Saint Mary's Regional Medical Center:

PATIENT SAFETY PLAN

DATE: 01/17/2023
VERSION: 01
REBECCA ROLEFF, MSN, RN

This plan was created and revised by Saint Mary's Patient Safety committee/team. Implementation of this plan is intended to optimize the healthcare quality and patient safety outcomes, encourage recognition, reporting, and acknowledgment of risks to patient, visitor, and employee safety, as well as reduce the medical/healthcare errors and /or preventable events.

All documents, materials and/or information prepared or created for the purpose of compliance with state law and/or peer review are confidential and deemed protected by the confidentiality provisions of any subsequent federal or state statute providing protection for related activities. Patient Safety files and their entire contents will be clearly marked —CONFIDENTIAL--and should not be copied or distributed without the advice of Legal Counsel.

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Contents

Commitment to Patient Safety....3
Mission, Vision, and Values....3
Scope and Purpose....3
Roles and Responsibilities....4
Roles and Responsibilities....5
Objectives and Goals of the Patient Safety Plan....7
Components and Methods....7
Root Cause Analysis....8
Model for Improvement....9
Data Collection and Reporting....10
Assessment of the Patient Safety Plan....11
Patient Safety Checklists and Patient Safety Policies....11
Approval of Patient Safety Plan....14
Reference....15
Appendix A: Terms and Definitions....16
Appendix B: Patient Safety Goals....18
Appendix C: RCA....21
Appendix D-1: PDSA Worksheet....25
Appendix D-2: PDSA Monthly / Quarterly Progress Report....27
Appendix E: Checklist Example: Code Neuro....28
Appendix F: Policy Example....29

Commitment to Patient Safety

Saint Mary's Regional Medical Center is committed to providing quality healthcare to all patients. The Patient Safety Plan serves as a framework to establish and maintain a safe patient care environment. It expands the organization -wide support for risk management, performance improvement, information management, education, human resources and patient's rights by implementing patient safety standards, measuring and monitoring their effectiveness, and creating a "culture of safety" as part of the overall quality program.

Mission, Vision, and Values

In support of our mission, vision, and values, Saint Mary's Patient Safety program promotes:

- Collaboration of healthcare, leadership, medical staff, and other healthcare providers to deliver integrated and comprehensive high-quality healthcare.
- Communicate honestly and openly to foster trusting and cooperative relationships among healthcare providers, staff members, and patients and their families, to ensure accountability for the patient safety priorities.
- Preservation of dignity and value for each patient, family member, employee, and other healthcare providers.
- Responsibility for every healthcare related decision and action.
- A focus on continuous learning and improving, system design, and the management of choices and changes, bringing the best possible outcomes or performances to the facility.
- Incorporation of evidence-based practice guidelines to deliver high quality healthcare.
- Education of staff and physicians to assure participation of healthcare providers.

Scope and Purpose

The scope of this Patient Safety Plan is organizational-wide/hospital-wide/agency-wide which includes but is not limited to

- Patient safety
- Visitor safety
- Employee safety

A. Saint Mary's recognizes that patients, staff and visitors have the right to a safe environment. Therefore, the organization commits to undertaking a proactive approach to the identification and mitigation of medical errors through the integration into and participation of all components of the hospital into the hospital wide program. This includes Performance Improvement, Risk, Infection Control and EOC programs.
B. The Patient Safety Plan promotes the use of internal and external knowledge and experience to identify, analyze, and prevent the occurrence of medical / healthcare errors and identify areas of opportunity to maintain and improve patient safety.
C. Patient safety information will be analyzed from aggregated data reports. All types of events can be addressed including "no harm", "near misses", and "sentinel events".

These reports will be reported to appropriate hospital and Medical Staff committees and to the Governing Board at regular intervals. The aggregate data will be used to prioritize organization-wide patient safety efforts.

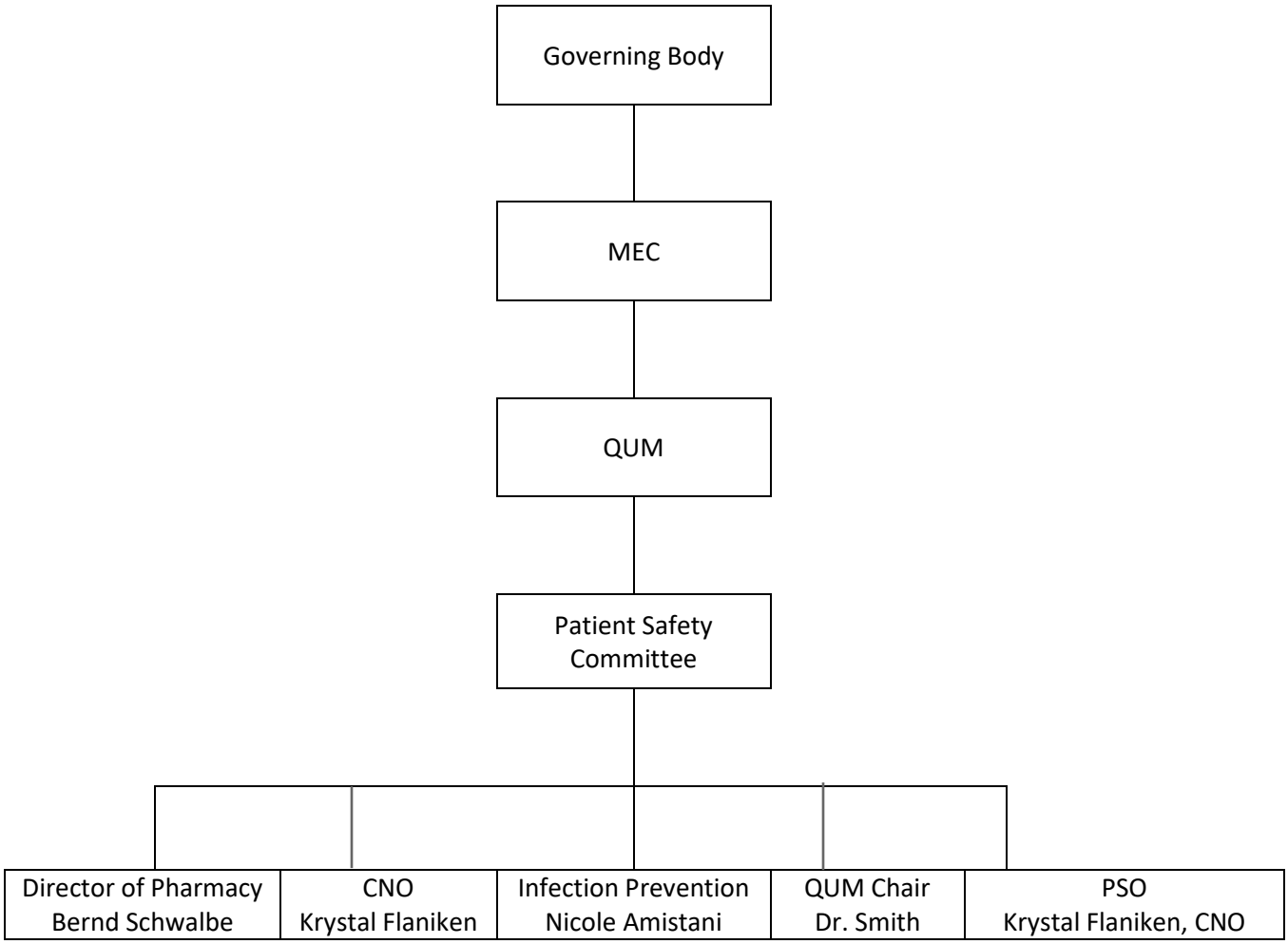
D. The organization also recognizes that despite our best efforts, errors can and will occur. Therefore, it is the intent of the organization to respond quickly, effectively, and appropriately when an error does occur.

