Patient Safety Plan

2016
I. INTRODUCTION

The Harris Health System (“Harris Health”) Patient Safety Plan (“Plan”) is a description of the Harris Health system-wide strategy to support Harris Health’s mission, vision, and values through the patient safety process. The Plan is systematic, data-driven, and reflects the complexity of the services provided by Harris Health. The Plan is a component of the Harris Health Quality Manual, which outlines Harris Health’s organizational approach to monitoring and improving quality, patient safety, and performance.

II. PURPOSE AND ORGANIZATION

The purpose of the Plan is to provide a framework for improving patient safety and reducing risk by providing a safe health care environment for Harris Health patients.

The Harris Health Quality Governance Council (“QGC”) oversees the Plan. The QGC delegates the Risk Management department to coordinate the Plan with support from the pavilion-based Quality Management departments and system-level Quality Programs department.

The Plan includes processes for:

- Identifying, detecting, and reporting events that impact or threaten patient safety;
- Describing proactive and corrective methods utilized to reduce risk;
- Collecting and analyzing data in order to identify opportunities to reduce risk;
- Internally reporting information and data about medical errors, adverse events, and reportable events that occur within the organization;
- Externally reporting information about certain events as required by law; and
- Incorporating organizational learning about medical errors, adverse events, and patient safety concerns.

III. PRIVILEGE AND CONFIDENTIALITY OF PATIENT SAFETY ACTIVITIES

Actions taken and documents developed during the patient safety process are privileged, confidential, and not subject to disclosure. Actions and documents include, but are not limited to, reports, investigations, analysis, data aggregation, summaries, and documentation of patient safety events. Actions are taken and documents are developed at the direction of the Quality Governance Council, which is both a medical peer review committee and medical committee as those terms are defined in Chapter 161 of the Texas Health & Safety Code and Chapter 151 of the Texas Occupations Code. Confidential information maintained by the Risk Management department includes, but is not limited to, committee minutes, organizational risk management and/or patient safety reports, electronic data gathering and reporting, and incident reports. The Harris Health Quality Manual contains further description of the privilege and confidentiality of patient safety activities.

In order to safeguard protected health information and to maintain the privileged nature of this data, the following must be observed:

- Electronic Incident Reporting System (“EIRS”) reports must not be printed, copied, or electronically copied and pasted into a document or email;
- No reference to the EIRS system, an incident report, or communication with Risk Management should be made in a patient’s medical record; and
- Information contained in EIRS should be extracted and shared with other departments only as needed.

Failure to follow these procedures may result in disciplinary action, up to and including termination.

IV. DEFINITIONS

A. Medical Error: The failure of a planned action to be completed as intended, the use of a wrong plan to achieve an aim, or the failure of an unplanned action that should have been completed that results in an adverse event.

B. Adverse Event: A patient care event that is unfavorable, undesirable, and usually unanticipated that causes death or serious injury to a patient or the risk thereof. Adverse events may result from unintentional actions or omissions. Adverse events may include, but are not limited to:
   a. Patient falls;
   b. Medication errors;
   c. Procedural errors/complications;
   d. Completed or attempted suicides;
   e. Iatrogenic injuries, i.e. injuries due to medical treatment or procedure;
   f. Failure to make a timely diagnosis;
   g. Untimely implementation of appropriate therapeutic intervention; and
   h. Missing patient events.

C. Reportable Event: A medical error, adverse event, or occurrence which the hospital is required to report to the Texas Department of State Health Services in accordance with 25 Tex. Admin. Code § 133.48.

D. Serious Reportable Event (“SRE”): An event that can result in death, loss of a body part, serious harm/injury/disability, loss of bodily function, or require major intervention for correction. It is also considered to be an event that is unambiguous, largely preventable, and serious, as well as adverse, indicative of a problem in a healthcare setting’s safety systems.

E. Electronic Incident Reporting System (“EIRS”): A real-time electronic reporting tool used to increase awareness of patient, visitor, or Workforce safety concerns throughout the organization.

F. Preventable Adverse Event (“PAE”): A list of adverse events that must be reported to the Texas Department of State Health Services in accordance with 25 Tex. Admin. Code §§ 200.2, 133.49, 135.26.

G. Root Cause Analysis (“RCA”): An investigative technique to dissect complex situations, identify factors associated with an incident, explore universal implications of an event, determine whether an event is recurrent, and recommend corrective actions.
Failure Mode Effectiveness Analysis (“FMEA”): An evaluation technique that proactively identifies and assesses potential failures, prioritizes corrective efforts, and evaluates the effectiveness of process and system changes.

Corrective Action Plan (“CAP”): A description of the steps taken to correct an adverse event or nonconformity that include designating responsibility for implementation and oversight of the plan, specifying timeframes for implementation, and including a strategy for measuring the effectiveness of the actions taken.

