HARRISHEALTH

BOARD OF TRUSTEES

Quality Committee

Tuesday, May 6, 2025
12:00 P.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. Andrea Caracostis**	**1 min**
II.	**Approval of the Minutes of Previous Meeting** • Quality Committee Meeting – April 8, 2025	**Dr. Andrea Caracostis**	**2 min**
III.	**Harris Health Safety Message: Minute for Medicine Video – *Dr. Steven Brass*** • Just Culture		**5 min**
IV.	**Consideration of Recommendation for Approval of Revisions to the Harris Health Patient Safety Plan – *Ms. Tiffani Dusang***		**5 min**
V.	**Executive Session**	**Dr. Andrea Caracostis**	**75 min**
	A. Report Regarding Harris Health Correctional Health Quality of Medical and Healthcare, Pursuant to Tex. Occ. Code Ann. §§151.002, 160.007 and Tex. Health & Safety Code Ann. §161.032 to Receive Peer Review and/or Medical Committee Report – ***Dr. O. Reggie Egins***		*(15 min)*
	B. Report Regarding Quality of Medical and Healthcare, Pursuant to Tex. Occ. Code Ann. §§151.002, 160.007 and Tex. Health & Safety Code Ann. §161.032, to Receive Peer Review and/or Medical Committee Reports in Connection with the Evaluation of the Quality of Medical and Healthcare Services, Including Report Regarding Harris Health Quality Review Councils – ***Dr. Steven Brass and Dr. Yashwant Chathampally***		*(55 min)*

C.	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 Tex. Health & Safety Code Ann. §161.032, and Possible Action Regarding this Matter Upon Return to Open Session **– *Ms. Carolynn Jones***		*(5 min)*
VI.	**Reconvene**	**Dr. Andrea Caracostis**	**1 min**
VII.	**Adjournment**	**Dr. Andrea Caracostis**	**1 min**

HARRISHEALTH

HARRIS HEALTH SYSTEM
MINUTES OF THE BOARD OF TRUSTEES
QUALITY COMMITTEE MEETING
Tuesday, April 8, 2025
12:00 PM

AGENDA ITEM	DISCUSSION	ACTION/RECOMMENDATIONS
I. Call to Order and Record of Attendance	Dr. Andrea Caracostis, Committee Chair, called the meeting to order at 12:01 p.m. It was noted that a quorum was present, and the attendance was recorded. The meeting may be viewed online through the Harris Health website: http://harrishealthtx.swagit.com/live.	
II. Approval of the Minutes of Previous Meeting	• Quality Committee Meeting – March 11, 2025	**Moved by Ms. Sima Ladjevardian, seconded by Dr. Andrea Caracostis, and unanimously approved the minutes of the March 11, 2025 meeting.**
III. Harris Health Safety Message: Minute for Medicine Video • Informed Consent Done Right	Dr. Steven Brass, Executive Vice President & Chief Medical Executive, presented a Minute for Medicine video series related to Informed Consent Done Right. A copy of the video series is available in the permanent record.	**As Presented.**
IV. Presentation Regarding Workplace Safety & Violence Prevention	Dr. Jacqueline Brock, Executive Vice President and Chief Nursing Executive, delivered a presentation regarding Workplace Safety & Violence Prevention. Harris Health's commitment to Workplace Safety & Violence is unwavering. Current improvements and methods to get the message to people were presented, i.e., snippets from current videos demonstrating current efforts and programs. Some of the improvements include Workplace Safety Briefs, an updated website, and new workplace violence resources. A copy of the presentation is available in the permanent record.	**As Presented.**
V. Executive Session	At 12:14 p.m., Dr. Caracostis stated that the Quality Committee of the Board of Trustees would go into Executive Session for items V. 'A through C' as permitted by law under Tex. Gov't Code Ann. §551.071, Tex. Health & Safety Code Ann. §161.032 and Tex. Occ. Code Ann. §§151.002, 160.007.	

