HARRISHEALTH SYSTEM

BOARD OF TRUSTEES

Quality Committee

Wednesday, June 22, 2022
7:30 A.M.

BOARD ROOM
4800 Fournace Place, Bellaire, Texas 77401

The meeting may be viewed online at: **http://harrishealthtx.swagit.com/live**

Notice: Some Board Members may participate by videoconference.

Mission

Harris Health is a community-focused academic healthcare system dedicated to improving the health of those most in need in Harris County through quality care delivery, coordination of care, and education.

AGENDA

I.	**Call to Order and Record of Attendance**	**Dr. Arthur Bracey**	**1 min**
II.	**Approval of the Minutes of Previous Meeting** • Quality Committee Meeting – May 10, 2022	**Dr. Arthur Bracey**	**2 min**
III.	**Harris Health Safety Message – *Dr. Steven Brass***		**5 min**
IV.	**Update Regarding DNV Re-accreditation Survey Summary – *Ms. Vivian Ho-Nguyen***		**5 min**
V.	**Consideration of Recommendation for Approval of the 2022 Harris Health Quality Manual – *Dr. Steven Brass***		**5 min**
VI.	**Consideration of Recommendation for Approval of the 2022 Harris Health Patient Safety Plan – *Dr. Steven Brass***		**5 min**
VII.	**Executive Session**	**Dr. Arthur Bracey**	**65 min**
	A. Report Regarding Quality of Medical and Healthcare, Pursuant to Tex. Health & Safety Code Ann. §161.032, Tex. Occ. Code Ann. §160.007, and Tex. Occ. Code Ann. §151.002, to Receive Peer Review and/or Medical Committee Report in Connection with the Evaluation of the Quality of Medical and Healthcare Services, Including the Harris Health System Quality and Safety Performance Measures, and Consideration of Recommendation for Approval of Neonatal Program Reports Upon Return to Open Session – ***Dr. Steven Brass and Dr. Yashwant Chathampally***		*(60 min)*

	B. Report by the Executive Vice President, Chief Compliance and Risk Officer, Regarding Compliance with Medicare, Medicaid, HIPAA, Other Federal and State Healthcare Program Requirements and an Update on the Status of Fraud and Abuse Investigations, Pursuant to Tex. Health & Safety Code Ann. §161.032, and Possible Action Regarding this Matter Upon Return to Open Session ***– Ms. Carolynn Jones and Ms. Vivian Ho-Nguyen***		*(5 min)*
VIII.	**Reconvene**	**Dr. Arthur Bracey**	**1 min**
IX.	**Adjournment**	**Dr. Arthur Bracey**	**1 min**

HARRIS HEALTH SYSTEM
MINUTES OF THE BOARD OF TRUSTEES
QUALITY COMMITTEE MEETING
Tuesday, May 10, 2022
8:00 AM

AGENDA ITEM	DISCUSSION	ACTION/RECOMMENDATIONS
I. Call to Order and Record of Attendance	Dr. Andrea Caracostis, Chair, called the meeting to order at 8:01 a.m. It was noted that a quorum was present and the attendance was recorded. Dr. Caracostis announced that while some board members are in the room, others will participate by videoconference as permissible by state law and the Harris Health Videoconferencing Policy. Only participants scheduled to speak have been provided dial in information for the meeting. All others who wish to view the meeting may access the meeting online through the Harris Health website: http://harrishealthtx.swagit.com/live.	
II. Approval of the Minutes of Previous Meeting Quality Committee Meeting – April 12, 2022		**Moved by Ms. Elena Marks, seconded by Dr. Arthur Bracey, and unanimously approved the minutes of the April 12, 2022 Committee meeting.**
III. Announcements / Special Presentations		
A. Employee Recognition	Dr. Steven Brass, Executive Vice President & Chief Medical Executive, presented the Zero Harm Award to employees in three (3) units, Mother Baby Unit at LBJ Hospital, Mother Baby Unit at Ben Taub Hospital, and Labor and Delivery Unit at Ben Taub Hospital. Dr. Brass explained that these units were being recognized for achieving twelve (12) consecutives months in 2021 without experiencing the following: • Catheter-associated Urinary Tract Infections (CAUTI) • Central Line-Associated Bloodstream Infection (CLABSI) • Clostridium difficile Infection (C. Diff) • Patient falls	

AGENDA ITEM	DISCUSSION	ACTION/RECOMMENDATIONS
	He noted that this achievement highlights the units' focus on leadership, safety, and quality, as well the effectiveness of Harris Health's High Reliability Training. Dr. Brass presented awards to four (4) nurse representatives as noted below: • Maria D'Souza, Administrative Director of Nursing, LBJ • Angelica Aja ,Director of Nursing, LBJ • Tamara Thompson, Nurse Manger, LBJ • Sandra Salgar, Director of Nursing – Labor & Delivery, Ben Taub	
IV. Executive Session	At 8:07 a.m., Dr. Andrea Caracostis stated that the Quality Committee of the Board of Trustees would go into Executive Session as permitted by law.	
V. Reconvene	At 8:54 a.m., Dr. Caracostis reconvened the meeting and stated that no action was taken in Executive Session.	
A. Report Regarding Quality of Medical and Healthcare, Pursuant to Tex. Health & Safety Code Ann. §161.032, Tex. Occ. Code Ann. §160.007, and Tex. Occ. Code Ann. §151.002, to Receive Peer Review and/or Medical Committee Report in Connection with the Evaluation of the Quality of Medical and Healthcare Services, Including the Harris Health System Quality and Safety Performance Measures, and Possible Action Regarding this Matter Upon Return to Open Session		**No action taken.**

AGENDA ITEM	DISCUSSION	ACTION/RECOMMENDATIONS
B. Report by the Executive Vice President, Chief Compliance and Risk Officer, Regarding Compliance with Medicare, Medicaid, HIPAA, Other Federal and State Healthcare Program Requirements and an Update on the Status of Fraud and Abuse Investigations, Pursuant to Tex. Health & Safety Code Ann. §161.032, and Possible Action Regarding this Matter Upon Return to Open Session		**No action taken.**
VI. Adjournment	Moved by Dr. Arthur Bracey, seconded by Dr. Ewan Johnson, and unanimously approved to adjourn the meeting. There being no further business, the meeting adjourned at 8:54 a.m.	

I certify that the foregoing are the Minutes of the Meeting of the Quality Committee of the Board of Trustees of the Harris Health System held on May 10, 2022.

Respectfully submitted,

Andrea Caracostis, M.D., MPH, Chair

Recorded by Yasmin Othman

Tuesday, May 10, 2022

Harris Health System Board of Trustees Board Meeting – Quality Committee Attendance

Note: For Zoom meeting attendance, if you joined as a group and would like to be counted as present, please submit an email to: BoardofTrustees@harrishealth.org before close of business the day of the meeting.

QUALITY COMMITTEE BOARD MEMBERS PRESENT	QUALITY COMMITTEE BOARD MEMBERS ABSENT	OTHER BOARD MEMBERS PRESENT
Dr. Andrea Caracostis (Chair)		Dr. Ewan Johnson
Dr. Arthur Bracey		
Ms. Elena Marks		
Ms. Alicia Reyes		

EXECUTIVE LEADERSHIP
Ms. Amy Smith, Senior Vice President, Transitions & Post-Acute Care
Dr. Ann Barnes, Senior Vice President & Chief Health Officer, Population Health
Ms. Antoinette Cotton, Chief Nursing Officer, Ben Taub Hospital
Ms. Carolynn Jones, Executive Vice President & Chief Compliance and Risk Officer
Ms. Debbi Garbade, Vice President, Patient Safety & Risk Management, Quality & Safety Office
Mr. Derek Curtis, Chief Nursing Officer, LBJ Hospital
Ms. Errika Perkins, Chief Assistant County Auditor, Harris County Auditor's Office
Dr. Esmaeil Porsa, President & Chief Executive Officer
Dr. Glorimar Medina-Rivera, Executive Vice President, Ben Taub Hospital
Dr. Jackie Brock, Executive Vice President & Chief Nursing Executive
Dr. Jason Chung, Associate Chief Medical Officer & Senior Vice President, Medical Affairs and Utilization
Dr. Jennifer Small, Interim Executive Vice President, Ambulatory Care Services
Dr. John Foringer, Chair, Medical Executive Board
Dr. Joseph Kunisch, Vice President, Quality Programs
Mr. Louis Smith, Senior Executive Vice President & Chief Operating Officer
Ms. Maria Cowles, Senior Vice President, Chief of Staff
Dr. Martha Mims, Vice Chair, Medical Executive Board

Dr. Matasha Russell, Chief Medical Officer, Ambulatory Care Services
Mr. Matthew Schlueter, Chief Nursing Officer, Ambulatory Care Services
Dr. Maureen Padilla, Senior Vice President, Nursing Affairs & Support Services
Ms. Monica Carbajal, Vice President, Contract Administration
Mr. Omar Reid, Executive Vice President & Chief People Officer
Dr. Otis Egins, Chief Medical Officer, Correctional Health
Ms. Patricia Darnauer, Executive Vice President, Lyndon B. Johnson Hospital
Ms. Sharon Brantley Smith, Assistant County Auditor, Harris County Auditor's Office
Dr. Steven Brass, Executive Vice President & Chief Medical Executive
Dr. Tien Ko, Chief of Staff, Lyndon B. Johnson Hospital
Dr. Yashwant Chathampally, Associate Chief Medical Officer & Senior Vice President, Quality and Patient Safety

OTHERS PRESENT	
Cherry Pierson	Jerald Summers
Daniel Smith	Nicholas Bell
Ebon Swofford	Paul Lopez
Elizabeth Winn	Randy Manarang
Hortincia Renee Williams	Tai Nguyen
Jennifer Zarate	Yasmin Othman

BOARD OF TRUSTEES

Quality Committee

HARRISHEALTH SYSTEM

Wednesday, June 22, 2022

Harris Health Safety Message

Board of Trustees
Quality Committee – Open Session
Patient Safety & Quality Presentation
June 22, 2022

HARRISHEALTH SYSTEM

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Harris Health Safety Message

Steven Brass, MD, MPH, MBA
EVP, Chief Medical Executive

HARRISHEALTH SYSTEM

SAFETY MESSAGE

HARRIS HEALTH SYSTEM | ZERO HARM

Safety 1st. Always.

Having a High-reliability Organization's Mindset

High-reliability Organizations (HROs) are those that successfully complete their missions despite massive complexity and high risk. Examples include the Federal Aviation Administration's Air Traffic Control system, aircraft carriers, and nuclear power plants. In each case, even a minor error could have catastrophic consequences. Yet, adverse outcomes in these organizations are rare. The key components of High Reliability Organizations (HROs), including leadership, a safety-focused culture, and a dedication to continuous learning and improvement.

HRO Safety Video

- 1-HarrisHealth_MinuteForMedicine_09AdoptingHighReliabilityMindset
- https://youtu.be/5sNYAkSMdw8

BOARD OF TRUSTEES

Quality Committee

HARRISHEALTH SYSTEM

Wednesday, June 22, 2022

Update Regarding DNV Re-accreditation Survey Summary

HARRISHEALTH SYSTEM

2022 DNV Reaccreditation Survey Summary

Vivian Ho-Nguyen, MBA, BS, MT(ASCP), CPHQ, ASQ-CQA

DNV Healthcare Accreditation Organization

- CMS approved deeming authority to assess hospitals' compliance with CMS Conditions of Participation
- Three (3) years accreditation cycle with annual assessment process
- Provide structure and framework for robust QAPI program via ISO 9001 Quality Management System
- Collaborative and process based approach to patient safety

Congratulations!