Workforce: Harris Health’s Board of Managers, Employees (permanent or temporary), volunteers, trainees, and other persons whose conduct, in the performance of work for Harris Health, is under the direct control of Harris Health, whether or not they are paid by Harris Health.

Medical Staff: All physicians, dentists, podiatrists and oral-maxillofacial surgeons who are appointed to the Medical Staff and who either (i) hold a faculty appointment at Baylor College of Medicine and/or The University of Texas Health Science Center at Houston or (ii) are employed by Harris Health to provide healthcare services at designated Harris Health Facilities.

Advanced Practice Professionals: An individual who holds a state license in their profession as well as other education credentials attesting to training and qualifications to provide services in one or more of the following categories: Physician Assistant (PA), Certified Registered Nurse Anesthetist (CRNA), Nurse Practitioner (NP) or Clinical Nurse Specialist (CNS), Optometrist (OD), Certified Nurse Midwife (CNM), Clinical Psychologist, Registered Dietician, and Clinical Pharmacist.

V. SERIOUS REPORTABLE EVENTS

Serious Reportable Events as defined by the National Quality Forum (http://www.qualityforum.org/topics/sres/serious_reportable_events.aspx), as well as those events described by Harris Health Policy 3.63, “Incident Reporting,” must be reported into the EIRS system. Serious Reportable Events include, but are not limited to:

A. SURGICAL OR INVASIVE PROCEDURE EVENTS

- Surgery or other invasive procedure performed on the wrong site;
- Surgery or other invasive procedure performed on the wrong patient;
- Wrong surgical or other invasive procedure performed on a patient;
- Unintended retention of a foreign object in a patient after surgery or other invasive procedure;
- Intraoperative or immediately postoperative/post procedure death in an ASA Class 1 patient.
B. PRODUCT OR DEVICE EVENTS

- Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting;
- Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended;
- Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a healthcare setting.

C. PATIENT PROTECTION EVENTS

- Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person;
- Patient death or serious injury associated with patient elopement (disappearance);
- Patient suicide, attempted suicide, or self-harm that results in serious injury, while being cared for in a healthcare setting.

D. CARE MANAGEMENT EVENTS

- Patient death, serious injury, or close call associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration);
- Patient death, serious injury, or close call associated with unsafe administration of blood products;
- Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting;
- Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy;
- Patient death or serious injury associated with a fall while being cared for in a healthcare setting;
- Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission/presentation to a healthcare setting;
- Artificial insemination with the wrong donor sperm or wrong egg;
- Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen;
- Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test reports.

E. ENVIRONMENTAL EVENTS

- Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in a healthcare setting;
- Any incident in which systems designed for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or are contaminated by toxic substances.
- Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process in a healthcare setting;
- Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a healthcare setting.

F. RADIOLOGIC EVENTS
- Death or serious injury of a patient or staff associated with the introduction of a metallic object into the MRI area.

G. POTENTIAL CRIMINAL EVENTS
- An instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider;
- Abduction of a patient/resident of any age;
- Sexual abuse/assault on a patient or staff member within or on the grounds of a healthcare setting;
- Death or serious injury of a patient or staff member resulting from physical assault (i.e., battery) that occurs within or on the grounds of a healthcare setting.

VI. INCIDENT REPORTING AND INVESTIGATION PROCESS

Medical Errors, Adverse Events, Reportable Events, and Serious Reportable Events involving patients, visitors, Medical Staff, Advanced Practice Professionals, and Workforce members shall be reported within 24 hours of becoming aware of the event using the Harris Health Electronic Incident Reporting System (“EIRS”). See Policy 3.63, “Incident Reporting.”

Patient grievances concerning the quality of care received by a patient, or the abuse, neglect, or exploitation of a patient occurring on Harris Health property will be reported in the EIRS system for investigation and response by the Risk Management department. See Policy 4200, “Patient Complaints and Grievances.”

If a Workforce member does not timely report an event into the EIRS system, the Workforce member’s supervisor will be notified and the employee will be counseled.

Once an EIRS report is filed, email notification of the report is automatically delivered to the administrator or the administrator’s designee of the clinical area where the event was reported to have occurred. The administrator or their designee is responsible for reviewing events that occur in their areas, performing an initial investigation, and documenting their findings within 5 days of the event. All Serious Reportable Event investigations must be initiated by the involved areas within 24 hours of becoming aware of the event.

All Serious Reportable Events and other significant events as determined by the Chief Medical Officer will proceed to a Root Cause Analysis (“RCA”). The findings of the RCA and the risk reduction strategies/corrective action plans will be presented at the Harris Health Patient Safety Committee. Other serious events, close calls, and near misses may proceed as a facility-level clinical case review and/or RCA as requested by facility administration.