AGENDA ITEM	DISCUSSION	ACTION/RECOMMENDATIONS
A. Report Regarding Quality of Medical and Healthcare, Pursuant to Tex. Occ. Code Ann. §§151.002, 160.007 and Tex. Health & Safety Code Ann. §161.032, to Receive Peer Review and/or Medical Committee Reports in Connection with the Evaluation of the Quality of Medical and Healthcare Services, Including Report Regarding Harris Health Quality Review Councils		**No Action Taken.**
B. 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 Tex. Health & Safety Code Ann. §161.032, and Possible Action Regarding this Matter Upon Return to Open Session		**No Action Taken.**

AGENDA ITEM	DISCUSSION	ACTION/RECOMMENDATIONS
C. Consultation with Attorney Regarding Quality Committee Charter, Pursuant to Tex. Gov't Code Ann. §551.071, Including Consideration of Recommendation for Approval of Revisions to the Board of Trustees Quality Committee Charter		**Moved by Ms. Sima Ladjevardian, seconded by Dr. Andrea Caracostis, and unanimously accepted that the Committee recommends that the Board accept item V.C., Revisions to the Board of Trustees Quality Committee Charter. Motion Carried.**
VI. Reconvene	At 1:00 p.m., Dr. Andrea Caracostis reconvened the meeting in open session; she noted that a quorum was present and that no action was taken in Executive Session. Dr. Caracostis state that the Committee will now take action on item "C" of the executive session agenda.	
VII. Adjournment	There being no further business, the meeting adjourned at 1:00 p.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 April 8, 2025.

Respectfully submitted,

Andrea Caracostis, MD, MPH, Committee Chair

Recorded by Cherry A. Joseph, MBA

HARRISHEALTH

Tuesday, April 8, 2025
Harris Health Board of Trustees Quality Committee Attendance

COMMITTEE MEMBERS PRESENT	COMMITTEE MEMBERS ABSENT	OTHER BOARD MEMBERS PRESENT
Dr. Andrea Caracostis *(Committee Chair)*	Afsheen Davis	
Sima Ladjevardian	Dr. Cody Pyke	

HARRIS HEALTH EXECUTIVE LEADERSHIP, STAFF & SPECIAL INVITED GUESTS	
Alexander Barrie	Louis Smith
Amineh Kostov	Dr. Lori Timmons
Berrlyn Nelson	Maria Cowles
Carolynn Jones	Dr. Matasha Russell
Cherry Joseph	Matthew Reeder
Daniel Smith	Matthew Schlueter
Derek Curtis	Dr. Michael Nnadi
Ebon Swofford *(Harris County Attorney's Office)*	Dr. Maureen Padilla
Dr. Esmaeil Porsa	Naomi Lockett
Dr. Esperanza "Hope" Galvan	Olga Rodriguez
Dr. Glorimar Medina	Omar Reid
Dr. Jackie Brock	Dr. Sandeep Markan
Dr. Jennifer Small	Sara Thomas *(Harris County Attorney's Office)*
Jennifer Zarate	Shawn DeCosta
Jessey Thomas	Dr. Steven Brass
Jocelyn Thomas	Tekhesia Phillips
John Matcek	Dr. Tien Ko
Dr. Joseph Kunisch	Tiffani Dusang
Lindsey "Katie" Rutherford *(Harris County Attorney's Office)*	Dr. Yashwant Chathampally

Virtual Attendee Notice: *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.*

Tuesday, May 6, 2025

Harris Health Safety Message: Minute for Medicine Video

High-reliability Organization (HRO) Safety Message Videos:

- Just Culture

Yashwant Chathampally, MD, MSc
Associate CMO & SVP, Quality & Patient Safety

High Reliability Organization (HRO)