E. The organization also recognizes that the patient has the right to be informed of the results of treatment or procedures whenever those results differ significantly from anticipated results.

Roles and Responsibilities

According to NRS 439.875, a medical facility shall establish a Patient Safety Committee (PSC). The PSC should ensure that the Quality and Patient Safety Plan is promoted and executed successfully.

The Patient Safety Committee Organization



Roles and Responsibilities

- In accordance with NRS 439.875, a patient safety committee must be comprised of:
- The infection control officer of the medical facility;
- The patient safety officer of the medical facility, if he or she is not designated as the infection control officer;
- At least three providers of healthcare who treat patients at the medical facility, including but, without limitation, at least one member of the medical, nursing and pharmaceutical staff of the medical facility; and
- One member of the executive or governing body of the medical facility.
- In addition to the above required members, this is an open committee and all employees are welcome to attend.

The roles and responsibilities are defined below

Patient Safety Committee Responsibilities (based on NRS 439.875 and NRS 439.877)

- Monitor and document the effectiveness of the patient identification policy.
- **On or before July 1** of each year, submit a report to the Director of the Legislative Counsel Bureau for development, revision and usage of the patient safety checklists and patient safety policies and a summary of the annual review conducted pursuant to NRS 439.877(4)(b).
- Receive reports from the patient safety officer pursuant to NRS 439.870.
- Evaluate actions of the patient safety officer in connection with all reports of sentinel events alleged to have occurred.
- Make recommendations to the executive or governing body of the medical facility to reduce the number and severity of sentinel events and infections that occur.
- At least once each calendar month (or quarter depending on the number of employees and contractors in the facility), report to the executive or governing body of the facility regarding:
  (1) The number of sentinel events that occurred at the medical facility during the preceding calendar month (or quarter);
  (2) The number and severity of infections that occurred at the facility during the preceding calendar month or quarter; and
  (3) Any recommendations to reduce the number and severity of sentinel events and infections that occur at the medical facility.
- Adopt patient safety checklists and patient safety policies as required by NRS 439.877, review the checklists and policies annually and revise the checklists and policies as the patient safety committee determines necessary.

Patient Safety Officer Responsibilities (based on NRS 439.870)

- Serve on the patient safety committee.
- Supervise the reporting of all sentinel events alleged to have occurred at the facility, including, without limitation, performing the duties required pursuant to NRS 439.835.
- Take such action as he or she determines to be necessary to ensure the safety of patients as a result of an investigation of any sentinel event alleged to have occurred at the facility.

- Report to the patient safety committee regarding any action taken in accordance with the responsibilities above.
- Selects at least one high-risk patient safety process for proactive risk assessment (FMEA) at least every 12-18 months. Coordinates the process throughout this period.
- Presents Patient Safety reports to all departments.
- Develops, and recommends new policies and procedures for patient safety based on analysis of data from events, and other relevant information.
- Works in conjunction with the EOC Chair to prioritize risks, review and analyze data and performs risk analysis as needed to address the safety of the patient environment.
- Maintains the confidentiality and legal privilege, as appropriate, of all data and information.
- Facilitates patient safety orientation and in-service education programs.

Infection Control Officer Responsibilities (based on NRS 439.873)

- Serve on the patient safety committee.
- Monitor the occurrences of infections at the facility to determine the number and severity of infections.
- Report to the patient safety committee concerning the number and severity of infections at the facility.
- Take such action as determines is necessary to prevent and control infections alleged to have occurred at the facility.
- Carry out the provisions of the infection control program adopted pursuant to NRS 439.865 and ensure compliance with the program.

Executive or Governing Body Staff Responsibilities

- Provide vision and leadership to Patient Safety process, and develop and foster a safe learning and improving culture.
- Provides oversight to the healthcare quality improvement processes and teams.

The Patient Safety Committee will meet monthly to accomplish the following:

- Report and discuss sentinel events which include:
  - Number of sentinel events from previous calendar month (or quarter).
  - Number of severe infections that occurred in the facility.
- Corrective Action Plan for the sentinel events and infections
  - Evaluate the corrective action plan.
- Patient safety policies and checklists
  - At least annually evaluate Patient Safety policies and checklists
  - Revise the patient safety policies and checklists as needed.
  - Monitor and document the effectiveness of the patient safety policy.

A meeting agenda and minutes noting follow-up tasks will be kept.