- Special thanks to the Survey Support Team
  - Escort Team Leads
  - Scribes
  - IT Support
  - Staff, Managers, Directors, Medical Staff, Administrators, Executive Leadership team, & Board of Trustees
  - Command Center staff support
- Additional thanks to the Survey Readiness Subcommittee of the Executive Corporate Compliance Committee

Noteworthy Efforts

- The culture of staff commitment to patient safety and the mission of Harris Health System is embedded in staff's DNA and their "muscle memory";
- Cutting edge technology; Cutting edge patient care and management processes; Exceptional services offered to the residents of Harris County; and
- The survey team was very impressed with:
  - Beautiful OR on the 2nd floor at Ben Taub Hospital;
  - Exceptional patient care/service in the ambulatory care platform.
  - Robust Infection Control & Prevention Program;
  - Pharmacy Operations and Opioid Oversight structure, including Meds To Beds and Prescription Home Delivery programs;
  - Excellent Patient Grievance/Complaint Resolution Program;
  - Solid Internal Quality Audit Program, where auditing for value is assured;
  - Patient Safety huddles with 4-tier approach; and

2022 Re-accreditation Survey Results

- Closed all six (6) findings from 2021
- The survey team found 8 nonconformities, which they noted is a very successful survey result for an organization of our size. The nonconformities will be discussed further with the Board in Executive Session.

Post-Survey Activities

Organization response due to DNV – 10 calendar days following receipt of final report (ETA May 27, 2022)

- NC-1-CL finding requires onsite follow up survey within 60 days following the last survey date (ETA July 12, 2022)
- NC-1 findings require full implementation and a progress report to DNV within 60 days (ETA July 12, 2022)

Review & Approval of corrective action plans (CAPs)

- Approve the plans as written - Organization proceeds with the implementation process
- Clarification/rejection of plans – Organization submits clarifications or action plans

Accreditation Decision

- Upon approval of all CAPs

Annual survey window

- Opens 9 – 12 months from the last survey date

BOARD OF TRUSTEES

Quality Committee

HARRISHEALTH SYSTEM

Wednesday, June 22, 2022

Consideration of Recommendation for Approval of the 2022 Harris Health Quality Manual

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Annual Review of the Harris Health System Quality Manual

The updates to the manual for 2022 include; refining the Plan Do Act Check (PDCA) approach by leveraging Lean Six Sigma (LSS) Methodology; defined the Harris Health System Balanced Score Card including updates in the analytics and use of the performance metrics; Defined the quality related information workflow through the performance improvement framework inclusive of Key Performance Indicators (KPI) reported to the Pavilion Quality Review Councils (QRC), Quality Governance Council (QGC), Quality Board of Trustees (QBoT) and the full Harris Health Board of Trustees.

HARRISHEALTH SYSTEM

Quality Manual

~~2021~~2022

Approved by:
Harris Health System
Quality Governance Council
May 17, 2022
Board of Trustees
June ~~March~~ 2021~~2~~2

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I. INTRODUCTION

The Harris Health System is a community-owned, healthcare system dedicated to providing high quality, cost effective, compassionate health care to residents of Harris County regardless of their ability to pay. Harris Health System is a teaching system for Baylor College of Medicine and The University of Texas Health Science Center at Houston (UT Health). We train the next generation of healthcare providers, nurses and allied health professionals.

A nine (9)-member Board of Trustees appointed by the Harris County Commissioners Court governs Harris Health System and approves this Manual. The Board of Trustees appoints the Harris Health System President /Chief Executive Officer to oversee operations of the system.

II. PURPOSE

The Quality Manual outlines Harris Health System's organizational approach to monitoring and improving quality of care, patient safety, and overall satisfaction. The manual supports our commitment to our patients in that it supports Harris Health System's mission, vision, values, and strategic goals. The manual also establishes a systematic, organization–wide approach to quality that cultivates a culture of patient safety and continual performance improvement. The Quality Manual documents the Quality Assessment and Performance Improvement (QAPI) requirements of the CMS Conditions of Participation (COP).

III. GUIDING PRINCIPLES

Creating a culture of safety, including providing safe care and a safe environment, and continual improvement, is the work of the entire organization. Harris Health System has adopted the Institute of Medicine (IOM) six (6) domains of Health Care Quality as the guiding principles for our Quality Manual. These six (6) aims (S.T.E.E.E.P.) guide our work to facilitate performance excellence:

A. Safe: Avoiding harm to patients from care that is intended to help them.

B. Timely: Reducing waits and sometimes-harmful delays for both those who receive and those who give care.

C. Effective: Providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoiding underuse and misuse, respectively.)

D. Efficient: Avoiding waste, including waste of equipment, supplies, ideas, and energy.

E. Equitable: Providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status.

F. Patient-Centered: Providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions.

IV. JUST AND ACCOUNTABLE CULTURE

It is inevitable that people will make mistakes. Thus, a Just and Accountable Culture creates an open, fair, and learning culture by recognizing that individuals demonstrate certain behaviors, which organizational leaders should identify and manage appropriately. Behavioral choices include Human Error, At-Risk Behavior, and Reckless Behavior.

A Just and Accountable Culture promotes learning so employees are engaged and encouraged to speak up and share near misses, etc. so that we could learn from the event and prevent future occurrences.

A Just and Accountable Culture recognizes that many errors represent predictable interactions between human operators and the systems in which they work. So, when mistakes are made, we must learn from them, and then design safer systems and processes to prevent them from occurring again.

A Just and Accountable Culture balances leadership management of the behavioral choices with individual accountability. Human error and at-risk behavior will be managed appropriately, but there will be zero tolerance for reckless behavior.

V. QUALITY POLICY – MISSION, VISION, VALUES, PROMISE

Harris Health System will continually improve its quality management system in order to fulfill its mission, vision, values, and promise in delivering high quality health care to Harris County residents.

Our Mission:

Harris Health is a community-focused academic healthcare system dedicated to improving the health of those most in need in Harris County through quality care delivery, coordination of care, and education.

Our Vision:

Harris Health will become the premier public academic healthcare system in the nation

We Value:

Harris Health values QUALITY:

Q Quality and Patient Safety
U United as One Harris Health System
A Accountable and Just Culture
L Leadership and Integrity
I Innovation, Education, Research
T Trust, Recognition, Respect
Y You: Patients, Employees, Medical Staff

VI. STRATEGIC GOALS AND QUALITY OBJECTIVES

Harris Health System leadership, in collaboration with the Board of Trustees and affiliated Medical Staff, has cooperatively developed strategic pillars related to Quality and patient safety, people, one Harris Health System, population health management and infrastructure optimization.

Goals and Objectives have also been developed to support the shared commitment to Safety, Quality and Performance Improvement. Refer to Harris Health System Strategic Plan 2021 - 2025 for Quality Strategic Goals and Objectives. The Strategic Plans are aligned with the targets and goals of each pavilion and further cascaded to the department levels. Please refer to the Executive Dashboard and the different metrics as identified by the pavilions and service area QAPI Committees.

Strategic Plan Overview:

- Quality and patient safety: Harris Health will become a high-reliability organization (HRO) with quality and patient safety as a core value where zero patient harm is not only a possibility but an expectation.

- People: Harris Health will enhance the patient, employee and medical staff experience and develop a culture of respect, recognition and trust by actively listening to feedback and developing strategies to address high-impact areas of opportunity.

- One Harris Health System: Harris Health will act as one system in its approach to the management and delivery of healthcare.

- Population health management: Harris Health will measurably improve patient health outcomes by optimizing a cross-continuum approach to health that is anchored in high-impact preventive, virtual and community-based services, deployed in coordination with clinical and social services partners, and underwritten by actionable population health analytics and technology.

- Infrastructure optimization: Harris Health will invest in and optimize infrastructure related to facilities, information technology (IT) and telehealth, information security, and health informatics to increase value, ensure safety and meet the current and future needs of the patients we serve.

The Pathway- A Transformative Model of Patient Care Delivery

As we build toward the future, our patient care priorities will be implementation of a robust quality and patient safety, people, one Harris Health System, population health management and infrastructure optimization. We will also vigorously sustain the mission of training the next generation of health care professionals through teaching and research.

VII. SCOPE

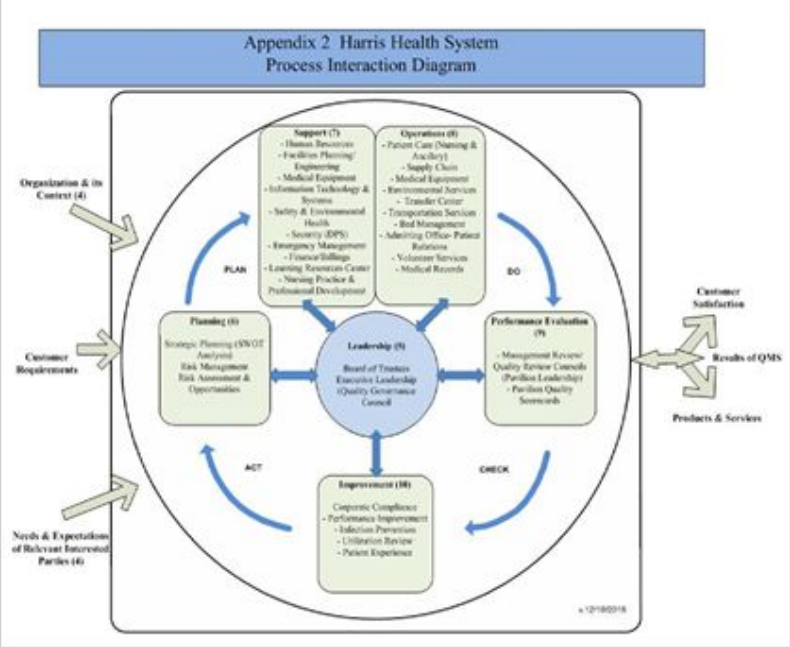
The Quality Manual encompasses all Harris Health System departments and services (including those furnished under contract or arrangement) that impact patient care, safety, and health outcomes.

A. Overview:

Harris Health System is a community-owned, comprehensive, integrated, healthcare system dedicated to providing high quality, cost effective, compassionate health care to all residents of Harris County regardless of their ability to pay. To fulfill its service mission, Harris Health System operates:

1. Two (2) acute care hospitals
2. Sixteen (16) Community Health Centers;
3. Three (3) Pediatric and Adolescent Health Centers;
4. Nine (9) Homeless Shelter Sites;
5. Five (5) School Based Clinics;
6. Six (6) Mobile Health Clinics;
7. Two (2) Specialty Clinic Sites;
8. Five (~~5~~3) Same-Day Clinics;
9. Dental Center;
10. Dialysis Center;
11. Contracted Outside Medical Services;
12. "Ask My Nurse" 24/7 Telephone Nurse Triage line;
13. Emergency Medical Services Fleet;
14. Ambulatory Surgery Center

B. Process Interaction:
The processes within Harris Health System Quality Management System are interrelated. The Harris Health System Process Interaction Diagram provides a high level illustration of these relationships.



C. Key Processes and Support Processes
Patient experience as a process approach can be grouped into 4 key processes:

1. Patient identification and assessment – includes patient intake, triage, registration and health assessment leading to admission or discharge.