Safety Message

Just Culture

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

Board of Trustees Quality Committee
May 6, 2025

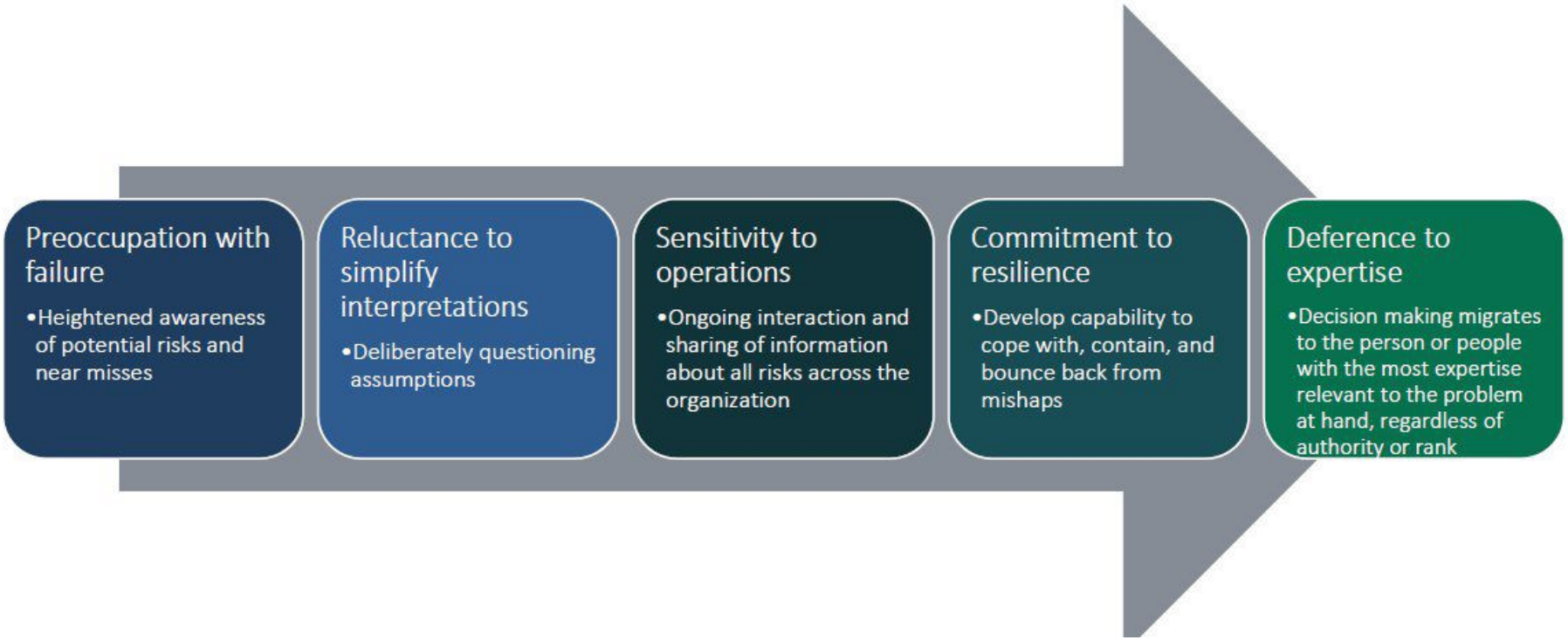
HARRISHEALTH

SAFETY MESSAGE

HARRIS HEALTH SYSTEM | ZERO HARM

Safety 1st. Always.

Five Principles of a High Reliability Organization



HARRISHEALTH

HRO Mindset:

Harris Health System Minute For Medicine:

- Just Culture
- https://youtu.be/kjbPY_mHoHk

BOARD OF TRUSTEES

Quality Committee

HARRISHEALTH

Tuesday, May 6, 2025

Consideration of Recommendation for Approval of Revisions to the Harris Health Patient Safety Plan

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Yashwant Chathampally, MD, MSc
Associate CMO & SVP, Quality & Patient Safety

Patient Safety Plan

Tiffani Dusang MSN, RN, CPPS, NEA-BC, AFN-BC
Vice President of Patient Safety & Risk Management

Board of Trustees Quality Committee
May 6, 2025

HARRISHEALTH

Summary of Changes

- Section I- Introduction
  - Highlights Plan is a component of Harris Health's Patient Safety Evaluation System
- Section II- Purpose
  - Updated to reflect Harris Health's commitment to zero harm through a Just and Accountable culture that promotes psychological safety
- Section IV- Privilege and Confidentiality of Patient Safety Activities
  - Replaced QGC with Patient Safety Collaborative as the committee who oversees Plan and directs actions
- Section V- Definitions
  - Added Workforce, High Risk Event, and One Harris Health Platform RCA
  - Updated Incident and all Event types

Summary of Changes

- Section VIII- Incident Reporting and Investigation Process
  - Added all communication surrounding the investigation of an incident is performed at the direction of Patient Safety and Risk Management
- Section IX- Event Report Escalation
  - Added Section B on Tiered Huddles as well as new Appendices F & G to highlight Leadership Escalation Guidelines
- Section XIII- Variance Management Filter Council (“Filter”)
  - New section with Definition and Objectives (Highlighted in Appendix M)
- Section XIV- Patient Safety Collaborative
  - Added PSC acts at the direction of the BOT and regularly reports to the QBOT
  - Charter added as Appendix N
- Appendices A-N
  - All references/guides added as an Appendices and referenced throughout Plan