Objectives and Goals of the Patient Safety Plan

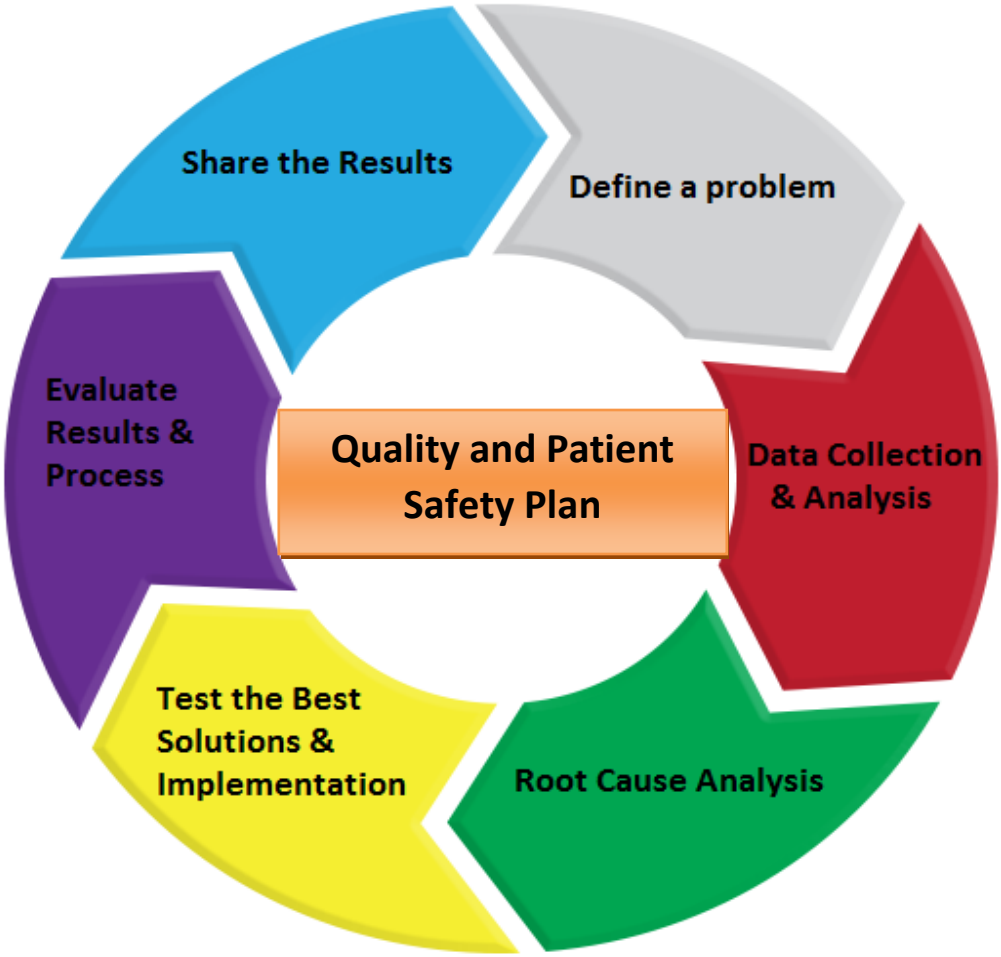
Objective	Goals	Plan	Planned Completion Date	Responsible Party
Improve compliance with pain medication administration and reassessment	100% compliance with safe pain medication administration and timely reassessment.	Implement a performance improvement team, including frontline leaders to educate nurses and physicians on requirements. Monitor pain medication administration and reassessments with reporting up through governing board. Provide just-in-time education when opportunities for improvement are recognized.	June 30, 2023	Jason Czaban
Improve staffing	Staff clinical units to target while reducing number of open positions housewide.	Daily review of staffing for compliance with staffing plan followed up with actions to improve staffing in the moment. HR to continue multi-modal recruitment and retention efforts in order to minimize number of open positions.	Dec 31, 2023	Derrick Glum, CEO
Reduce hospital associated infections	Reduce hospital associated infections to SIR <1.0	Multi-disciplinary approach according to the infection control risk assessment and plan.	Dec. 31, 2023	Nicole Amistani
Improve response rate of AHRQ Safety Attitude Survey	Improve respondents to 80%	Improve education related to existing action plans. Improve staff engagement through employee communication plans. Complete survey during required education days.	June 30, 2023	Erin Madewell

Components and Methods

Pursuant to NRS 439.837**,** a medical facility shall, upon reporting a sentinel event pursuant to NRS 439.835, conduct an investigation concerning the causes or contributing factors, or both, of the sentinel event and implement a plan to remedy the causes or contributing factors, or both, of the sentinel event."

Saint Mary's will use RCA process to determine the contributing factors and the underlying reasons for the deficiencies or failures. The Plan-Do-Study (check)-Act (PDSA or PDCA) is the model, which was developed by the Institute of Health Care Improvement, which we will use to test the

changes.



Root Cause Analysis

A Root Cause Analysis is a process for identifying the root causes of the problem(s). It focuses on the process, instead of individuals.

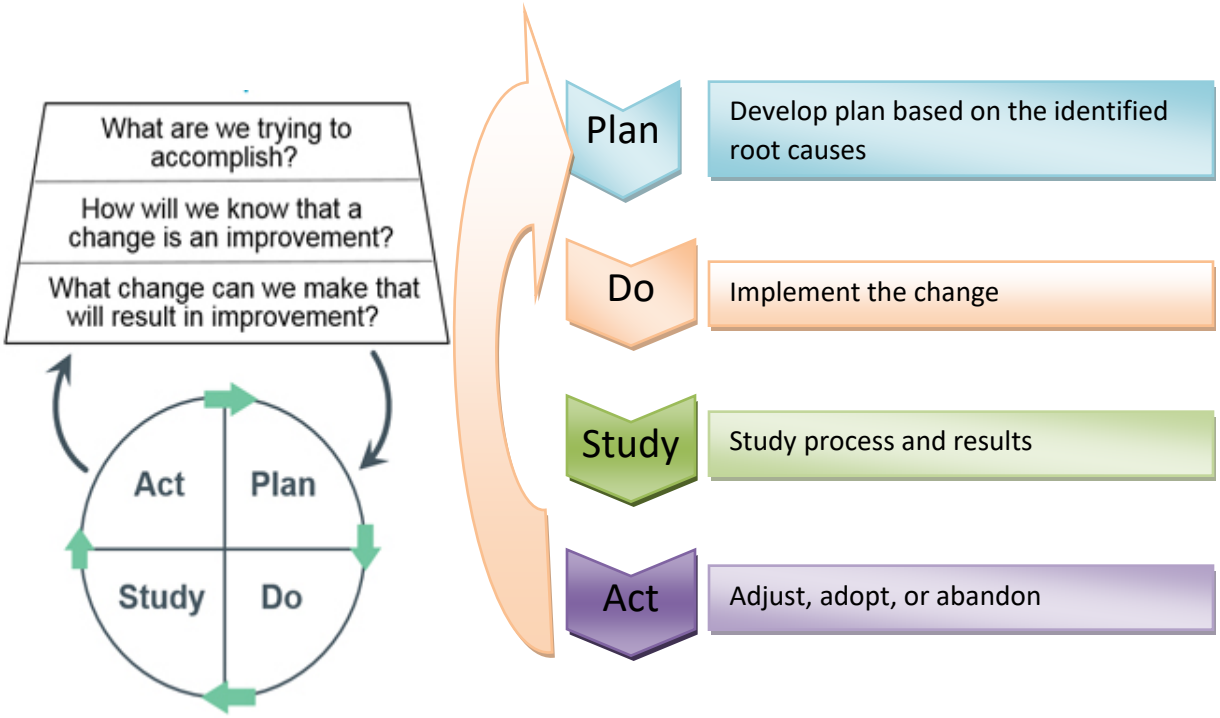
Before analyzing the root causes, defining problems based on facts and data is essential for successfully conducting root cause analysis.

Root cause analysis and action plan framework table, which was introduced by the Joint Commission. It contains 24 analysis questions. It guides the organization to the steps in a root cause analysis. Not all the questions apply to all the events or cases. This table can be used individually or with the fishbone diagram.

