper maintenance/inspection or testing
- Lack of adequate equipment
- Product adverse outcome.
- User error
- Not following manufacturer instructions
- Loaning and returning equipment issues
- Product/Equipment recall or warning issued.

Smoking Related: Any occurrence involving the use of smoking materials in non-smoking designated areas.

Missing Client/Elopement: Any occurrence where the client is not accounted for; specifically the client has an unassisted, unsupervised, unscheduled or unauthorized departure from the unit, facility, organization or place of residence.

Self Discharge (Against Medical Advice): the client leaves the health care facility against advice from health care professionals.

Unplanned Return to Operating Room (OR) – an unplanned return to the operating room within 48 hours of the initial surgery.

Unplanned Return to Emergency Department (ER) – an unplanned return to the emergency department within 24 hrs for a similar or related complaint.

Breach of Confidentiality – Confidentiality refers to a third party's obligation to ensure that personal information is only accessible to those authorized to have access. Examples include but are not limited to:

- Discussion of confidential client information in public areas, such as elevators, lobbies, cafeterias or off premises;
- Discussion of confidential client information in the presence of persons not entitled to such information
- Inappropriate access to and/or distribution of e-mails
- Inappropriate access to and/or distribution /communication of information related to co-workers, relatives, or neighbors

Restraint Related:
Refers to any occurrence involving restraints. A restraint refers to any physical, chemical or environmental means of restricting, limiting and/or inhibiting an individual's freedom of movement.
For Example a physical restraint is: any device, material or equipment that restricts freedom of movement or access to his/her (the resident's) body. This may include, but is not limited to, vest restraints, lap belts (in front or behind closures), pelvic restraints, mittens, chairs with lap trays and anklets/wristlets. These items are not restraints if used for customized seating purposes as prescribed by an Occupational Therapist, and/or can be easily removed by the resident, or if, without the device, the resident could not voluntarily move the part of the body over which the device is attached. (Ref SJNHB Least Restraint policy). " Bed rails are not included in this definition."

Consent Related Occurrence:
Any occurrence resulting from the inadequate disclosure and/or documentation of information by the health care provider which thereby prevents the patient/resident/client from making an informed health care decision. This includes, but is not limited to, the following examples:

- Failure to obtain informed consent/waiver as per organizational policies and procedures
- Failure to obtain informed consent under current legislative requirements (i.e. legal/mental capacity)
- Failure to properly instruct the patient/resident/client or family.
- Issues relating to the application of the advanced health care directives act.

Suicide Attempt – any occurrence where a patient/resident/client attempts to end his or her own life.

Assault/ Abuse/Harassment: Any occurrence resulting from intimidation, domination or violent assault which threatens the person's health, safety and well-being. The abuse may be physical, emotional, sexual or financial. This includes but is not limited to the following examples:

- Mistreatment or neglect of a child
- Action or inaction which results in harm to or jeopardizes the health, well being and safety of an adult
- Threats of violence or endangerment
- Unwelcome comments or physical advances which are intimidating, humiliating, malicious or sexually explicit
- Improper or illegal use of a person's funds, assets, property or resources for another person's profit or gain.

Anaesthesia Related: Any occurrence involving anaesthesia. Examples include, but are not limited to:

- Improper pt assessment
- Failure to monitor
- Improper airway maintenance
- Improper anaesthesia administration
- Improper choice of anaesthesia
- Improper positioning

OB Related- any occurrence involving the perinatal period, including but not limited to:

- Delay/failure to monitor/treat fetal status
- Delayed delivery (induction/C Section)
- Choice of delivery methods
- Injury to mother or baby
- Retained foreign body

Significant Complaint:
A complaint that has resulted in or has the potential for an adverse occurrence; or has implications for legal action, and which requires follow-up and/or investigation.
(Note: A minor complaint is a complaint which can be resolved satisfactorily at the staff or department level and where the perceived risk is minimal – these will not be included with the aggregate data collection tool.)

Complaint Category Definitions:

Access - Concerns that relate to a person's access to treatment or diagnostic services being offered by ……(organization's name). This includes concerns re wait times and inability to contact appropriate staff. For our purposes this has been broken down into Access to Diagnostic Services and Access to Treatment by health care providers.

Administrative - This includes issues that relate to matters arising from ……..(organization's name) policies or procedures.

Attitude/Communication - Attitude includes a person's response to a situation. Communication includes breakdowns of communication, lack of information. For our purposes this has been broken down into three categories i.e. Nursing, Medical, and Other (Disciplines).

Confidentiality - Issues with relate to the Freedom of Information and Protection of Privacy Act. These may relate to patients/residents/clients or family members requesting information or access to personal data being kept or stored by the …….(Organization's Name).

Environment - those issues, which relate to the level of noise, availability of parking or level of heat, etc.