Risk Management reviews all EIRS reports to determine what, if any, further action and/or analysis is warranted based on the information provided in the report. Risk Management assigns a harm severity level to each event to uniformly evaluate the degree of harm caused by the event. The
Harms Severity Level, as described in the table below, is based on the Common Formats Harm Scale Version 1.1 developed by the Agency for Healthcare Research and Quality (“AHRQ”).

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>Level 0</td>
<td>No Event</td>
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<tr>
<td>Level 1</td>
<td>Unsafe Condition/Potential Event</td>
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<td></td>
<td>- Any circumstance that increases the probability of a patient safety event; includes a defective or deficient input to or environment of a care process that increases the risk of an unsafe act, care process failure or error, or patient safety event. An unsafe condition does not involve an identifiable patient.</td>
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<tr>
<td>Level 2</td>
<td>Near Miss/Did not Reach Patient</td>
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<tr>
<td>Level 3</td>
<td>No Harm</td>
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<td>- Event reached the patient, but no harm was evident</td>
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<tr>
<td>Level 4</td>
<td>Emotional Distress or Inconvenience</td>
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<td></td>
<td>- Mild and transient anxiety or pain or physical discomfort, but without the need for additional treatment other than monitoring (such as by observation; physical examination; laboratory testing, including phlebotomy; and/or imaging studies). Distress/inconvenience since discovery, and/or expected in the future as a direct result of event.</td>
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<tr>
<td>Level 5</td>
<td>Additional Treatment</td>
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<tr>
<td></td>
<td>- Injury limited to additional intervention during admission or encounter and/or increased length of stay, but no other injury. Treatment since discovery, and/or expected treatment in future as a direct result of event.</td>
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<tr>
<td>Level 6</td>
<td>Temporary Harm</td>
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<td>- Bodily or psychological injury, but likely not permanent. Prognosis at the time of assessment.</td>
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<tr>
<td>Level 7</td>
<td>Permanent Harm</td>
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<td>- Lifelong bodily or psychological injury or increased susceptibility to disease. Prognosis at the time of assessment.</td>
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<tr>
<td>Level 8</td>
<td>Severe Permanent Harm</td>
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<tr>
<td></td>
<td>- Severe lifelong bodily or psychological injury or disfigurement that interferes significantly with the functional ability or quality of life. Prognosis from time of assessment.</td>
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<tr>
<td>Level 9</td>
<td>Death at the time of the assessment</td>
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The findings of each event investigation and the risk reduction strategies are maintained in EIRS in accordance with Harris Health Policy 8.03, “Records Retention and Destruction.”

VII. PREVENTIVE AND CORRECTIVE ACTIONS TO REDUCE RISK

A. Failure Mode Effectiveness Analysis (“FMEA”) is conducted to proactively identify and assess potential failures, prioritize corrective efforts, and evaluate the effectiveness of process and system changes. Harris Health identifies the need for FMEA through point of service engagement. FMEA may be conducted by the Risk Management department or the pavilion-based Quality Management departments. As potential risk concerns are identified within the Risk Management or Quality Management departments, FMEA criteria are applied to determine whether FMEA is warranted. Areas of high risk or error-prone
processes are selected for concentrated activity, ongoing measurement, and periodic analysis.

The process in question is assessed to determine the steps where there is or may be undesirable variation (failure modes). Information from internal or external sources will be used to minimize risks to patients affected by the new or redesigned process. For each failure mode, the possible effects on patients, as well as the seriousness of the effect, will be identified. The process will be redesigned to minimize the risk of failure modes, and the redesigned process will be tested and implemented. Measures to determine the effectiveness of the redesigned process will be identified and implemented. Strategies to maintain success over time will be identified.

B. Root Cause Analysis (“RCA”) is an investigative technique to dissect complex situations, identify factors associated with an incident, explore universal implications of an event, determine whether an event is recurrent, and recommend corrective actions. The RCA process focuses primarily on systems and processes, not on individual performance.

Risk Management will initiate an investigation of a reported Serious Reportable Event immediately after notification and will notify pavilion and system leadership of the event. An RCA may be conducted for Adverse Events that do not meet the criteria for a Serious Reportable Event if the CMO and/or Risk Management department determines that it is appropriate.

Risk Management will develop a timeline of events based on interviews with staff directly involved in the event, medical record review, and other investigatory methods, as needed.

Risk Management will present the investigation findings to the team of administrators and physicians from the involved/affected areas, as well as a representative from Quality Management, to identify the root causes and develop a Corrective Action Plan (“CAP”). The CAP is implemented by the responsible parties in the affected areas. Risk Management will present the findings of the RCA investigation to the Patient Safety Committee for review and approval of the CAP.

In accordance with the Medical Staff Bylaws, members of the Medical Staff and Advanced Practice Professionals shall participate in the root cause analysis when requested.