5 Whys technique will be used in Saint Mary's to explore the cause and effect relationship underlay a problem. One can find the root causes by asking "why" no less than five times.

Model for Improvement

The Model for Improvement is a collaborative and ongoing effort model to improve the product and services quality and process. It provides multi-disciplinary quality team guidance from identifying the root causes; conducting the best tests to assess possible changes, and working in collaboration for implementation of the new approaches and solutions. It guides the test of a change to determine if the change is an improvement.



The cycle is defined as follows:

- Plan--collect data and establish appropriate goals. Identify the problem and the possible root causes, and answer the following questions.
  - What is the objective of the test?
  - What are the steps for the test - who, what, when?
  - How will you measure the impact of the test?
  - What is your plan to collect the data needed?
  - What do you predict will happen?

- Do--make changes designed to correct or improve the situation. Use the following questions for the guidance.
  - What were the results of the test?
  - Was the cycle carried out as designed or planned?
  - What did you observe that was unplanned or expected?

- Study -- Study the effect of the changes on the situation. Data should be collected on the new process and compared to the baseline or expected results. Results should be evaluated and by using the following questions as guidance.
  - Did the results match your prediction?
  - What did you learn?
  - What do you need to do next?

- Act--If the result is successful or desirable, standardize the changes and then work on the next prioritized problem or the further improvements. If the outcome is not yet successful, look for different ways to identify the causes or change the testing process.

PDSA worksheet will be used to map the potential change strategies and to establish a course of action. The PDSA worksheet and the PDSA progress report are attached in Appendix D-1.

Data Collection and Reporting

To reduce the likelihood of patient incidents and negative outcomes, Saint Mary's shall track the frequency and type of medical errors and compile them in order to learn from and prevent future negative occurrences.

1. External data sources are those data sources which are collected outside the supervisory structure of the case. External data which will be utilized for Quality and Patient Safety plan include the data from:
   a. AHRQ: Agency for Healthcare Research & Quality
   b. CDC: Centers for Disease Control and Prevention
   c. CMS: Centers for Medicare & Medicaid Services
   d. NQF: National Quality Forum
   e. NHSN: National Healthcare Safety Network
   f. TJC: The Joint Commission
2. Internal data sources:
   a. Risk incident reports with database compilation
   b. Adverse Drug Events and Adverse Drug Reactions
   c. Data from patient complaints
   d. Risk Management and Safety findings
   e. Compliance findings
   f. PI and special study findings
   g. Infectious Disease information
   h. Employee surveys
3. Risk Assessment (Failure Mode and Effect Analysis)
   An assessment that examines a process in detail including sequencing of events; accesses actual and potential risk, failure, points of vulnerability; and through a logical process, priorities areas for improvement based on the actual or potential patient care impact (criticality).

4. Data Analysis
   Analysis of collected data will be undertaken to monitor and identify levels of performance, trends or patterns that vary significantly from expected outcomes and the need for possible change/improvement in systems or processes.
5. Process Improvement
   When undesirable outcomes are identified, the hospital shall involve the personnel, resources, disciplines, and department/services most directly involved with the process to reduce future risk.

Ongoing Reporting and Review

Data points such as the following will be reviewed according to the schedule prescribed:

Monthly	Quarterly	Annually
1) Sentinel event monthly report 2) Severity of infection report 3) RCA assessment	1) Sentinel event quarterly report 2) Severity of infection report 3) Review and evaluate the measure of improvement of patient safety	1) Quality and Patient Safety Plan update 2) Checklists and Policies reviewing and revising

Assessment of the Patient Safety Plan

Please see the Patient Safety Assessment Tool (PSAT) from the VA National Center for Patient Safety for your reference.

Patient Safety Checklists and Patient Safety Policies

By NRS 439.865, the patient safety plan must include the patient safety checklists and patient safety policies for use by:

- Providers of healthcare who provide treatment to patients at the facility;

- Other personnel of the facility who provide treatment or assistance to patients;
- Employees of the facility who do not provide treatment to patients but whose duties affect the health or welfare of the patients at the facility, including, without limitation, a janitor of the medical facility; and
- Persons with whom the facility enters into a contract to provide treatment to patients or to provide services which may affect the health or welfare of patients.

The patient safety checklists must follow protocols to improve the health outcomes of patients at the medical facility and must include, without limitation:

- Checklists related to specific types of treatment. Such checklists must include, without limitation, a requirement to document that the treatment provided was properly ordered by the provider of healthcare.
- Checklists for ensuring that employees of the medical facility and contractors with the medical facility who are not providers of healthcare follow protocols to ensure that the room and environment of the patient is sanitary.
- A checklist to be used when discharging a patient from the facility which includes, without limitation, verifying that the patient received:
    - Proper instructions concerning prescription medications;
    - Instructions concerning aftercare;
    - Any other instructions concerning his or her care upon discharge; and
    - Any other checklists which may be appropriate to ensure the safety of patients at the facility.

The patient safety policies must include, without limitation:

- A policy for appropriately identifying a patient before providing treatment. Such a policy must require the patient to be identified with at least two personal identifiers before each interaction with a provider of healthcare. The personal identifiers may include, the name and date of birth of the patient.
- A policy regarding the nationally recognized standard precautionary protocols to be observed by providers of healthcare at the medical facility including, without limitation, protocols relating to hand hygiene.
- A policy to ensure compliance with the patient safety checklists and patient safety policies adopted pursuant to this section, which may include, active surveillance. Active surveillance may include a system for reporting violations, peer-to-peer communication, video monitoring and audits of sanitation materials.

Based on NRS 439.865, the patient safety plan must also include an infection control program that carries out the infection control policy. Saint Mary's has a separate Infection Prevention Plan developed by our certified Infection Preventionist. This document is available upon request.

The patient safety checklists are listed in Appendix E. (The following links provide some patient safety checklists for your reference— a checklist example is shown in **Appendix E**.)

http://www.hpoe.org/Reports-HPOE/CkLists_PatientSafety.pdf

http://www.who.int/patientsafety/implementation/checklists/en/

The patient safety policies are listed in Appendix F. ~~(The following link provides you some patient safety policies for your reference—a policy example is shown in **Appendix F**.) https://www.mercyhospital.org.nz/about-us/mercy-hospital/policies/ruleFile/1~~

Approval of Patient Safety Plan

According to NRS 439.865, a medical facility shall submit its patient safety plan to the governing board of the facility for approval. After a facility's patient safety plan is approved, the facility shall notify all providers of healthcare who provide treatment to patients of the existence and requirements of the plan.

The patient safety plan must be reviewed and **updated annually** in accordance with the requirements for approval set forth in this section.

According to NRS 439.843, on or before March 1 of each year, a copy of the most current patient safety plan established to NRS 439.865 must be submitted to the Division of Public and Behavioral Health.