2. Development of treatment plan – includes care and treatment planning, provided either for inpatient or outpatient.

3. Delivery of care – includes delivery and coordination of care (treatment and ancillary services such as diagnostic, therapeutic and custodial.

4. Transition of care – includes assessment of treatment plan effectiveness, analysis of patient outcomes, patient status determination to either continue treatment, change treatment or discharge, and patient feedback.

D. Services:
The services provided are detailed in the Harris Health System Schedule of Benefits – Authorization Matrix. Refer to Harris Health Intranet Site

VIII. GOVERNANCE, STRUCTURE, AND LEADERSHIP RESPONSIBILITIES

A. Harris Health System designed quality structure and processes to enhance engagement and collaboration, to define accountability and improve outcomes.

1. Governance:
Board of Trustees
The Harris Health System Board of Trustees (BOT) is the governing body of Harris Health System. It has the ultimate authority and responsibility for the review, approval, and monitoring of Harris Health System's Quality Management System. The BOT ensures that an integrated plan is implemented throughout Harris Health System. The BOT designates the President/Chief Executive Officer as the executive agent who oversees the operation of the organization's Quality Management System. Refer to the Harris County Hospital District Board of Trustees Bylaws.

2. BOT Quality Committee
This is a committee of the Board of Trustees that oversees the Quality, Safety and Performance Improvement (PI) Programs Harris of Harris Health System in order to maintain high quality, patient and staff safety, and overall satisfaction within Harris Health System.

3. Quality Governance Council (QGC)
The QGC provides executive oversight for Harris Health Quality Management System to support and facilitate the continual improvement of quality health care. The QGC has the responsibility and authority to determine if the Quality Management System (QMS)/Quality Assessment and Performance Improvement (QAPI) plan has been effectively implemented and maintained.

The QGC ensures conformance to the National Integrated Accreditation for Healthcare Organizations (NIAHO) standards and other statutory requirements as stipulated by State and Federal agencies. The QGC performs the management review functions as defined by the ISO 9001 standard requirements. According to the ISO 9001:2015 standard 9.3 Management Review, top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization. This review shall include assessing for risks, opportunities, and the need for changes to the quality management system, including the quality policy and quality objectives.

The review includes information on:

a) The status of actions taken from previous management reviews;
b) Changes in external and internal issues that are relevant to the quality management system;
c) Information on the performance and effectiveness of the quality management system, including trends in:
    - Customer satisfaction and feedback from relevant interested parties;
    - The extent to which quality objectives have been met;
    - Process performance and conformity of products and services;
    - Nonconformities and corrective actions;
    - Monitoring and measurement results;
    - Audit results;
    - The performance of external providers;
d) The adequacy of resources;
e) The effectiveness of action taken to address risks and opportunities;
f) Opportunities for improvement.

The review also includes the decisions and actions related to:

a) Opportunities for performance and quality improvement;
b) Any need for changes to the quality management system;
c) Resource needs.

Refer to QGC Bylaws for its membership composition and committee's oversight responsibility.

4. Pavilion Quality Review Council (QRC)
The QRC provides oversight for the Quality Management System/QAPI Plan at the Pavilion level. Each Pavilion has its own QRC. The QRC has the responsibility and authority to determine the Quality Management System has been effectively implemented and maintained at the Pavilion. The QRC is responsible for measurement, monitoring and analysis of the National Integrated Accreditation for Healthcare Organizations (NIAHO) QM.7 Standard Requirements (SR).1-SR.19 quality of care metrics and other regulatory survey

findings. The QRCs develop performance goals that are in alignment with the Harris Health System strategic objectives. In addition, all accredited and ~~/~~certified programs are required to routinely report (minimum of once per year) outcomes and performance metrics to QRC. The different service area ~~QAPI~~ Committees are to report up to the QRCs. The QRCs may also initiate performance improvement teams for issues that are unique to the departments within the pavilion. Refer to Ben Taub Hospital QRC Bylaws, Lyndon B. Johnson Hospital QRC Bylaws, and Ambulatory Care Services QRC Bylaws for their respective membership composition and oversight responsibility.

5. Medical Executive Board and Pavilion Medical Executive Committees
The Medical Executive Board (MEB) is a delegated BOT authority to oversee the operations of the Medical Staff. The Medical Executive Board and Pavilion Medical Executive Committees receive quality information and share Medical Staff quality information at the appropriate Harris Health System quality forum(s). See Medical Staff Bylaws for the committees' membership composition and oversight responsibility.

6. System Level Committees
Harris Health System has multiple forums with specific functions that support the Quality Management System. These committees include but are not limited to the following:

Service Area ~~QAPI~~ Committees
The Service Area ~~Quality Assessment and Performance Improvement (QAPI)~~ Ceommittees areis responsible for ensuring that quality and safe care is delivered to its patients. Each area~~The QAPI~~ cCommittee shall ensure that the service and~~rea~~ quality management system is established that includes a leadership structure, key processes, ~~and~~ key support processes, outcome metrics, performance improvement processes, and reporting processes from the service delivery up to the board. Each service area ~~QAPI~~ cCommittee is responsible for implementing and reviewing the effectiveness of its charter.

Evidence Based Practice Committee (EBPC)
This committee supports the development of clinical practice guidelines, standing delegated orders and care protocols for Harris Health System. It ensures that the care provided to patients is current and based on evidenced based practices.

Policy and Procedure Committees
Structure and Organizational Standards (SOS) Committee: A system-level executive Policy committee that maintains executive approval authority for system-level Policies, Procedures, Standards, and Standard Operation Procedures (SOPs) involving non-clinical operations. The SOS also serves as executive-level decision point of authority for all non-clinical and clinical

practice and operations Policies, Procedures, Standards, and Standard Operating Procedures.

Interdisciplinary Clinical Committee (ICC)
A system-level executive policy committee that maintains executive approval authority for system-level Policies and Procedures, Standing Medical and Delegation Orders, and Clinical Practice Guidelines, Clinical Pathways, and Protocols (non-Research) involving clinical practice and operations. ICC membership is restricted to identified Harris Health executive clinical decision makers and executive medical staff members appointed by the Harris Health Chief Executive Officer (CEO).

Physical Environment
This committee ensures that the Physical Environment and supporting functional area processes are implemented, maintained, measured and improved so that the condition of the physical plant and overall healthcare environment is developed and maintained for the safety and well-being of patients, visitors and staff. Refer to Physical Environment Committee Charter.

7. Department/Service Committees/Councils
As part of the Quality Management System, each service and/or department conducts quality and patient safety focused activities as described in the documented procedures outlined in Section VIII of this Manual. The Harris Health System Process Interaction Diagram lists Harris Health System Departments/Services.

8. Medical Staff Committees
Harris Health System Medical Staff Bylaws outlines Medical Staff Committees and their duties. These committees are coordinated through Harris Health System Medical Staff Services and are accountable for ongoing monitoring and reporting of key quality indicators as appropriate to the committee's scope. Medical Staff Committees receive the organization's quality information and share Medical Staff quality information with appropriate Harris Health System quality forums. Refer to the Medical Staff Bylaws for the various committees' membership composition and oversight responsibility.

B. Structure
The diagram below illustrates the structure and flow of quality information within Harris Health System. Refer to organization chart in Appendix A.

C. Leadership Responsibilities
The Harris Health System Quality Programs (QP) Department has an integral role in facilitating quality, safety, and performance improvement activities and forums. The QP Department collaborates with Medical Staff, Harris Health System leadership, and staff to facilitate measurement and improvement in an effective and timely manner. The QP

Department also assists in the implementation of an interdisciplinary approach and provides quality resources through an integrated delivery network and information management. The QP Department serves as an improvement subject matter expert resource. Accountability of metrics and improvements is owned by the leadership of the reporting service and/or department.

IX. MEASUREMENT, ANALYSIS AND IMPROVEMENT

Measurement of processes and outcomes are essential for performance improvement. Both process and outcome measures are monitored at system, pavilion and department levels of the organization to ensure quality performance.

A. Quality Measures

Key performance indicators are identified and monitored at the system, pavilion, and department levels of the organization. These indicators are reflected in the department, pavilion and system scorecard.

Harris Health follows the guidance referenced in the National Integrated Accreditation for Healthcare Organizations (NIAHO) standard, Quality Management System section 7, 1-19 (QM.7 SR.1-19) to monitor for the effectiveness of the Quality Management System. It also correlates with the ISO (International Standard) 9001:2015 Clause 9 Performance Evaluation.

B. Internal Quality Audits

Internal quality audits (IQA) are conducted to determine the effectiveness of the quality management system~~/QAPI Plan~~. Please refer to the Annual IQA Program Plan. Results of the IQA Program provide a measure of Harris Health's compliance with Conditions of Participation (COPs) and other regulatory requirements and support a continual readiness program for regulatory, accreditation and certification surveys. Performance indicators related to quality audits are measured based on the compliance to the audit schedule as prescribed in the Internal Quality Audit Plan.

C. Reporting Communication

Effective communication is fundamental to Performance Improvement (PI) and patient safety. Many forms of communication exist to keep leadership and staff informed and engaged. Communication vehicles include scorecards and other quality reports that are disseminated through system, pavilions, and departmental quality councils, committees and other forums, as well as, departmental and unit leadership and staff meetings. An annual reporting schedule is established for quality information across the system.

- See Appendix B for the Quality Reporting Procedure, Flow Diagram and Consent Agenda Guidance

D. Data Governance – Information Request, Design and Approval Process

1. Quality information request, design and approval

   Harris Health System monitors and reports many performance indicators that reflect the quality and safety of services that we provide. Quality information

request and design are facilitated by the Quality Programs Department, and approval is made at the QRC and QGC levels. Approval criteria includes the degree to which the indicator/quality information addresses patient safety, meets regulatory or compliance requirements, facilitates and documents achievement of national standards, monitors and supports operations performance and decision making and supports PI. The focus is on monitoring the quality, effectiveness and safety of patient care.

E. Data Management

1. Data Acquisition/Collection

Quality Programs Department provides data collection support for ~~some~~ key performance indicators (KPI) identified under the Harris Health Performance Improvement Framework. The data collection for ~~all other indicators~~service area KPIs are ~~is~~ the responsibility of the department where the specific measure is indicated. Acquiring and responding to real time data is the key to impact current performance/quality of patient care.

2. Data Sampling

When data sampling is used during the data collection process, the following minimum sample sizes are to be used to ensure the data set provides a statistically significant result when the data is analyzed for process improvement:

- For a population size fewer than thirty (30) cases, the sample size is one hundred percent (100%);
- For a population size of thirty to one hundred (30 -100), sample thirty (30) cases; Population size of one hundred and one to five hundred (101 – 500), sample fifty (50) cases; or
- For a population size greater than five hundred (500) cases, sample seventy (70) cases. Focus reviews sample size may vary.

3. Validation

The organization makes decisions based on the information reported, so the data and reports must undergo validation and verification to assure they are accurately representing what is intended. Implementing processes to assure the integrity and validity of data and reports is essential to maintain effective quality, safety, and PI processes. All data and reports will be validated, at the point of service, to assure correct, complete, and reliable information is being communicated.

4. Data Analysis Display and Report Development
   Harris Health System shall determine, collect and analyze appropriate data to demonstrate suitability and effectiveness of its quality management system. The organization will also evaluate where continual improvement of the effectiveness of the quality management system can be made. This process shall include data generated as a result of monitoring and measurement and from other relevant sources.