HARRISHEALTH

Patient Safety Plan

~~June 2024~~

~~I. Introduction~~

~~The Harris Health System ("Harris Health")~~ April ~~March~~ 2025

Contents

I. Introduction

Harris Health's Patient Safety Plan ("Plan") is a description of the Harris Health system-wide strategy to support Harris Health's mission, vision, and values ~~and~~, as well as the strategic plan, through the patient safety process. The Plan defines how the organization will focus on an uncompromising commitment to high-quality, safe, and efficient care by reducing risk, preventing harm, and promoting optimal patient safety through a systematic and data-driven approach that reflects the complexity of the services provided by Harris Health.

The Plan is a ~~component of the~~counterpart to Harris Health's Quality Manual, which outlines Harris Health's organizational approach to monitoring and improving quality, patient safety, and performance. Additionally, this Plan is a component of Harris Health's Patient Safety Evaluation System under the federal Patient Safety and Quality Improvement Act of 2005 (PSQIA) and Patient Safety Rule.

II. Purpose

The purpose of the ~~Patient Safety~~ Plan is to provide a framework for fostering a culture of safety and high reliability within ~~our organization~~Harris Health where zero patient harm is not only a possibility but an expectation. ~~Our~~The goals include eliminating preventable harm through standardization and robust process improvements ~~while~~and proactively identifying and managing risks and opportunities. ~~Committed~~Harris Health's commitment to ~~establishing~~ a Just and Accountable Culture~~, we empower~~ (JAC), empowers every workforce member to prioritize patient safety. By promoting ~~Psychological Safety, we ensure~~psychological safety, workforce members can voice concerns and share insights without fear of ~~retribution, fostering~~reprisal, as well as foster continuous improvement and shared accountability. Through these principles, ~~we strive~~Harris Health strives to deliver the highest standards of care, minimizing risks and enhancing outcomes for ~~our~~all patients.

III. Governance

The Senior Vice President (SVP) of Quality and Patient Safety is the designated Patent Safety Officer (PSO) who oversees initiatives related to patient safety and quality improvement. The PSO is the primary contact ~~of~~for the patient safety program.

The Harris Health Board of Trustees (BOT) and the Patient Safety Collaborative

Committee (PSC) ~~oversees~~oversee the ~~Patient Safety~~ Plan. The BOT and PSC ~~delegates and directs~~~~delegate~~ delegate ~~direct~~s the Patient Safety and Risk Management department to carry out the patient safety duties ~~of patient safety~~ within Harris Health and coordinate the Plan with support from the pavilion-based Quality Management departments and system-level Quality Programs department.

IV. Privilege and Confidentiality of Patient Safety Activities

All actions taken and documents developed by the Patient Safety and Risk Management department or at the direction of the Patient Safety and Risk Management department during the patient safety process are at the direction of the PSC and are privileged, confidential, and not subject to disclosure pursuant to Chapter 161 of the Texas Health & Safety Code and Chapters 151 and 160 of the Texas Occupations Code. 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~~PSC, a medical peer review committee and/or medical committee as those terms are defined in Chapter 161 of the Texas Health & Safety Code and Chapters 151 and 160 of the Texas Occupations Code~~.~~, are privileged, confidential and not subject to disclosure pursuant to those statutes. 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 for furtherance of patient safety functions.

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

V. Definitions

A. Workforce: ~~Harris Health~~ All employees, trainees, ~~Medical Staff, contractors, including consultants,~~ volunteers, affiliated healthcare providers, and ~~vendors. This definition includes President~~contractors, who perform work and ~~Chief Executive Officer (CEO).~~/or clinical care under the direct control of Harris Health and may need to access PSWP to carry out any employment or other duty/responsibility.

~~a.~~B. 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.

~~b.~~

C. ~~c.~~Incident ("Event"): A circumstance that is not consistent with the standard care of a patient or routine operations, and does not follow established policy, procedure or guideline, and results in or has the potential to result in harm or injury to a person, patient or property. Events may be considered unsafe conditions, near misses, incident, adverse event, preventable adverse event, serious reportable event, and high-risk event. Events may or may not result in an error.