VIII. PATIENT SAFETY COMMITTEE

The Patient Safety Committee (“Committee”) reviews the RCA findings and CAP for Serious Reportable Events and other significant events as determined by the Chief Medical Officer. The Committee reviews data to identify trends of Serious Reportable Events and recommends interventions to address the noted trends.

The Committee is chaired by the Chief Medical Officer. The CMO designates a vice chair. The Committee meets on the second Tuesday of each month and is comprised of the following leadership representatives:
Harris Health System
Patient Safety Plan
2016

Voting Members

- Chief Medical Officer (“CMO”)
- Chief Executive Officer (“CEO”)
- Chief Compliance Officer (“CCO”)
- Chief Nurse Executive (“CNE”)
- Member of the Harris Health System Board of Managers
- Pavilion Chiefs of Staff (3)
- Pavilion Executive Vice Presidents (3)
- Pavilion Chief Nursing Officers (3)
- Ben Taub Hospital Chief of Surgery
- Lyndon B. Johnson Hospital Chief of Anesthesiology
- Lyndon B. Johnson Hospital Chief of Medicine

Non-voting Members

- Administrative Director of Risk Management/Patient Safety
- Director of Patient Safety
- Risk Managers

A quorum is made by a majority of the voting members (nine voting members) of the Committee and may include the CMO. One member of the quorum must be a physician. The Chair may appoint additional voting and/or non-voting members at his or her discretion.

The Committee will approve the CAP for each Serious Reportable Event or other significant event presented to the Committee. The Committee may modify the CAP before approval. The Committee is charged with utilizing the information gained by their participation in the Committee to identify areas of risk and implement the CAP, if applicable, at their respective pavilions to decrease the risk of an Adverse Event.

After the CAP is approved by the Committee, the CAP is submitted to the Quality Review Council (“QRC”) for approval. The pavilion-based Quality Management departments will manage the CAP in the Plan-Do-Check-Act (“PDCA”) Model for Improvement. Please see the Harris Health Quality Manual for further information.

The Committee may determine that a physician, nurse, or other Workforce member requires a professional review. If this determination is made, the Risk Management department will ensure that the provider is referred to the appropriate peer review and/or licensing board.

IX. DATA COLLECTION AND USE

Information and data collected by EIRS and the Risk Management department is shared with pavilion-level administrators and system-level administrators on an as needed basis. Risk Management analyzes data obtained from EIRS and reports the findings quarterly at QRC meetings and biannually at QGC meetings. Aggregate data derived from the RCA process is reviewed annually at the Patient Safety Committee.

The Director of Patient Safety/Patient Safety Officer reports Preventable Adverse Events to the Texas Department of State Health Services (“TDSHS”) as required by state law. Other significant events are reported to TDSHS and other regulatory agencies as required with the assistance of the Harris Health Accreditation and Regulatory Affairs department.
Risk Management facilitates the AHRQ Patient Safety Culture survey, which is conducted at the discretion of the CMO to evaluate the culture of patient safety at all levels of Harris Health. Pavilion-level leadership is responsible for evaluating the findings and developing a CAP to address areas of concern.

X. DISCLOSURE OF ADVERSE EVENTS

Harris Health communicates Adverse Events to patients and/or their Legal Representative in accordance with the process set forth in Harris Health Policy 3.64, “Disclosure of Adverse Events.”

XI. MANAGEMENT OF THE PATIENT SAFETY PLAN

The Risk Management department, including the Director of Patient Safety/Patient Safety Officer, is responsible for the implementation, development, supervision, and evaluation of the Patient Safety Plan. Risk Management department members are trained in the methods of risk management and patient safety and attend patient safety education and training annually.

The Workforce receives annual Patient Safety training as part of the mandatory Quality course provided by the Harris Health Learning and Resource Center. Additionally, the Risk Management department provides risk management and patient safety training to the Workforce as needed.

XII. EVALUATION AND APPROVAL OF THE PATIENT SAFETY PLAN

The Patient Safety Plan, as part of the Harris Health Quality Manual, is approved by the Harris Health System Board of Managers. The Plan is reviewed annually and revised as needed. Any changes made to the Plan will be approved by the Board of Managers.

REFERENCES

Harris Health System Quality Manual
25 Tex. Admin. Code § 133.48
Texas Health & Safety Code § 161
Texas Occupations Code § 151
DNV Standard QM.8 Patient Safety System
Harris Health Policy 3.63, “Incident Reporting”
Harris Health Policy 3.64, “Disclosure of Adverse Events”
Harris Health Policy 8.03, “Records Retention and Destruction”
Harris Health Policy 4200, “Patient Complaints and Grievances”
Harris Health Policy 6000, “Preventive Action”
Harris Health Policy 7000, “Corrective Action”
Harris Health Medical Staff Bylaws, May 2015