~~Approvals~~

~~_____ _____~~

~~Director Risk Management Date~~

~~_____ _____~~

~~Chief Nursing Officer / Administrator Date~~

~~_____ _____~~

~~Chief Executive Officer Date~~

~~_____ _____~~

~~Chairman, QUM Committee Date~~

~~_____ _____~~

~~Chief of Staff Date~~

~~_____ _____~~

~~Governing Board Date~~

Reference

- Root Cause Analysis Toolkit http://www.health.state.mn.us/patientsafety/toolkit/
- Quality and Service Improvement Tools http://www.institute.nhs.uk/quality_and_service_improvement_tools/quality_and_service_improvement_tools/plan_do_study_act.html
- CQI 101 An Introduction to Continuous Quality Improvement: https://www.coursehero.com/file/13827355/CQI-Overviewppt/
- Quality Improvement http://www.hrsa.gov/quality/toolbox/methodology/qualityimprovement/
- Root Cause Analysis http://www.patientsafety.va.gov/professionals/onthejob/rca.asp
- Patient Safety Systems Chapter, Sentinel Event Policy and RCA2 https://www.jointcommission.org/sentinel_event.aspx
- Hospital Policies https://www.mercyhospital.org.nz/about-us/mercy-hospital/policies/ruleFile/1
- Checklists to Improve Patient Safety http://www.hpoe.org/Reports-HPOE/CkLists_PatientSafety.pdf
- Patient Safety Checklists http://www.who.int/patientsafety/implementation/checklists/en/
- Minutes of the Meeting of the Quality and Patient Safety Committee http://www.cookcountyhhs.org/wp-content/uploads/2013/12/09-23-14-QPS-scan-Minutes.pdf
- Title 40 – Public Health and Safety https://www.leg.state.nv.us/NRS/NRS-439.html

Appendix A: Terms and Definitions

Patient Safety: The Agency for Healthcare Research Quality (AHRQ) defines patient safety as "a discipline in the healthcare sector that applies safety science methods toward the goal of achieving a trustworthy system of healthcare delivery. Patient safety is also an attribute of healthcare systems; it minimizes the incidence and impact of, and maximizes recovery from, adverse events." http://www.ahrq.gov/downloads/pub/advances2/vol1/advances-emanuel-berwick_110.pdf

Sentinel event (NRS 439.830)

1. Except as otherwise provided in subsection 2, "sentinel event" means an event included in Appendix A of "Serious Reportable Events in Healthcare--2011 Update: A Consensus Report," published by the National Quality Forum.

2. If the publication described in subsection 1 is revised, the term "sentinel events" means the most current version of the list of serious reportable events published by the National Quality Forum as it exists on the effective date of the revision which is deemed to be:

(a) January 1 of the year following the publication of the revision if the revision is published on or after January 1 but before July 1 of the year in which the revision is published; or

(b) July 1 of the year following the publication of the revision if the revision is published on or after July 1 of the year in which the revision is published but before January 1 of the year after the revision is published.

3. If the National Quality Forum ceases to exist, the most current version of the list shall be deemed to be the last version of the publication in existence before the National Quality Forum ceased to exist.

(Added to NRS by 2002 Special Session, 13; A 2005, 599; 2013, 217)

Institute for Healthcare Improvement (IHI) defines **medical harm** as "unintended physical injury resulting from or contributed to by medical care (including the absence of indicated medical treatment) that requires additional monitoring, treatment or hospitalization, or results in death."

Facility-Associated Infection: (NRS 439.802)

"Facility-acquired infection" means a localized or systemic condition which results from an adverse reaction to the presence of an infectious agent or its toxins and which was not detected as present or incubating at the time a patient was admitted to a medical facility, including, without limitation:

- Surgical site infections;
- Ventilator-associated pneumonia;
- Central line-related bloodstream infections;
- Urinary tract infections; and
- Other categories of infections as may be established by the State Board of Health by regulation pursuant to NRS 439.890.

(Added to NRS by 2005, 599; A 2009, 553)

Medical facility (NRS 439.805)

"Medical facility" means:

- A hospital, as that term is defined in NRS 449.012 and 449.0151;

- An obstetric center, as that term is defined in NRS 449.0151 and 449.0155;
- A surgical center for ambulatory patients, as that term is defined in NRS 449.0151 and 449.019; and
- An independent center for emergency medical care, as that term is defined in NRS 449.013 and 449.0151.

(Added to NRS by 2002 Special Session, 13)

Near miss: An event or a situation that did not produce patient harm, but only because of intervening factors, such as patient health or timely intervention. (National Quality Forum (NQF), Serious Reportable Events in Healthcare 2009 Update.)

Mandatory reporting: Legal requirement for physicians and other professionals providing health services to report suspected incidents of abuse and neglect. As mandated reporters, they are generally afforded legal immunity for such reports and most jurisdictions impose a civil or criminal penalty for failure to report. (Council on Scientific Affairs. AMA Diagnostic and Treatment Guidelines Concerning Child Abuse and Neglect. JAMA. 1985;254(6):796-800.)

Risk: Possibility of loss or injury. (Merriam-Webster's Online Dictionary, Risk, Available at http://www.merriamwebster.com/dictionary/risk. Last Accessed August 2009.)

Preventable event: Describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure (National Quality Forum (NQF), Serious Reportable Events in Healthcare 2011 Update.)

Catheter Associated Urinary Tract Infection (CAUTI): A urinary tract infection (UTI) that occurs in a patient who had an associated indwelling urethral urinary catheter in place within the 7-day period before the onset of the UTI (Centers for Disease Control and Prevention, The National Healthcare Safety Network (NHSN) Manual: Patient Safety Component Protocol; 2009. Available at http://www.premierinc.com/safety/topics/guidelines/downloads/NHSN_Manual_PatientSafetyProtocol_CUR RENT_b.pdf.)

Central Line Associated Bloodstream Infections (CLABSI): Primary bloodstream infections that are associated with the presence of a central line or an umbilical catheter, in neonates, at the time of or before the onset of the infection.

Appendix B: Patient Safety Goals

Goal 1 - Improve the accuracy of patient identification.

NPSG.01.01.01

Use at least two patient identifiers when providing care, treatment, and services.

NPSG.01.03.01

Eliminate transfusion errors related to patient misidentification.

Goal 2 - Improve the effectiveness of communication among caregivers.

NPSG.02.03.01

Report critical results of tests and diagnostic procedures on a timely basis.

Goal 3 - Improve the safety of using medications.

NPSG.03.04.01

Label all medications, medication containers, and other solutions on and off the sterile field in perioperative and other procedural settings.

Note: Medication containers include syringes, medicine cups, and basins.

NPSG.03.05.01

Reduce the likelihood of patient harm associated with the use of anticoagulant therapy.