5. Data Analysis Tools and Methodology
   Several methods are used to analyze performance data to identify trends against established goals. For example, trend charts, fish bone diagrams, value mapping, bubble charts, statistical process control charts (SPCC's), Failure Mode and Effects Analysis (FMEA) and Root Cause Analysis (RCA) are being used. Several risk adjusted methodologies are available for patient outcome-based information [such as Vizient and National Surgical Quality Improvement Project (NSQIP)]. These electronic tools will be utilized to support the translation of the data analysis to action plans.

6. Benchmarking
   Harris Health System's performance is compared to other national organizations via participating in a variety of comparative databases. For example, but not limited to: Vizient, NSQIP, National Healthcare Safety Network (NHSN), CMS Core Measures, Value Based Purchasing, Hospital Consumers Assessment of Healthcare Providers and Systems (HCAHPS), Healthcare Effectiveness Data and Information Set (HEDIS). When regional or national benchmarks are not available, Harris Health will determine a one year baseline performance period than set internal improvement goals to assure the performance goal is tracking towards reducing variation and/or patient harm.

X. QUALITY GOALS

Harris Health System ~~Executive Quality~~Balanced Scorecard (BSC)

The Harris Health System ~~Executive~~ Quality Balanced Scorecard reflects nationally reported ~~benchmarks~~ quality measures that supports reducing patient harm and improves the delivery of quality patient care. ~~that measure achievements of quality of care.~~The Harris Health BSC is an interactive electronic dashboard with advanced analytic functions built to identify the quality metrics in close to real-time performance. This dashboard will have the ability to stratify the quality measures by individual pavilions with drill down capabilities to identify the drivers behind the metrics performance and where the areas of greatest opportunity exists. This dashboard will be used to track the specific areas of focus for Harris Health and updated on an annual basis to determine additional or removal of other quality metrics and readjust benchmarks and/or internal goals. The BSC will serve as the official quality scorecard for the entire organization.

XI. CONTINUAL IMPROVEMENT (PERFORMANCE IMPROVEMENT)

A. Overview

Harris Health System utilizes improvement cycles to include but not limited to Define-Measure-Analyze-Improve-Control (DMAIC) supported by LEAN Six Sigma methodologies for performance improvement. Harris Health System shall continually improve its quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventative actions and management review. System level improvement projects will be initiated and chartered via an effective planning and approval process at QGC. Pavilion level improvement projects will be initiated and chartered via an effective planning and approval process at the pavilion QRC and reported to QGC. A database of ongoing and completed performance improvement and quality improvement initiatives is available in the System PI Project Database (Repository).

B. Models for Improvement

1. DMAIC (Define, Measure, Analyze, Improve, and Control) these five steps represent an improvement cycle that is data driven and meant to improve processes by identifying best practices and standardizing work.

2. LEAN Six Sigma experts use the steps of the DMAIC (define, measure, analyze, improve, control) model, in a specific order, to develop, design and redesign a process so that there's effectively a minimal chance that an error will occur with the goal of zero harm. To attain their goal, the experts work to achieve six sigma, a measurement for standard deviation originating from statistics, to perfect their processes. This supports the Harris Health philosophy of doing no harm to patients. These experts will also use the methodologies to eliminate waste and optimize processes that supports the delivery of quality driven low cost healthcare.

3. Risk Based Thinking (Preventative Action)

Harris Health System also embraces the concept of risk-based thinking when planning for care and services. By doing so, it allows the organization to determine the risks and opportunities during the process improvement phase. Risk is the possibility of events or activities impeding the achievement of an organization's strategic and operational objectives. Risk can be defined by two (2) parameters:

- Severity – Seriousness of the harm
- Probability – Probability that harm will occur

Proactive risk assessment may be completed at any time as part of comprehensive systematic analysis. In a proactive risk assessment, the healthcare system evaluates the process to see how it could potentially fail, to understand the consequences of such failure and to identify parts of the process that need improvement. Determining why the breakdown or failures occurred and designing/re-designing of the process or underlying systems minimizes the risk of the effect on patients. Proactive risk reduction prevents harm before it

reaches the patient.

4. Project Management
The project management approach will be utilized in conducting performance and quality improvement initiatives. The process starts with identification of the gap or need from key performance indicators and other metrics, selection and prioritization of projects are determined by multidisciplinary teams to determine the impact of care and resources available. ~~using an importance and complexity grid~~ I, ~~i~~dentification of the project team ~~including~~ includes the executive sponsor, process owner as team lead and project facilitator. The project facilitator shall ensure the project management process is carried out from planning, implementing, monitoring and reporting, closure and project handoff.

Performance and quality improvement projects can be performed as a team or as an individual, at the system level, service area, pavilion, and at the unit level.

5. Innovation
Harris Health System has a Center for Innovation with a goal of creating a culture of innovation throughout the organization. The innovation program was founded on the profound hope that each and every member of Harris Health will have the desire and opportunity to share their ideas to create better work or patient experience, enhance patient care, or improve processes. Harris Health believes that the only way a culture of innovation can truly emerge is when everyone is given permission to be innovative and is committed to bringing their vision to fruition.

C. Education/Training
For continual quality improvement and patient safety efforts to succeed, it is essential that all leadership, staff, and physicians participate in education/ training regarding process improvement and patient safety issues identification and reporting. A system-wide training plan on quality and patient safety shall be established, implemented and reviewed for effectiveness. Education on quality and patient safety will be provided to the members of the Board of Trustees, system and pavilion executive leaders, service area and department leaders, staff and physicians at orientation and on ongoing basis. Basic and advanced education modules that will include topics in PI, measurement and monitoring techniques and the use of the DMAIC methodology as well as risk-based thinking are also provided on a recurring basis. The Performance Improvement Team within the Quality Programs Department provides on-line and face-to-face education sessions regarding performance improvement to the leadership and staff.

D. Coordination and Support
In order to coordinate and support PI activities, the ~~Department of~~ Performance Improvement Team within the Quality Programs Department for Harris Health System shall:

1. Establish a process for selecting and completing PI projects at the service area and system levels.
2. Establish a process for prioritizing PI initiatives based on importance and alignment with the Harris Health System strategic goals, as well as on the complexity of project management and implementation.
3. Monitor and report the status of PI projects to the QRCs, QGC, and other forum, as appropriate.
4. Establish a process for conducting identified PI projects from initiation, planning, implementing, monitoring, status reporting, to hand-off of project to process owners.
5. Ensure the availability, integrity, accurate analysis and validation of data used to document and evaluate outcomes.
6. Collaborate with PI teams and project sponsors to support the PI initiative through completion and hand-off.
7. Establish and maintain a framework for educating the leaders and staff others on Harris Health System's PI methodologies for continual quality improvement.
8. Provide consult regarding PI activities at all levels to encourage and support continual improvement.
9. Provide project management and facilitation for PI teams, as needed.

E. Point of Service Performance Improvement

Staff at all levels in the organization will be trained on Harris Health System's PI methodology. PI activities may be initiated at the point of service. These activities are encouraged and may evolve into formal PI initiatives at the point of service, department, and pavilion or system level. Depending on the support and resources required, issues/initiatives may also be addressed and resolved at the point of service, applying PI methodology, without formalizing the PI initiative through the approval process.

XII. PATIENT SAFETY/RISK MANAGEMENT

See Patient Safety Plan for activities, responsibilities, processes and risk reduction strategies.

XIII. CONFIDENTIALITY & PRIVILEGE

BOT Quality Committee

The BOT Quality Committee is a medical peer review committee *only when* it is evaluating the competence of a Medical Staff member or the quality of medical and healthcare services provided by Harris Health System, and to the extent that the evaluation involves discussion or records that specifically or necessarily identify an individual patient or Medical Staff member. This committee meets in "executive session" to conduct medical peer review activities, and when the committee is conducting peer review activities, the committee's proceedings and records, as well as any communication made to the committee are confidential, legally privileged, and protected from discovery. Texas Health & Safety Code §161.0315; Tex. Occ. Code §151.002 and §160.007.

PRIVILEGE/CONFIDENTIALITY OF QUALITY MANUAL ACTIVITIES

Quality Manual Committees and Councils, (Quality Committee/Council) described in the Quality Manual all function as "medical committees" and/or "medical peer review committees" pursuant to state law. The Quality Committee/Council's records and proceedings are, therefore, confidential, legally privileged, and protected from discovery under certain circumstances.

The function that the Quality Committee/Council performs determines the protected status of its activities. Information is protected by the privilege if it is sought out or brought to the attention of the medical committee and/or medical peer review committee for purposes of an investigation, review, or other deliberative proceeding. Medical peer review activities include the evaluation of medical and health care services, including the evaluation of the qualifications of professional health care practitioners and of patient care provided by those practitioners. These review activities include evaluating the merits of complaints involving health-care practitioners, and determinations or recommendations regarding those complaints. The medical peer review privilege applies to records and proceedings of the committee, and oral and written communications made to a medical peer review committee when engaged in medical peer review activities. Medical committee activities also include the evaluation of medical and health care services. The medical committee privilege protection extends to the minutes of meetings, correspondence between committee members relating to the deliberative process, and any final committee product, such as any recommendation or determination.

In order to protect the confidential nature of the quality and peer review activities conducted by the Quality Committee/Council, their records and proceedings must be used only in the exercise of proper medical committee and/or medical peer review functions to be protected as described herein. Therefore, Quality Committee/Council meetings must be limited to only the Quality Committee/Council members and invited guests who need to attend the meetings. Quality Committees/Councils must meet in executive session when discussing and evaluating the qualifications and professional conduct of professional health care practitioners and patient care provided by those practitioners. At the beginning of each meeting, the Quality Committee/Council members and invited guests must be advised that the records and proceedings must be held in strict confidence and not used or disclosed other than in Quality Committee/Council meetings, without prior approval from the Quality Committee/Council Chair. Documents prepared by or considered by Quality Committees/Councils in these meetings must clearly indicate that they are not to be copied, are solely for use by the Quality Committee/Council, and are privileged and confidential.

The records and proceedings of Harris Health departments *that support* the quality and peer review functions of Quality Committees/Councils, such as the Patient Safety/Risk Management and Quality Programs & Accreditation departments are also confidential, legally privileged, and protected from discovery, if the records are prepared by or at the direction of the Quality Committees/Councils, and are not kept in the ordinary course of business. Routine administrative records prepared by Harris Health System in the ordinary course of business are not legally privileged or protected from discovery. Documents that are gratuitously submitted to the Quality Committee/Council, or which have been created without Quality Committee/Council impetus and purpose, are also not

protected. All work performed pursuant to this Quality Manual must also comply with state and federal (HIPAA) privacy laws, as well as Harris Health policies and procedures.

XIV. ANNUAL EVALUATION

A. The annual evaluation of the Harris Health System ~~Executive~~ Balanced Quality Scorecard, including the inpatient and ACS data, will be part of the organization's strategic planning process and the plan will reflect Harris Health System's strategic goals and the recommendations. Each year, the QGC will evaluate the effectiveness of the prior year's goals, including analysis of goal achievement and accomplishments. Based on this evaluation, emerging trends and requirements in the healthcare environment, internal quality information, and identified areas for improvement, the QGC will establish priorities for improvement that drive patient quality, safety and PI initiatives The outcomes of this process is a plan that supports Harris Health System's strategic goals and high-level improvement priorities that create a set of aligned improvement initiatives for the next year. The final determination of the BSC will be approved by the Quality Board of Trustee Committee

B. The Harris Health System Quality Manual with be reviewed on an annual basis, with periodic reviews and updated as appropriate.