D. Event Types:

1. Unsafe (or Hazardous") Condition: Circumstances or events that have the capacity to cause error.

2. Pre-Patient Event/Near Miss (also known as a close call): An event or circumstance where an error occurred and could have resulted in an accident, injury, or illness but did not, either by chance or through timely intervention.

    a. Good Catch: Recognition of an event or circumstance where an error occurred that had the potential to cause an accident, injury, or illness, but did not occur thanks to a corrective action and/or timely intervention.

3. Adverse Event: An event or circumstance that reached a patient that may have contributed to or resulted in harm. Adverse events may or may not be a result of a deviation from expected practice.

    a. Safety Event ("SE"): A deviation from expected from expected practice that results in minimal harm or no detectable harm.

b. 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.

c. Serious Reportable Event ("SRE") (or "Never Event"): As defined by the National Quality Forum (NQF), Serious Reportable Events are adverse events that are serious, but largely preventable, and of concern to both the public and health care providers for purposes of public accounting.

d. Serious Safety Event ("SSE"): A deviation from expected practice that resulted in results in death, permanent harm, or severe temporary harm.

~~B.~~e. High Risk Event ("HRE"): Deviation or error that has the potential to cause severe harm or death to a future patient but did not necessarily harm a patient related to the incident. The severity of the potential risk will generally supersede the outcome-based safety event score.

~~B.~~E. Root Cause Analysis (RCA): A process for identifying causal factor(s) that lead to performance gaps, including the occurrence or possible occurrence of an SSE1, SSE2, HRE, or reportable event. Includes an assessment of the problem, identification of opportunities to implement improvement strategies, and creation of a quality improvement plan for sustained improvement.

~~a.~~1. One Harris Health ~~Risk~~Platform (OHHP) Root Cause Analysis ~~Platform a~~(RCA)- A system service line forum to conduct an RCA where improvement strategies will have a one system comprehensive approach.

VI. Preventable Adverse Events (PAE)

Preventable Adverse Events are defined by the Texas Department of State Health Services and must be reported every six months.
https://www.dshs.texas.gov/sites/default/files/IDCU/HSU/Files/Definitions-and-Guidance-2018.pdf
These events as well as those events described by Harris Health policy 3.63, "Incident Reporting," must be reported into the eIRS system. (**Appendix A).**

VII. Serious Reportable Events (Never Events):

Serious Reportable Events are defined by the National Quality Forum (http://www.qualityforum.org/topics/sres/serious_reportable_events.aspx)

These events as well as those events described by Harris Health policy 3.63, "Incident Reporting," must be reported into ~~the~~ eIRS ~~system~~. (**Appendix B)**.

VIII. Incident Reporting and Investigation Process:

~~The~~A Workforce Member, ~~or~~ assigned delegate (e.g. designated leader), who observes, discovers, or is directly involved in an ~~event~~Event shall notify their supervisor (if applicable- refer to section IX- Event Escalation Reporting) and enter a report in e~~E~~IRS before they leave at the end of their shift. An eIRS report must be completed for all ~~events~~Events 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 Harris Health Workforce member, or assigned delegate (e.g. designated leader), does not timely report an event into the eIRS system, the Workforce member's supervisor will be notified, and the employee will be addressed according to ~~our~~Harris Health's JAC algorithm.

Once an eIRS report is filed, an email notification of the report is automatically delivered to the ~~administrator or the administrator's designee~~leadership team member of the clinical area where the ~~event was reported to have~~Event occurred. The administrator or their designee is responsible for reviewing ~~events~~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.~~ Event. All communication surrounding the investigation of an incident is performed at the direction of patient safety and risk management.

Team members of the Patient Safety and Risk Management department 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 (**Appendix C**).
The Patient Safety and Risk Management team assigns a harm severity level to each ~~event~~Event to uniformly evaluate the degree of harm caused by the ~~event~~Event. The Harm Severity Level~~,~~ is assigned using the NCC MERP Index

(**Appendix D**).
All Serious Reportable Events, Serious Safety Events, High Risk Events, and other significant ~~events~~Events will proceed to the pavilion Variance Management Filter Council for a review and determination of next steps to include a One Harris Health Risk Analysis (RCA) or referral to the Performance Improvement Council, Nursing Peer Review, or Human Resources. The findings of the RCA and the risk reduction strategies (RRS) for SSE1s, SSE2s and HREs will be presented at the Harris Health Patient Safety Collaborative Committee. Other serious ~~events~~Events, close calls, and near misses may proceed as a pavilion -level clinical case review and/or OHHP RCA as requested by pavilion administration (**Appendix E**).