Note: This requirement applies only to hospitals that provide anticoagulant therapy and/or long-term anticoagulation prophylaxis (for example, atrial fibrillation) where the clinical expectation is that the patient's laboratory values for coagulation will remain outside normal values. This requirement does not apply to routine situations in which short term prophylactic anticoagulation is used for venous thrombo-embolism prevention (for example, related to procedures or hospitalization) and the clinical expectation is that the patient's laboratory values for coagulation will remain within, or close to, normal values.

NPSG.03.06.01

Maintain and communicate accurate patient medication information.

Goal 6 - Reduce the harm associated with clinical alarm systems.

NPSG.06.01.01

Improve the safety of clinical alarm systems.

Goal 7 - Reduce the risk of health care-associated infections.

NPSG.07.01.01

Comply with either the current Centers for Disease Control and Prevention (CDC) hand hygiene guidelines or the current World Health Organization (WHO) hand hygiene guidelines.

NPSG.07.03.01

Implement evidence-based practices to prevent health care-associated infections due to multidrug-resistant organisms in acute care hospitals.

Note: This requirement applies to, but is not limited to, epidemiologically important organisms such as methicillin-resistant staphylococcus aureus (MRSA), clostridium difficile (CDI), vancomycin-resistant enterococci (VRE), and multidrug-resistant gram-negative bacteria.

NPSG.07.04.01

Implement evidence-based practices to prevent central line-associated bloodstream infections.

Note: This requirement covers short- and long-term central venous catheters and peripherally inserted central catheter (PICC) lines.

NPSG.07.05.01

Implement evidence-based practices for preventing surgical site infections.

NPSG.07.06.01

Implement evidence-based practices to prevent indwelling catheter-associated urinary tract infections (CAUTI).

Note: This NPSG is not applicable to pediatric populations. Research resulting in evidence-based practices was conducted with adults, and there is no consensus that these practices apply to children.

Goal 15 -The hospital identifies safety risks inherent in its patient population.

NPSG.15.01.01

Identify patient at risk for suicide.

1. Conduct a risk assessment that identifies specific patient characteristics and environmental features that may increase or decrease the risk for suicide.
2. Address the patient's immediate safety needs and most appropriate setting for treatment.
3. When a patient at risk for suicide leaves the care of the hospital, provide suicide prevention information (such as a crisis hotline) to the patient and his or her family.

Universal Protocol

UP.01.01.01

Conduct a pre-procedure verification process.

UP.01.02.01

Mark the procedure site.

UP.01.03.01

A time-out is performed before the procedure.

Appendix C: RCA

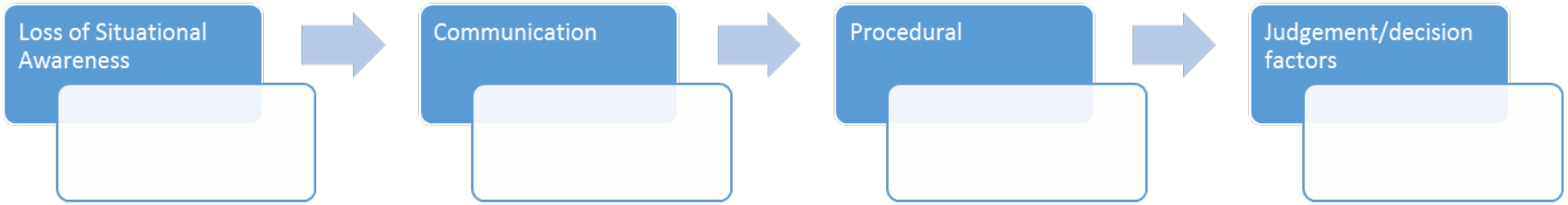
Narrative:

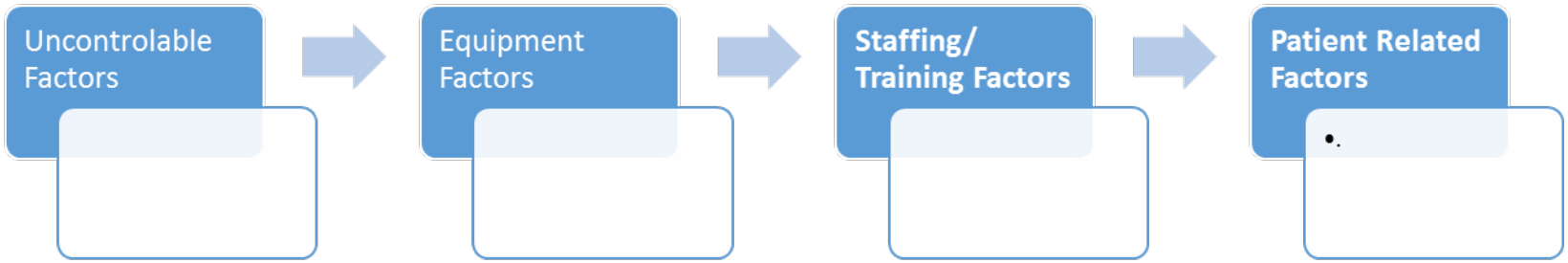
Key Factors:

Timeline:

Date / Time	Description of Event as relates to RCA	Concerns Noted	Employee(s) involved

Cause and Effect Diagram (or process flow chart):





Undesirable Outcome:

Search for Causes:	Cause Identified	Description of Cause	Human Error	Described Human Error and/or Variance from P/P	Causal Link	Take Action?
Patient Related						
Situational Awareness						
Communication						
Proficiency						
Judgment						
Training						
Leadership						
Staffing						
Mechanical Failure						
Other						

Action Plan

Concerns	Action Plan	Responsible Party	Due Date	Status

Participants:

Literature Review:

Appendix D-1: PDSA Worksheet

PDSA Worksheet

Topic:			
Person Completing Worksheet:		**Date:**	
Telephone/ Email:		**Cycle:**	
Patient Safety Committee Members			
CNO/COO			
Patient Safety Officer			
Infection Control Officer			
Other Medical Staff			
Other team members			
Aim: (Describe the overall SMART goal that your team wishes to achieve.)			
Plan:			
1. List the tasks needed to set up this test of change.			
2. Predict what will happen when the test is carried out.			

3. List the steps to develop the test-who, what, and when.

Steps	**By Whom**	**By When**	**Desired Outcome**

Do: (Describe what actually happened when you ran your test, including any problems and unexpected findings.)

Study: (Describe what you learned and did you meet your measurement goal?)

Did you meet your measurement goal? Explain.	**Summarize what was learned: success, failure, unintended consequences, etc.**

Act: (Describe what you concluded from this cycle.)