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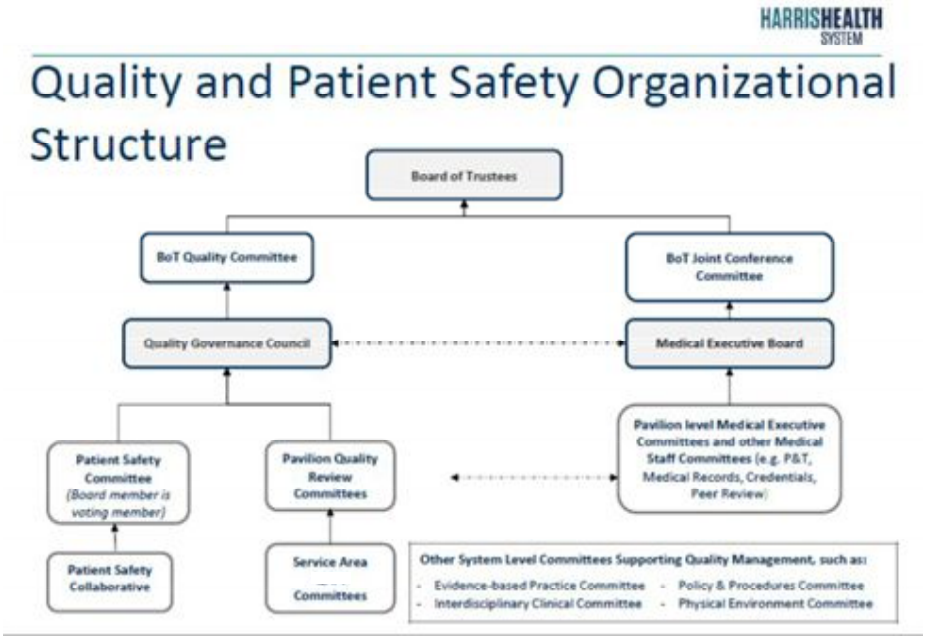
Appendix A

Quality and Patient Safety Organizational Chart

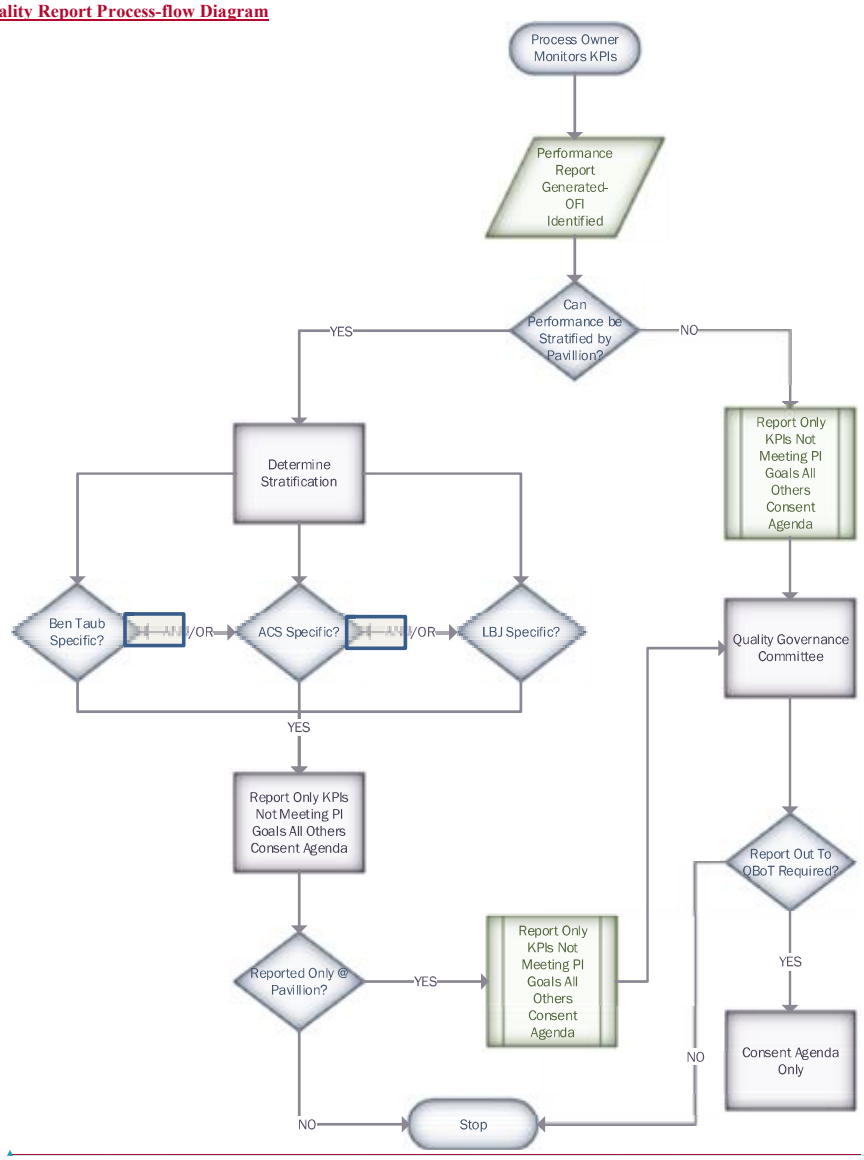


Appendix B

Quality Reporting Procedure

1) Process owners will be responsible for monitoring Key Performance Indicators (KPI) for their area including areas identified for Opportunities For Improvement (OFI)
2) KPIs will focus on patient impacting quality metrics. Operational metrics will only be included when required by accrediting organization (DNV)
3) For presentations, only KPIs that are below system goals AND not demonstrating an improving trend line will be reported verbally along with corrective action plan and/or process improvement initiatives along with any barriers identified. All other metrics will be added to the consent agenda items as approved by Committee Chair
4) Presentations will be limited to no more than five slides and five minute time limit in order to be succinct and efficient for time management
5) KPI process owners will determine if performance data can be stratified by each pavilion or is specific only to one pavilion. KPI performance specific to each pavilion will be reported out at the corresponding pavilion Quality Reporting Committee (QRC).
6) System aggregated KPI metrics will be reported out at the Quality Governance Committee (QGC) using the same criteria stated in line 3. Any entity demonstrating an improving trend and/or are meeting system improvement goals will be added to the consent agenda items with approval of Committee Chair.
7) All required reporting entities will report their KPI metrics performance and corrective action plans/ process improvement initiatives on a standard time interval as established by the Quality Program Leadership to assure that all regulatory requirements are met.
8) Any reporting entity is required to report out on their assigned month(s). If KPI metrics are not available, reporting entity will report out updates on their progress of developing KPI metrics and/or dashboards or barriers hindering their progression. Any requests to delay report outs must be approved by Committee Chair and added to the consent agenda to be captured in the meeting minutes.

Quality Report Process-flow Diagram



Field Code Changed

Consent Agenda Guidance:

1. **Purpose**
   - improves the efficiency and effectiveness of committee meetings
   - provides an efficient process to acknowledge receipt of reports or approve regular, non-controversial, routine issues that come before the committee, or matters where no debate, discussion or explanation is expected or required
   - helps to manage time, as the committee addresses all items listed within or under the consent agenda as a single item with one vote

2. **Description**
   A consent agenda groups routine items and reports which require no discussion or debate into one agenda item called the consent agenda. These items may include KPI reports and/or summary reports including informational only reports. The consent agenda practice allows the committee voting members to approve or acknowledge receipt of all items listed under the consent agenda that are unanimously agreed to with one vote instead of filing multiple motions.

3. **Content of Consent Agenda**
   All materials and items proposed in the consent agenda shall be clearly identified as such in the meeting packages. All committee members must receive and review the consent agenda items prior to the meeting, with the expectation that no discussion will take place during the committee meeting.

4. **Consent agenda items may include:** Key Performance Indicator reports that require no discussion. This is based on a demonstrated performance that either meets predetermined goals and/or clear evidence that trend lines indicated positive movement towards reaching goals.

5. **Approval of Consent Agenda**
   The consent agenda will be approved by the committee at the beginning of each meeting.

   - Committee members may request that matters be added, deleted or that the order of items be moved and the committee chair shall make a decision on each request. Any decision may be subject to challenge and reversed by the committee.

   - Any item may be moved out of the consent agenda section at the request of any committee member, before approval of the agenda. A member may request to move an item to further discuss it, inquire about it, or vote against it. No motion or vote of the committee is required to a request to move an item out of the consent agenda.

   - When a committee member requests that an item be moved out of the consent agenda section, the committee chair shall decide where to place that item on the agenda.

   - When only one item on the consent agenda list does not qualify as a consent agenda item or is requested to be moved, that item shall be moved out of the consent agenda and the rest of the items shall remain on the consent agenda.

   - Approval of the consent agenda by the committee constitutes approval of each of the items listed under the consent agenda portion of the meeting. No separate vote to approve each consent agenda item is required.

6. **Motion to Approve Consent Agenda**

When the requested changes have been made to the consent agenda:

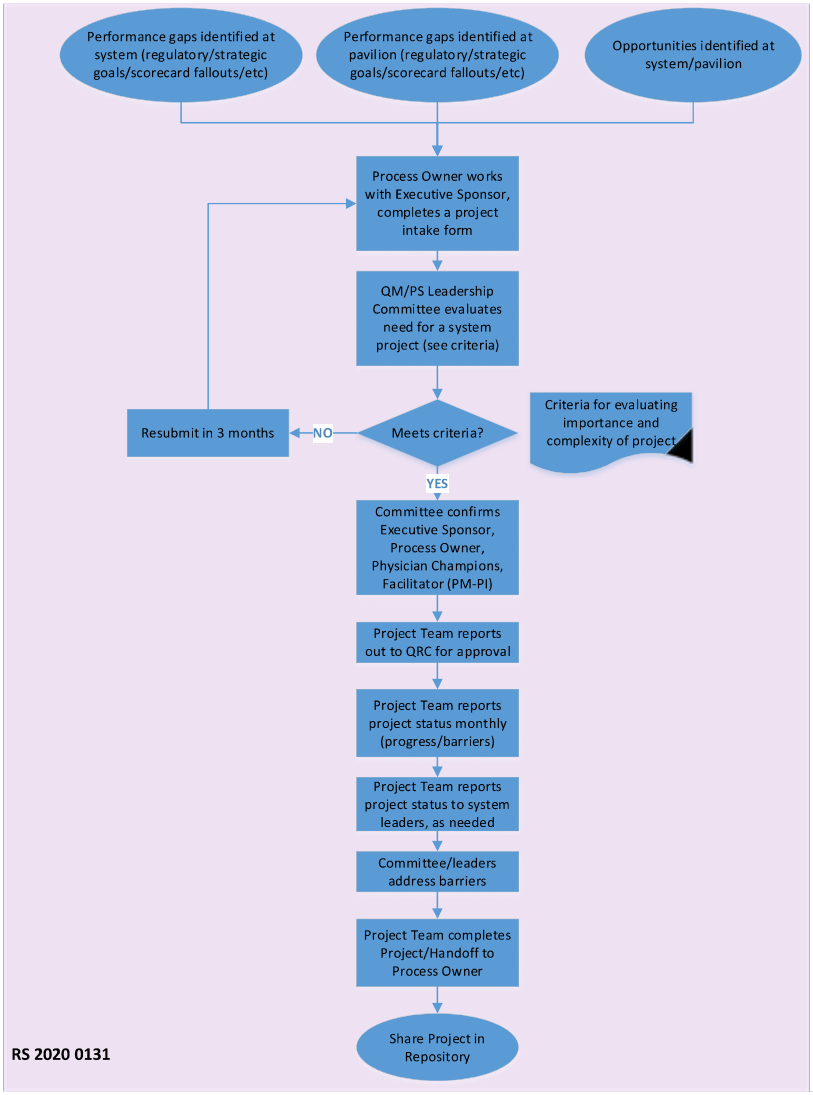
- Chairperson reads items listed under consent agenda.
- Chairperson asks "would any committee member like to remove any of the items from the consent agenda", if no requests are made, then states: "If there is no objection, these items will be adopted".
- The chairperson calls for a motion to accept the consent agenda and a vote is taken and recorded.