Financial - issues related to additional room fees or other fees.

Hospital Services - concerns that relate to the cleanliness of rooms, meals, access to amenities etc

Inadequate Information - issues which relate to the patient/resident/client not being given enough information that he/she feels should have been shared with him/her concerning his/her treatment.

Lost Articles - concerns raised relating to lost or misplaced personal items during patient/resident/client's stay in hospital/clinics/departments.

Patient/Resident/Client Safety - occurrences due to lack of physical or procedural safety measures (eg patient falls), also includes concerns re other patients/residents/clients.

Quality of Care - those issues which relate to deficiencies in actual care provided by health care professionals, usually nursing or medical (also includes concerns of misdiagnosis). Again this has been broken down into three categories (Nursing, Medical & Other).

Other - e.g. wanting information on health related issues and/or how to contact ……(*organizations name*) etc.

NLAHRM PATIENT/RESIDENT/CLIENT SAFETY MANUAL

SAMPLE FAILURE MODE, AND EFFECT ANALYSIS FORM

High Risk Process: _____

Selected Through:

☐ JCAHO Sentinel Occurrence Alert on _____ (attach alert)

☐ Patient/resident/client Safety Tracking Tool (OCCURRENCE REPORT)-Occurrence:

Severity

_____

☐ 3 - An occurrence occurred that resulted in the need for treatment and/or intervention and caused temporary patient/resident/client harm

☐ 4 - An occurrence occurred that resulted in initial or prolonged hospitalization, and caused temporary patient/resident/client harm.

☐ 5 - An occurrence occurred that resulted in permanent patient/resident/client harm or near death occurrence, such as anaphylaxis

☐ 6 - An occurrence occurred that resulted in patient/resident/client death.

☐ Multiple OCCURRENCE REPORTs - # of occurrences _____ within _____ months

☐ Other (specify): _____

Review conducted by: _____ Date: _____ Participants: _____

Complexity (Steps in process from initial activity to identification of error)

	Would failure at this step adversely affect patient/resident/ client?	If yes, rank possibility: 1 = remote 5 = already documented elsewhere 10= documented & almost certain to occur	If yes, rank severity of overall failure: 1 = no harm to patient/resident/client 5 = may affect patient/resident/client adversely 10 = injury or death will occur	If yes, likelihood of detection BEFORE accident takes place: 1 = will always be detected 5 = might be detected 10 = detection not possible	Criticality Index: (mean of possibility, severity, detection – divide by 3): 1 = no action needed 5 = action must be considered 10 – action a must
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					

9.					
10.					

Is Root Cause Analysis (RCA) indicated (anything above 5 in Severity or in Criticality Index)? If yes, attach RCA Summary & complete information on reverse side of this form

ERROR REDUCTION ACTION(s)

Remove Alternatives

- ☐ Eliminate dangerous items/procedures
- ☐ Limit use or access
- ☐ Certification or privileging
- ☐ Avoid potential confirmation bias (look-alike containers, names, abbreviations)
- ☐ Minimize consequence of error
- ☐ Other (specify): _____

Improve Detection

- ☐ Orientation, education, additional training
- ☐ Protocols & procedures
- ☐ Hazard warnings & signs
- ☐ Technology
- ☐ Improved inspection process
- ☐ Other (specify): _____

Prevent Completion of Action

- ☐ Fail safe (automatic shut-off, locking device, etc)
- ☐ Forcing function (non-compatible connectors, etc)
- ☐ Technology (automatic med dispensing system, etc.)
- ☐ Other (specify): _____

Minimize Consequence of Error

- ☐ Reduce supply (volume, concentration, number, etc)
- ☐ Modify defaults
- ☐ Other (specify): _____

FOLLOW-UP FOR EFFECTIVENESS OF ERROR REDUCTION ACTION(s)

Date of First Review: _____ Reviewer: _____
(individual or committee)

☐ Action(s) resolved problem

☐ Action(s) reduced problem.
Needs modification as follows:
_____
_____
_____
Date action will commence: _____

☐ Action did not resolve problem,
New action to be implemented:
_____
_____
_____
Date action will commence: _____

If not completely resolved, review on: _____
(date)

Date of Second Review: _____ Reviewer: _____
(individual or committee)

☐ Action(s) resolved problem

☐ Action(s) reduced problem.
Needs modification as follows:
_____
_____
_____
Date action will commence: _____

☐ Action did not resolve problem,
New action to be implemented:
_____
_____
_____
Date action will commence: _____

INSERT ASHRM'S FMEA WHITE PAPER

Insert JCAHO Documents on Root Cause Analysis

NLAHRM PATIENT/RESIDENT/CLIENT SAFETY MANUAL

Insert the three ASHRM Monographs on Disclosure