Based on what was learned, please indicate what action will be considered.	**Describe what modifications to the plan will be made for the next cycle based on what you learned.**
☐ Adapt: modify changes and repeat PDSA Cycle	
☐ Adopt: expanding changes throughout organization	
☐ Abandon: change approach and repeat PDSA cycle	

Appendix D-2: PDSA Monthly / Quarterly Progress Report

Event:			
Person Complete Report:		Date:	
Patient Safety Officer		Contact Information:	

Monthly / Quarterly Report	
Items	**Description**
1. What is your goal?	
2. Report on the PDSA cycle	
3. What system and practices are working well? Explain.	
4. What areas for improvement did the data identify?	
5. What barriers or system issues have been encountered implementing action activities?	
6. Action plans to address the barriers or system issues	
7. Lesson learned	
8. Support needed	
9. Additional discussion	
Notes:	

Appendix E: Checklist Example: Code Neuro

Code Neuro - New Item

EDIT

Save Cancel Commit | Paste Cut Copy Clipboard | Attach File Actions | ABC Spelling Spelling

Last Known Well Time 12 AM 00

Events prior to Code Neuro Call

Total NIHSS Score

Was head CT done

Were Labs ordered

Was Primary MD called

Was Stroke Program Coordinator notifed

Name of recorder

Name of primary MD

Name of Primary RN

Name of Code Neuro Team RN

Supervisor

Was Patient transfered

Save Cancel

Reference: Checklists to Improve Patient Safety. June 2013. Health Research & Educational Trust.

Appendix F: Policy Example

Saint Mary's Regional Medical Center	Policy and Procedure	Perioperative Services Labor & Delivery/OR Cath Lab Interventional Radiology
Universal Protocol		

POLICY: Universal Protocol (Procedure Verification, Correct Site Management and Time Out For Invasive Procedures)

All patients undergoing a surgery or invasive procedure are to be considered at risk for the potential of a wrong patient, procedure or wrong site surgery/invasive procedure. The process to prevent wrong patient, wrong procedure and wrong site surgery or invasive procedure includes all required elements of the *Universal Protocol.* To assure that the correct procedure (operative or invasive) is performed on the correct patient and body part or site. Certain patients are considered at higher risk for error such as those undergoing multiple procedures with one or more physicians, those undergoing emergency procedures, or those patients that have unusual characteristics such as a physical deformity or massive obesity.

DEFINITIONS:

Procedure Verification: Includes verification of patient, procedure and site and as applicable, any implants, diagnostic/radiology results, blood, devices and special equipment (as appropriate to the type of surgery or procedure) AND is applicable to all departments performing surgical or invasive procedures, inclusive of bedside procedures.

Invasive Procedure: Any procedure performed which involves a puncture or incision of the skin, or insertion of an instrument or foreign material into the body, including but not limited to percutaneous aspirations, biopsies, cardiac and vascular catheterization, central line placements, epidurals and endoscopies. This policy does not apply to certain routine minor procedures such as peripheral IV line placement, insertion of an NG tube or urinary catheter insertion.

Procedure Room: Any room where a surgical or invasive procedure may occur to include the patient's bedside.

Procedure Personnel: The RN or credentialed personnel who are participating in the invasive procedure

PROCEDURE:

A. General Information

- Procedures NOT within the Scope of the Universal Protocol and this policy:
  - Venipuncture
  - Peripheral intravenous line placement
  - Insertion of nasogastric tube
  - Urinary catheter placement
  - ECT (electroconvulsive therapy)
  - Closed reduction
  - Radiation oncology
  - Lithotripsy (this does have laterality, but the stone is visualized during the procedure)
  - Dialysis (except insertion of the dialysis catheter**)**

- All other invasive procedures are within the scope of the Universal Protocol and this policy.

- Department staff and physicians participating in a surgical or invasive procedure will actively participate in the Procedure Verification process (to include pre-procedure verification, site marking, and time out) as described in this policy, to assure the correct patient, procedure and site (as applicable) is assessed prior to any surgical or invasive procedure. Staff will document the verification steps in the medical record.

- Anytime there is a discrepancy in the Procedure Verification process, the person discovering the discrepancy will re-verify all the previously completed steps against the surgery schedule, the history and physical, the permit, the patient and notify the physician and department manager. The procedure will not begin until clear verification of the patient, procedure and/or site is completed.

- All actual and "near miss" wrong patient, wrong procedure or wrong site procedures will be reported promptly to the Department Manager or designee and Risk Manager.

B. Pre-Procedure Verification

- Verification of the correct person using two identifiers (patient's name & date of birth), correct site, and correct procedure will occur with the patient/family/legal representative involved, awake and aware, if possible and documented.

- Additionally, persons responsible for scheduling the procedure, completing preadmission testing/assessment and admitting the patient will verify the procedure and site with the physician, physician's office or physician order.

- Pre-procedure verification will occur at the following times:
  - At the time the procedure is scheduled (to include implant information if applicable).
  - At the time of preadmission testing & assessment
  - At the time of admission or entry into the facility for a procedure, whether elective or emergent
  - Before the patient leaves the pre-procedure area (i.e. Same Day Unit or Pre-op Holding) or enters the procedure room

  - Anytime the responsibility for care of the patient is transferred to another member of the procedural care team, (including the anesthesia providers), the above information will be communicated during the hand-off

- Additionally, in the pre-procedure area, procedure verification will include the following for patients undergoing a surgical or invasive procedure and be documented. All applicable items will be available in the procedure room/area and matched to the patient:
  - Identification of the procedure scheduled and identified in physician documentation
  - Presence of current, updated and complete History and Physical
  - Consent accurate, complete and signed by patient/representative
  - Provider assessment (MD, Nursing, PA, APN) and pre-anesthesia /procedural sedation assessment completed and documented
  - Marking of the procedure site by the physician prior to the procedure (if applicable)
  - Verification of the correct patient position
  - Availability and documentation of correct and labeled implants, diagnostic/radiology results, blood, devices and special equipment, or special requirements

- Scheduled procedures that involve anatomical sites that have laterality, surface (flexor, extensor), levels or specific digits or lesions, the word(s) left or right or bilateral will be written out fully on the procedure/operating room schedule and on all relevant documentation including the procedural consent or permit.

C. Site Marking

- Site marking is conducted for all procedures involving incision or percutaneous puncture or insertion.

- The marking takes in to consideration anatomical laterality, the surface (flexor, extensor), the level (spine) or specific digit or lesion to be treated.

- In cases where bilateral structures are removed (such as tonsils or ovaries) the site does not need to be marked.

- If one side is definite and the other is possible, only mark the definite site (example: right ovary, possible left ovary, only mark the right side).