7. **Minutes**

Minutes of the meeting will include the full text copy of approved resolutions, recommendations or reports received under the consent agenda portion of the meeting to ensure a record is kept for future reference.

Appendix C~~B~~

System Performance Improvement Process



Commented [MS1]: I edited to include exec. Sponsor on the front end, QRC approval-as defined earlier in this document- and that committee confirms-not assigns- the exec. Sponsor, physician champion, and process owner

Appendix D~~C~~

Service Area ~~QAPI~~ Committee Charter

The Quality Governance Council (QGC) under the direction of the Board of Trustees Quality Committee (BQC) of the Harris Health System (the "System") has authorized the formation of a Service Area ~~QAPI~~ Committee (the "Committee") and approved the following charter to set forth the purpose, structure, authority, and duties and responsibilities of the Committee and the members thereof. In accordance to the National Integrated Accreditation for Healthcare Organizations (NIAHO) QM.7 Standard Requirements, Service Area Committees will function as outlined below.

I. Purpose:

As a core driver of its activities and responsibilities, the Committee will promote the System's dedication to:

- Delivery of safe, high quality health care across the System to the patients and community that the System serves;
- Full compliance with applicable Federal, state and county laws and regulations, and adherence to professionally recognized standards of care; and
- An enterprise-wide culture of safety and just behavior (Just and Accountable Culture).

II. Duties and Responsibilities :

The Committee's responsibilities include:

- Promoting a culture focused on safety and just behavior, including non-retaliation.
- Overseeing and evaluating the structure, operations and effectiveness of the Service Area ~~QAPI~~ initiatives and activities in support of the System Quality Program and in coordination with the Chief Quality and Safety Officer (CQSO).
- Reporting data and information specific to the Service Area according to established criteria and requirements to the QGC (e.g., data fallouts) and any other designated Quality Program resource/committee for proper analysis and identification of trends for prioritization of improvement efforts and/or corrective measures.
- Evaluating key and support activities and processes related to the Service Area's provision of care and/or other services to determine relevant and appropriate measures/metrics to monitor the effectiveness and quality of the services provided (Service Area Dashboard).
- Reviewing and evaluating identified measures/metrics on a regular basis to identify opportunities for improvement and changes that will lead to improvement.
- Reviewing and analyzing safety event data related to the Service Area on a regular basis for trends and/or other areas of focus/corrective measures.
- Promoting and participating in auditing and monitoring activities related to the Service Area conducted by internal or external resources as part of the Quality Program, and ensuring appropriate corrective actions are developed and implemented timely in response to the findings.

Selecting and conducting performance improvement (PI) initiatives/projects utilizing the PI Project Selection and Completion Process.

- Reviewing and evaluating quality and PI initiatives/projects, innovations, corrective action plans, and risk reduction activities initiated in response to data fallouts, safety events and/or other negative trends to determine the effectiveness of those activities to address the identified issues/goals.
- Performing, at least annually, a review and evaluation of the Service Area Dashboard for any necessary revisions to established measures/metrics and benchmarks.
- Maintaining oversight of survey readiness for the Service Area, including staying abreast of significant developments relating to regulatory requirements and standards and expectations of accrediting bodies in coordination with the Accreditation/Regulatory Affairs Department.
- Assessing periodically, and no less than annually, the Service Area's oversight of its quality and safety~~QAPI~~ plan as evidenced by its operation in conformance with all Charter requirements and reporting such to the QGC.
- Maintain departmental quality and safety documents as a portion of their respective operational manual as required for survey readiness.

III. Membership

The Committee will be composed of:

- Service Area Executive Sponsor
- Service Area System Lead – Committee Chair
- Service Area Medical Director, as applicable
- Service Area Nursing Representative(s), as applicable
- Service Area Pavilion Representative(s)
- Designated Director of Quality
- Risk and Patient Safety Representative
- Infection Prevention Representative, as applicable
- Support Services Representative(s)

IV. Meetings, Minutes and Committee Action

The Committee will meet regularly and no less than ten (10) times per year unless the Committee determines otherwise. At every meeting, the Chair will designate a secretary to take and maintain minutes.

Minutes of the meetings shall include discussions, decisions and action plans of the committee and will be prepared after every meeting. The Committee shall follow the Robert's Rules of Order including voting process for approvals.

Meetings should be conducted in person whenever possible. All Committee members are expected to attend each meeting. A quorum representing a majority of the Committee members must be present to transact business.

V. Amendments

This Charter may be amended or revised only upon approval by the QGC. The Service Area System Lead shall be responsible for timely advising the QGC of any proposed amendments or revisions to this Charter.

REVISION HISTORY:

Effective Date	Version # (If Applicable)	Review or Revision Date (Indicate Reviewed or Revised)	Reviewed or Approved by: (Directors, Committees, Managers and Stakeholders, etc.)
06/14/2016	Original 1.0	Reviewed 06/14/16	Approved by Harris Health System Quality Governance Council
07/14/2016		Reviewed 07/04/16	Approved by Harris Health System Board of Managers
11/08/2016	2.0	Revised 11/08/16	Approved by Harris Health System Quality Governance Council
01/25/2017		Reviewed 01/25/2017	Approved by Harris Health System Board of Managers
02/22/2018		Reviewed 02/22/2018	Approved by Harris Health System Board of Trustees
3/13/2019		Reviewed 3/13/2019	Approved by Harris Health System Quality Governance Council
3/13/2019		Reviewed 04/11/2019	Approved by Harris Health System Board of Trustees
3/10/2020		Reviewed 3/12/2020	Approved by Harris Health System Quality Governance Council
3/10/2020		Reviewed 3/14/2020	Approved by Harris Health System Board of Trustees
12/29/2021			

Wednesday, June 22, 2022

Consideration of Recommendation for Approval of the 2022 Harris Health Patient Safety Plan

Annual Review of the Harris Health System Patient Safety Plan

The updates to the plan for 2022 include updates to the definition of Serious Safety Event as well as an update to the Patient Safety Event Determination Algorithm. Additionally, the Level of Harm descriptions were updated to exactly reflect the verbiage in the National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) Index for Categorizing Errors. This is the scoring strategy we have been using, but the descriptions of the scores were not verbatim from the tool in the previous plan.

Harris Health System
Patient Safety Plan
2022

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's 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 aim of Harris Health is to become a high-reliability organization (HRO) with quality and patient safety as a core value where zero patient harm is not only a possibility but an expectation. The goals include eliminating never events and high-harm reportable events, eliminate preventable hospital-acquired conditions, and create/permeate throughout the organization a just and accountable culture. Increasing transparency of information and learning to identify and resolve system issues while addressing human error, at risk or reckless behavior is a key objective. An additional objective is to increase staff willingness to report events that impact or potentially impact patient safety.

The Harris Health Quality Governance Council ("QGC") oversees the Patient Safety Plan. The QGC delegates the Patient Safety and 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 Patient Safety and 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 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. 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:

1. Patient falls;
2. Medication errors;
3. Procedural errors/complications;
4. Completed or attempted suicides;
5. Iatrogenic injuries, i.e. injuries due to medical treatment or procedure;
6. Failure to make a timely diagnosis;
7. Untimely implementation of appropriate therapeutic intervention; and
8. Missing patient events.

B. 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 result in an adverse event.

C. 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.

~~D. Reportable Event: A medical error, adverse event, or occurrence which the hospital is~~ serious harm/injury/disability, loss of bodily functions, 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.

Serious Safety Event ("SSE"): ~~In any healthcare setting, is a deviation from generally~~

course of the patients' condition in which we failed to do all nationally recognized best practices to prevent or treat the condition that is scored as an SSE 1, SSE 2, or HRE by the Filter Committee~~.~~

F. Safety Event: Same as Serious Safety Event except the Filter Committee scores as SE 3-5

~~H.~~G. 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.

~~I.~~H. 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.

~~J.~~I. 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.

Root Cause Analysis ("RCA"): ~~An investigative technique to dissect complex situations,~~

~~K.~~J. 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.

~~L.~~K. 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.

~~M.~~L. Workforce: Employees (permanent or temporary), Board of Managers, 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.

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:

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.

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 of 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.

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 severe harm, while being cared for in a healthcare setting.

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.

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.

RADIOLOGIC EVENTS

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

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 immediately notify their supervisors of all incidents and complete an incident report at the time they become aware of or witness an incident, recommended to report no later than then end of shift. An incident report must be completed for all incidents regardless of severity 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 7

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 will proceed to a Root Cause Analysis ("RCA"). The findings of the RCA and the risk reduction strategies (RRS) /corrective action plans (CAP) will be presented at the Harris Health ~~Patient Safety~~Collaborative 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.

For events meeting the criteria of a safety event, ~~T~~team members of the Patient Safety and Risk Management department ~~reviews~~ will review all eIRS reports to determine what, if any, further action and/or analysis is warranted based on the information provided in the report. The Patient Safety and Risk Management team assigns a harm severity level to each event to uniformly evaluate the degree of harm caused by the event. The Harm Severity Level, as described in the table below, is based on the following:

Type	Category	Severity Level	Level Description
~~?~~	~~?~~	~~No Error Identified~~	~~?~~
~~?~~	~~?~~	~~Unknown~~	~~?~~
No Error	A	~~Unsafe Condition~~No Event	~~Circumstance or events that have the capacity to cause error~~.
Error, No Harm	B	~~Near Miss~~Unsafe Condition/Potential Event	~~An error occurred but the error did not reach the person affected (An "error of omission" does reach the person affected")~~Any circumstance that increases the probability of a patient safety event; includes a defective or deficient input toor environment of a care process that increases the risk of an unsafe act, care process failure or error, or patient saety event. An unsafe condition does not involve an identifiable patient
	C	~~No Harm: Incident Reached Individual~~ Near Miss / Did not Reach Patient	~~An error occurred that reached the person affected but did not cause harm.~~

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	D	~~No Harm: Incident Required Monitoring~~ No Harm	~~An error occurred that reached the patient but did not cause harm.~~ Event reached the patient but no harm was evident
Error, Harm	E	~~Harm: Required Intervention~~ Emotional Distress or Inconvenience	~~An error occurred that may have contributed to or resulted in temporary harm to the person affected and required intervention.~~ 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.
	F	~~Harm: Required Hospitalization~~ Additional Treatment	~~An error occurred that may have contributed to or resulted in temporary harm to the person and required initial or prolonged hospitalization.~~ 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 the future as a direct result of event.
	G	~~Harm: Permanent~~Temporary Harm	~~An error occurred that may have contributed to or resulted in permanent harm to the person affected.~~ Bodily or psychological injury, but likely not permanent, prognosis at the time of assessment.
	H	~~Harm: Required Intervention to Sustain Life~~ Permanent Harm	~~An error occurred that required intervention necessary to sustain life.~~ Lifelong bodily or psychological injury or increased susceptibility to disease, prognosis at the time of assessment.