- The only exceptions to site marking are:
  - Midline, single organ procedures
  - When both bilateral structures are to be removed.
  - Endoscopies without laterality
  - Procedures when there is no pre-determined site of insertion, such as cardiac catheterization, interventional radiology and amniocentesis.
  - When the use of direct imaging (fluoro x-ray, ultrasound imaging, CT fluoro or MRI imaging) is utilized by a physician present from the time the site is selected through the completion of the procedure. This applies to all cases where the performing physician uses imaging to select and/or navigate and/or complete the procedure.

- The site marking is completed for all procedures involving incision or percutaneous puncture or insertion by the physician or proceduralist performing the procedure prior to the time the patient is moved in to the procedure room/location. The patient/family/legal representative should be involved in the site marking process.

- The physician or proceduralist will identify the patient (using the two patient identifiers) and verify the procedure and site with the patient/family/legal representative.

- In collaboration with the patient or patient's family member, the site will be marked with the initials of the physician performing the procedure using an indelible marker prior to the patient being transferred to the procedure/operating room unless the anatomical site is exempted per policy.

- The site initialed will be made at or adjacent to the incision site, and must be visible after the patient is prepped and draped and positioned in the final position.

- If the procedure involves multiple sides/sites during the same operation, each side and site must be initialed.

- Do not mark any non-operative site(s).

- In limited circumstances, the licensed independent practitioner may delegate site marking to an individual who is permitted by the organization to participate in the procedure, is familiar with the patient, will be present when the procedure is performed, and is either qualified through a medical residency program or is a licensed individual who performs duties requiring collaboration or supervisory agreements with the licensed independent practitioner (i.e., PA, APN).

- For spinal surgery, a two-stage marking process will occur as follows:
    - The general level of the procedure (cervical, thoracic, lumbar, or sacral) will be initialed pre-procedure, along with an indication of the right vs. left if applicable.
    - Intra-operatively, the exact interspace will be precisely marked using the standard intraoperative x-ray.

- The site will not be marked with the letter "X" or the word "No."

- A new marking pen will be used for each patient

- If the patient refuses to be marked, procedural personnel will re-educate the patient regarding the importance of site marking and document. If the patient still declines to be marked, the procedural personnel will notify the physician, document what alternative means was utilized for marking. The patient's refusal to be marked must be resolved between the procedural physician and the patient prior to the invasive procedure.

- If the consent was signed and the patient was marked accordingly, and then it was discovered that the site was incorrect before the incision was made, the procedure can proceed at the discretion of the procedural physician. The procedural personnel as per hospital policy will document an occurrence report.

D. Difficult to Mark Site:

- Sites which are technically difficult or anatomically impossible to mark or minimal access procedures treating a lateralized internal organ, will apply the alternative process below:

- Examples: Arm in cast, ureters through a cystoscope, teeth, or premature infants.

- After verifying with the patient/family/legal representative that the patient identification and procedural information is correct, the procedural personnel will place a patient sticker and the procedural information on an orange band, indicating the 'side' with 'Left' or 'Right'.

- The orange band information will be verified and initialed by the physician, then placed on the patient's ankle. If the patient's anatomy or procedural draping prevents visualization of the band during the time out process then the band will be placed on the patient's wrist.

- The orange band will be removed in the PACU or post-procedure recovery location.

- Teeth. The physician will initial on the dental radiographs or dental diagram each tooth involved in the surgery/procedure. The dental radiograph or diagram will be used during the time-out before the procedure to identify the site during the "time-out".

- Premature Infants: The orange band will be applied as in no. 1 above.

E. Time Out

- The time out is the suspension of all other activities to permit all members of the surgical/ procedural team to focus on active confirmation of the required time out elements. The circulating nurse or technologist will initiate the time out, although any member of the team may do this. These elements include:
    - Correct Patient: Patient identification using the two patient identifiers (patient name & date of birth.
    - Correct Site: Verification/confirmation of procedure site and side as specified on the consent and visualization of site marking that it is correct and agrees with consent
    - Correct Procedure: Accurate procedure and consent form per physician's order.
    - Confirmation of antibiotic administration
    - Consensus with all team members that above information is correct
    - Documentation of the "time out/procedure verification" process

- The procedure will not be initiated until all members agree with all elements included in the time out.

- The time out will be initiated by the procedural personnel after the patient has been prepped and draped and immediately prior to the initiation of the procedure with all team members present in the room or at the bedside.

- Whenever there is more than one procedure performed by separate procedure teams, there will be a time-out completed and documented by the separate procedure teams. The time out will precede each individual procedure.

- If there is any discrepancy among the team members during the time-out, re-verification will occur with a review of the surgical/department procedure schedule, history and physical, procedure consent, radiology films, consultations and any other information available to validate the correct patient, procedure and site.

F. Management Following Discovery of Wrong Patient/ Wrong Site/ Wrong Procedure

- If, after induction of anesthesia, during the course of a surgical/invasive procedure, or after a surgical/ invasive procedure has been completed, it is determined that the procedure being performed or completed is the wrong patient, wrong procedure or at the wrong site, the surgeon/physician and anesthesiologist will:
    - Act in accord with the patient's best interests and to promote the patient's well-being.
    - Record the event accurately in the medical record.

- Procedural personnel will immediately inform the department manager who will immediately notify the Risk Manager per hospital policy.

G. Fire Risk Assessment

- A fire risk assessment shall be done prior to the start of all surgical procedures (Perioperative Areas)
    - Performed before start of procedure
    - All members of the team participating
    - Communicated during the "Time Out"
    - Documented in patient record
    - Fire Risk Assessment Tool:
        - A. Is an alcohol-based prep agent or other flammable solution being used preoperatively?
        - B. Is the surgical procedure being performed above the xiphoid process or in the oropharynx?
        - C. Is open oxygen or nitrous oxide being administered?
        - D. Is an electrosurgical unit, laser, or fiber-optic light being used?
        - E. Are there other possible contributors (i.e. defibrillators, drills, saws, or burrs)?

H. Quality Improvement:

Compliance with the Universal Protocol Policy will be monitored by conducting documentation/observation audits on a monthly basis.

DOCUMENTATION:

Surgical/Procedural Consent

Procedural/Surgical Nursing Record

Preprocedure Safety Checklist

REFERENCE/EVIDENCE BASED PRACTICE:

Prime HealthCare Policy: Universal Protocol: PeriOperative

AORN Position Statement: Preventing Wrong-Patient, Wrong-Site, Wrong-Procedure Events; August 2015

AORN's Fire Safety Tool Kit

The Joint Commission, 2016 National Patient Safety Goals.

The Joint Commission FAQ's 2009 Universal Protocol; November, 2008 Sentinel Event Alert-Wrong Site Surgery

Physician Insurer's Association of America (PIAA). Claims Data
American Academy of Orthopedic Surgeons: Report on Wrong-Site
Surgery Feb 1998

Bulletin of the American College of Surgeons, Vol. 87, No. 12, December 2002.

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APPROVAL:

Committee Approvals	**Date**
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