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Error, Severe Harm	I	Severe Permanent Harm	Severe lifelong bodily or psychological injury or disfigurement that interferes significantly with the functional ability or quality of life; prognosis from time of assessment
Error, Harm Death	J	Death at the time of the assessment	

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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." Event investigations are to be completed within 45 days. When necessary, extensions may be approved by the System Patient Safety Leadership.

VII. STANDARDIZED SCORING

The ~~Patient Safety Department~~Filter Committee will utilize the revised Healthcare Performance Improvement Safety Event Classification (SEC) Levels of Harm as an approach to identify possible safety events, accurately screen events to determine if they are Serious Safety Events, and calculate those events occurring ~~from a deviation from generally accepted performance standards and resulting in moderate to severe patient harm or death~~ as meeting the definition of Serious Safety Events. The Serious Safety Event Rate (SSER) provides a consistent methodology for measuring patient harm and improvement in reducing patient harm. The SSER is calculated monthly as the number of Serious Safety Events for the previous 12 months per 10,000 adjusted patient days. The Safety Event Classification (SEC) provides common definitions and an algorithm for the classification of safety events. The classification is based on the degree of harm that results from the error, injury, harm or death not related to the natural course of the patients codition.~~a deviation from expected performance or standard of care~~. The Safety Event Classification (SEC) serves as the foundation for identification and scoring of Serious Safety Events. The committee members of the Patient Safety Collaborative and Patient Safety Committee shall use the following algorithm and classification tools to classify and score deviations from expected performance:

Once a ~~deviation from generally accepted performance standards~~ safety event is identified, the next level of assessment considers the level of harm experienced by the patient and determines the safety event classification. Serious Safety Events results in harm that ranges from moderate to severe patient harm or death. A Close Call Safety Event results in minimal harm, no ~~detectable harm, or no harm. In a Near Miss or Good Catch Safety Event, the initiating error is~~ caught before it reaches the patient by either a detection barrier built into the process or, sometimes by chance.

Scale Qualifying Harm Assessment

Event types:

A. Safety Event: likely caused by one or more deviations in an existing generally accepted process or expected performance
B. New Hazard Event: an unsafe condition likely caused by a previously unidentified gap in care delivery requiring a new process in order to prevent recurrence. (Unique to HHS)
C. Sentinel Event - A patient safety event (not primarily related to the natural course of the patient's illness or underlying condition) that reaches a patient and results in any of the following
    1. Death
    2. Permanent Harm
    3. Severe temporary harm

The safety event in question has a reasonable likelihood of having caused or meaningfully contributing to:

- SSE1 / SNHE1- Death

- SSE2 ~~/ SNHE2~~ Severe harm: physical or psychological injury (including pain or disfigurement) that interferes significantly with functional ability or quality of life
- HRE: Deviation or error that has the potential to cause ~~major~~ severe harm or death to a future patient but ~~did~~ may not have harmed a patient related to the incident. In addition to future harm, the risk assessment should include likelihood of recurrence ranging from high (frequent) to remote (rare). Examples of "high risk - no harm" events include dangerous actions, EMTALA, Red Rule and other policy violations in which system errors are identified.
- SE3 / NHE3 - Moderate harm: physical or psychological injury adversely affecting functional ability or quality of life, but not at the level of severe harm
- SE4 / NHE4 - Mild harm: Minimal symptoms or loss of function, or injury limited to additional treatment, monitoring, and/or increased length of stay. The duration of impact must be temporary.
- SE5 / NHE5- No harm: Event reached patient, but no harm was evident or detectable
- SE-U / NHEU—Unknown
- PPE6 / PPNHE6 – Did not reach the patient
- NE – Never Event: Errors in medical care that are clearly identifiable, preventable, and serious in their consequences for patients, and that indicate a real problem in the safety and credibility of a health care facility

~~**Classification for duration of impact**~~

It is important to note that events of harm in which there are no system issues identified, and it is purely an individual failure will be referred to Human Resources for the application of the employee discipline policy.

Harris Health System
Patient Safety Plan
2022

Safety Event Class	Level of Harm	Code	Patient Outcome
Serious Safety Event (Reaches the patient)	**Death**	**SSE-1/ SNHE-1**	Unexpected death not related to the natural or expected course of the patient's illness or underlying condition. On balance of probabilities, was caused by or brought forward in the short term by incident.
	Severe **Permanent or Temporary Harm**	**SSE-2/ SNHE-2**	Patient outcome is symptomatic, requiring life-saving intervention or major medical-surgical intervention, shortening life expectancy or causing major, permanent or temporary harm or loss of function.
High Risk Error	**Deviation or error that has potential to cause major harm or death**	**HRE**	Deviation or error that has the potential to cause major harm or death to a future patient but did not harm a patient related to the incident. In addition to future harm, the risk assessment should include likelihood of recurrence ranging from high (frequent) to remote (rare). Examples of "high risk - no harm" events include dangerous actions, EMTALA, Red Rule and other policy violations.
Safety Event (Reaches the patient)	**Moderate** **Permanent or Temporary Harm**	**SE-3/ NHE-3**	Patient outcome is symptomatic, requiring intervention (e.g. Additional operative procedure, additional therapeutic treatment) an increased length of stay, or causing permanent or temporary harm, or loss of function.
	Mild **Temporary Harm or None**	**SE-4/ NHE-4**	Patient outcome is symptomatic, symptoms are mild, loss of function or harm is minimal or intermediate, but short-term, and minimal or intervention (e.g. Extra observation, investigation, review, or minor treatment), is required.
	No Detectable Harm/No Harm	**SE-5/ NHE-5**	Patient outcome is asymptomatic. No symptoms are detected and no treatment is required. Not able to discover or ascertain the existence, presence, or fact of harm, but harm may exist: Insufficient information is available, or unable to determine any harm. Harm may appear later.
	Unknown	**SEU / NHEU**	Unknown

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Pre-Patient Event (Does not reach the patient)	**Almost Happened**	**PPE-6 / PPNHE6**	Did not reach the patient. Error or capacity to cause harm was caught by an error by an error detection barrier prior to reaching the patient. √The system worked.
Possible Event Type Across All Event Classes	**Never Event**	**NE**	Errors in medical care that are clearly identifiable, preventable, and serious in their consequences for patients, and that indicate a real problem in the safety and credibility of a health care facility

Adapted from ASHRM White Paper Series: Serious Safety Events: Getting to Zero™ (2014)

Risk Reduction Strategy and Action Hierarchy Levels and Categories

	Action Category	Example
Stronger Actions	Architectural/physical plant changes	Replace revolving doors at the main patient entrance into the building with powered sliding or swinging doors to reduce patient falls.
	New devices with usability testing	Perform heuristic tests of outpatient blood glucose, meters, and test strips with selection of the most appropriate for the patient population being served.
	Engineering control (forcing function)	Eliminate the use of universal adaptors and peripheral devices for medical equipment and use tubing/fitting that can only be connected the correct way (e.g. IV tubing and connectors that cannot physically be connected to sequential compression devices or SCDs).
	Simplify process	Remove unnecessary steps in a process.
	Standardize on equipment or process	Standardize on the make and model of medication pumps used throughout the institution. Use bar coding for medication administration.
	Tangible involvement by leadership	Participate in unit patient safety evaluation and interact with staff; support the RCA^2 process; ensure staffing and workload are balanced.
Intermediate Actions	Redundancy	Use two RNs to independently calculate high-risk medication dosages.
	Increase in staffing/decrease in workload	Make float staff available to assist when workloads peak during the day.
	Software enhancements, modifications	Use computer alerts for drug-drug interactions.
	Eliminate/reduce distractions	Provide quiet rooms for programming PCA pumps; remove distractions for nurses when programming medication pumps.
	Education using simulation based training with periodic refresher sessions and observations	Conduct patient handoffs in a simulation lab/environment with after action critiques and debriefing.
	Checklist/cognitive aids	Use pre-induction and pre-incision checklists in operating rooms. Use a checklist when reprocessing flexible fiber optic endoscopes.
	Eliminate look- and sound-alikes	Do not store look-alikes next to one another in the unit medication room.
	Standardized communication tools	Use read-back for all critical lab values. Use read-back or repeat-back for all verbal medication orders. Use a standardized patient handoff format.
	Enhanced documentation, communication	Highlight medication name and dose on IV bags.

Weaker Actions	Double checks	One person calculates dosage, another person reviews their calculations.
	Warnings	Add audible alarms or caution labels.
	New procedure/ memorandum policy	Remember to check IV sites every 2 hours.
	Training	Demonstrate the hand-to-use defibrillator with hidden door during an in-service training.

Action Hierarchy levels and categories are based on Root Cause Analysis Tools, VA National Center for Patient Safety, http://www.patientsafety.va.gov/docs/joe/rca_tools_2_15.pdf. Examples are provided here.

VIII. 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 Quality Management department. 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.

~~.~~ 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 after notification and will notify system and pavilion leadership of the event. An RCA may be conducted for Adverse Events that do not meet the criteria for a Serious Reportable Event if leadership determines that it is appropriate.~~

~~Patient Safety and Risk Management team 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.~~

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. An investigation of a patient safety event. This may involve several levels of investigation which may include timelines, interviews, process mapping, observations, policy and best practice review, and data evaluation. All events scored with SSE 1, SSE2, or HRE will have an RCA with at least a timeline pertinent to the event and a case summary addressing system and individual failures noted during the investigation. Action plans will be related to the identified failure modes.

C.

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 risk reduction strategies (RRS) and/or a Corrective Action Plan ("CAP"). All RRS and/or CAP will be implemented by the responsible parties in the affected areas. Patient Safety and Risk Management team will present the findings of the RCA investigation to the Patient Safety Collaborative ~~and Patient Safety Committee~~ for review and approval of the RRS and/or CAP.

In accordance with the Medical Staff Bylaws, members of the Medical Staff and Advanced Practice Professionals involved in the event will be required to participate in the root cause analysis.

~~XIII. PATIENT SAFETY COMMITTEE~~

The Patient Safety Collaborative is an interdisciplinary ~~workgroup~~ Committee that aims to promote a culture of transparency to provide a multidisciplinary objective review and analysis of patient safety events. The Patient Safety Collaborative workgroup shall use a consistent scoring system to determine a final severity level of patient safety events. The workgroup will review and approve Serious Safety Event root causes and recommendations of developed risk reduction strategies. A review of eIRS trends and near misses will be completed to prioritize risk for process improvement, education, and awareness initiative. Voting members will provide physician and nursing peer review recommendation to the pavilion chief nursing officer and/or chief of staff. The impact of the Patient Safety Collaborative is to optimize a rapid system-wide response to patient safety with intent to drive Harris Health System towards becoming a high reliability organization where zero harm is expected for patients served.

The Patient Safety Collaborative workgroup meets bi-weekly (second and fourth Monday) and is comprised of the following representatives:

VOTING MEMBERS		NON-VOTING MEMBERS
SYSTEM EXECUTIVE LEADERSHIP	**PHYSICIAN EXPERTS (Ad Hoc – case dependent)**	**RISK AND PATIENT SAFETY**
Chief Medical Executive	Family Medicine	VP Patient Safety
Chief Compliance Officer	Psychiatry	Pt Safety Director -BTH
VP- Pharmacy	Family Med	QM Analyst
VP-Qlty Programs Chief Quality &	OB	Pt Safety Director-LBJ
Pt. Safety Officer	Neonatology	Pt Safety Director-ACS
Chief Nurse Executive	Ortho	Patient Safety Specialists
Chief Operating Officer	Pulmonary	
VP Dir Quality Programs	Surgery	**COUNTY ATTORNEY'S OFFICE**
VP Patient Safety & Risk Mgmt	EC	
	Internal Medicine	

PAVILION LEADERSHIP
Ben Taub, LBJ, ACS
Executive Vice President – (3)
Chief Nursing Officer – (3
Associate CMO
PAVILION QUALITY
Ben Taub, LBJ, ACS
Director (3)
PAVILION INFECTION PREVENTION
Admin Director
ACS (Ad hoc)
LBJ (Ad hoc)
BT (Ad hoc)

Psychiatry
IM/CC
Ortho Surgery
EC

NURSING EXPERTS (Ad hoc – case dependent)
Med/Surg
EC
Psychiatry
Surgery
IMU/CC
Women & Infants

Deputy Managing Attorney
Alternate as applicable

Ad hoc members as applicable to specific safety events

~~XLIII.~~X. THREAT ASSESSEMENT TASKFORCE

The Threat Assessment team works under direction of the Harris Health System Patient Safety Committee. The County Attorney's Office advises the Threat Assessment team as necessary. The Threat Assessment Taskforce shall complete the following: review the eIRS system for reports of Workplace Violence; assess and evaluate reports of Workplace Violence; provide recommendations for process improvements, interventions, or mitigation strategies in response to reports of Workplace Violence; and support the training and education related to Workplace Violence prevention. The Threat Assessment Taskforce will meet on a minimum bimonthly schedule.

The Threat Assessment Taskforce is an ad hoc task force, which consists of representatives from Patient Safety/Risk Management, Human Resources, Corporate Compliance, Healthcare Systems Engineering, the Department of Public Safety, and other pertinent stakeholders, as requested. The Threat Assessment Taskforce consists of the following representatives:

SYSTEM EXECUTIVE LEADERSHIP
Chief Quality & Patient Safety Officer
Chief Nurse Executive
Chief Compliance Officer
Sr. VP-Operations
Admin Dir –Accreditation
Director Emergency Management
Program Director-DPS
Director-Corporate Compliance
Director- HR Org Services
Director-LRC
Dir Patient Access
Manger Occupational Health
County Attorney's Office
VP-Quality
VP Pt Safety & Risk Management

AMBULATORY CARE LEADERSHIP
VP Operations
Admin Director -Ancillary Services
Director-Security & Park
Director- Quality
Safety Specialist

BEN TAUB LEADERSHIP
VP-Operations
Admin Director – EC
Admin Director-IMU/CC
Director-Quality

LBJ LEADERSHIP
VP-Operations
Director Security/Parking
Admin Director-EC
Direct-Quality

RISK AND PATIENT SAFETY
~~Admin Director~~
~~Pt Safety Director-ACS~~
~~Pt Safety Director-BTH/QM~~
~~Pt Safety Director-LBJ~~
QM Analyst

*Ad hoc members are invited based on current circumstances and need as applicable

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~~XLIV.~~XI. DATA COLLECTION AND USE

Information and data collected by eIRS and the Patient Safety and Risk Management department is shared with pavilion-level administrators and system-level administrators on an as needed basis. Patient Safety and 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 VP of Patient Safety and Risk Management and 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.

Patient Safety and Risk Management facilitates the AHRQ Patient Safety Culture survey, which is conducted biennial 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.

~~XLV.~~XII. 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."

~~XLVI.~~XIII. EVENT REPORTING NOTIFICATION

The Event Reporting Notification categorizes the actual/potential consequences to a patient or consumer. The matrix provides a three-tiered alert system: red alert, orange alert, and routine alert with communication expectations to the appropriate executive leadership. Each alert category details actions and reporting requirements. The following list of events was generated from the following sources: Texas Preventable Adverse Event, the National Quality Forum Serious Reportable Event, and the Agency for Healthcare Research and Quality Serious Safety Events.

	Red Alert	Orange Alert	Routine Alert
Actual/potential consequence to patient/consumer	Serious harm or death that is specifically caused by health care rather than the patient's underlying condition or illness.	Moderate harm that is specifically caused by health care rather than the patient's underlying condition or illness.	Minor or no harm that is or could be (near miss) specifically caused by health care rather than the patients underlying condition or illness.

Type of event/Incident (Examples, but not limited to)	1. Procedure involving wrong site, wrong patient. 2. Procedure involving wrong procedure resulting in serious harm. 3. Suicide of a patient while in the hospital 4. *Suicide of a patient within 72 hours if discharge. 5. Patient death as a result of: • Medication error • Fall • Improper use of restraints or bedrails • Maternal or infant death in a low-risk pregnancy • *Infant death with birth weight greater than 2,500 grams, unrelated to congenital condition • After patient elopement • *Intraoperative or immediate postoperative/ post procedure death in an ASA Class 1 patient 6. Abduction of a patient of any age. 7. Hemolytic reaction due to the administration of ABO incompatible blood or blood products 8. A series of adverse events that cause the death of a patient.	1. Retrained foreign object requiring re-operation or additional surgical procedures. 2. A surgical procedure performed on a patient that is inconsistent with the documented informed consent for that patient 3. Patient Fall with injury (fracture, surgical intervention) 4. Patient disability • Within 24 hours of procedure/ surgery of a normally healthy patient. • related to hypoglycemia (5 types) • associated with an electrical shock • associated with a burn incurred • resulting from a physical assault / sexual assault/ rape that occurs within or on the grounds of a facility • Failure to communicate laboratory, pathology, or radiological test results • Associated with intro of metallic object into MRI area 5. Attempted Suicide of a patient 6. Patient harm from contaminated drug or device. 7. Patient harm from a device used in manner other than as intended 8. Resulting from irretrievable loss of irreplaceable biological specimen 9. Discharge of patient to unauthorized person 10. Alleged sexual assault or inappropriate touching of a patient. 11. *Severe neonatal hyperbilirubinemia (bilirubin >30 mg/dl) 12. *Prolonged fluoroscopy with cumulative dose > 1,500 rads to a single field or any delivery of radiotherapy to the wrong body region or >25% above planned radiotherapy dose 13. *Incident in which systems designed for oxygen or other gas contains no gas, wrong gas, or is	1. Medication error with no harm to the patient. 2. Patient fall with no harm 3. Stage 3 or 4 hospital acquired pressure injury 4. DVT/PE after THA or TKA 5. Iatrogenic Pneumothorax with venous cauterization 6. SSI- spinal, shoulder, elbow, Lap gastric bypass, cardiac implantable device

		Contaminated. 14. *Instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed Healthcare provider.	

Communication of Event	Risk/Patient Safety will notify the following staff within one hour of notification:
	• CME and/or Chief Quality and Patient Safety Officer for Quality Programs
	  ○ The CME/ CQOof Quality will notify the CEO/COO
	• EVP of Pavilion where event occurred.
	  ○ The EVP is responsible for notification to other members of their team as deemed appropriate.
	• Compliance Officer
	• The CEO/CQO will notify the Chair of the Board of Trustees or designee within 4 hours.
		Risk/Patient Safety will notify the following staff within 4 hours of notification:
		• Associate Administrator of Quality Programs
		  ○ The AA of Quality will notify the CEO/COO/CME
		• EVP of Pavilion where event occurred.
		  ○ The EVP is responsible for notification to other members of their team as deemed appropriate.
		• Compliance Officer
		• The CME/CQO will present a trend of events quarterly to the Board of Trustees.
			Summary review of event monthly to Associate Administrator of Quality Programs

Action required	Initiate an investigation within 24 hours of knowledge of event. Schedule an RCA upon investigation completion; develop action plans during the RCA. • Red Alert will be sent for notification of event to CQO of Quality Programs for dissemination to CEO/COO and CME. . • Implementation of action plans will begin within 30 days. • Report achievement of action plans within 90 days to QRC, QGC, and Patient Safety Committee, and the Board of Trustees.	• Initiate an investigation within 24 hours of knowledge of event. Schedule an RCA upon investigation completion; RCA may be delayed due to higher priority case identification. Develop RRS develop action plans during the RCA. • Implementation of action plans will begin within 30 days. • Report achievement of action plans within 90 days to QRC, QGC, and Patient Safety Committee, and the Board of Trustees.	• Department Manager receives eIRS and conducts review. • Risk/ Pt Safety is involved with review when event seen as systems issue.
Reporting requirements	Texas Preventable Adverse Event as appropriate TDHS / CMS – to be determined after RCA completed and deemed applicable by this team: CEO/ COO/CME/ CQO/ Compliance Officer	Texas Preventable Adverse Event as appropriate	Texas Preventable Adverse Event as appropriate

* These events are from the National Quality Forum (NQF), the Agency for Healthcare Research and Quality (AHRQ) and are not required to be reported as a Texas Preventable Adverse Event.

Application of Harris Health System Just and Accountable Culture (JAC) Algorithm will be utilized by HR and Pavillion Leadership for individual incidents resulting in patient harm.

~~XLVII.~~XIV. MANAGEMENT OF THE PATIENT SAFETY PLAN

The Risk Management and Patient Safety Department, 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, patient safety, and attend patient safety education and training annually. Access to online learning through Institute for Healthcare Improvement (IHI) is provided by Harris Health System for learning opportunities and engagement in best practice standards.

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

~~XLVIII.~~XV. 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 for significant changes as applicable. Any changes made to the Plan will be approved by the Harris Health System Board of Managers.

REFERENCES

Harris Health System Quality Manual

National Quality Forum, http://www.qualityforum.org/topics/sres/serious_reportable_events.aspx

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

ASHRM, “Serious Safety Event.”

IHI Serious Safety Events and RCA

BOARD OF TRUSTEES

Quality Committee

HARRISHEALTH SYSTEM

Wednesday, June 22, 2022

Executive Session Agenda Item

Report Regarding Quality of Medical and Health Care, Pursuant to Tex. Health & Safety Code Ann. §161.032, Tex. Occupations Code Ann. §160.007, and Tex. Occupations Code Ann. §151.002 to Receive Peer Review and/or Medical Committee Report in Connection With the Evaluation of the Quality of Medical and Health Care Services, Including the Harris Health System Quality and Safety Performance Measures, and Possible Action Regarding This Matter Upon Return to Open Session.

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BOARD OF TRUSTEES

Quality Committee

HARRISHEALTH SYSTEM

Wednesday, June 22, 2022

Executive Session Agenda Item

Report by the Executive Vice President, Chief Compliance and Risk Officer, Regarding Compliance with Medicare, Medicaid, HIPAA and Other Federal and State Health Care Program Requirements and a Status of Fraud and Abuse Investigations, Pursuant to Texas Health & Safety Code §161.032, and Possible Action Regarding This Matter Upon Return to Open Session

This information is being presented for informational purposes only.

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