The findings of each ~~event~~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 and Risk Management Leadership.

IX. Event Reporting Escalation

A. Escalation Guiding Principles

1. Err in favor of timely escalation if any doubt.
2. Welcome and own the escalation – offload frontline staff.
3. Create a list of unit specific risks front of mind for team as part of daily standard work.
4. Share escalation experiences with the team to refine process with real examples in safety huddles.
5. Patient ~~safety, Legal~~Safety, ~~the~~ Harris Health Legal~~County Attorney's Office~~, and Corporate Compliance are available to help 24/7.

We should work to create safer systems following a safety event that was prevented by team member rather than a safety event that could have been prevented.

B. The Tiered Huddle System allows teams to share and make real time decisions that positively impact patient care, identify risks, address issues, and escalate safety events and/or concerns. Harris Health has a dedicated meeting free zone to allow frontline leaders to focus on patient safety through rounding, attending Tier 1 and 2 huddles, reviewing daily incident reports, and preparing to escalate any ~~their~~ safety findings or concerns in the pavilion Tier 3 huddle. Safety issues

and concerns identified in the Tier 3 huddle are the escalated and reported at Harris Health's Tier 4 huddle. ~~Pavilion leaders will then escalate in the system's Tier 4 huddle.~~

C. Harris Health ~~System~~Leadership Event Notification and Escalation ~~Flow Chart~~Guidelines (**Appendix F**)

D. ~~C~~. Harris Health ~~System~~Leadership Event~~/Risk~~ Notification -and Escalation ~~Policy~~Flow Chart
(**Appendix G**)

X. Scale for Harm and Risk Classification

Scale for Harm Classifications (**Appendix H**)

1. SSE1: Death
2. SSE2: Severe permanent or temporary harm
3. HRE: Deviation or error that has potential to cause major harm or death
4. SE3: Moderate harm
5. SE4: Mild harm
6. SE5: No harm
7. SE-U: Harm Unknown
8. PPE/Near Miss: Did not reach the patient

The One Harris Health Risk Analysis Platform will first utilize a revised Healthcare Performance Improvement Safety Event Classification (SEC) Levels of Harm with a *Determining Deviation* and *Known Complication* checklist to accurately determine Safety Events, Serious Safety Events, or Near Misses. Next, the platform participants will determine if the safety event or near miss is high, medium or low risk to a future patient (based on worst case scenario) by utilizing a 5X5 risk matrix for severity and probability. (**Appendix E, I & J**).

XI. Standardized Scoring

The Patient Safety Collaborative Committee will utilize the revised Healthcare Performance Improvement Safety Event Classification (SEC) Levels of Harm as an approach to~~,~~ accurately screen safety events to determine if they are Serious Safety Events or High-Risk Events. The Serious Safety Event Rate (SSER) provides a consistent methodology for measuring patient harm and improvement in patient harm

reduction. 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 patient's condition. 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 shall use the algorithm to score deviations from expected performance (**Appendix K**)

XII. Preventative, Proactive, and Corrective Actions to Reduce Risk

A. Risk Based Thinking (Preventative Action)

Harris Health ~~System embraces the concept of~~utilizes risk-based thinking when planning for patient 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:

1. Severity – Seriousness of the harm
2. Probability – Probability that harm will occur

B. Proactive Risk Assessment

A comprehensive systematic analysis where the system proactively 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.

C. Failure Mode Effectiveness Analysis ("FMEA")

~~Conducted~~FMEAs are 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.

D. Root cause analysis ("RCA")

An RCA is an investigation of a patient safety event scored as an SSE1, SSE2, or HRE. 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 with a system design concern will~~that progress to the One Harris Health Risk Analysis Platform for a one system comprehensive approach to analyze the case, determine causal factors, identify root causes and develop an action plan to address identified failure modes.

During the One Harris Health Risk Analysis, Patient Safety and Risk Management will collaborate with leaders for a presentation of the event timeline to a preidentified team of leaders, frontline workforce members, and ad hoc experts from the involved/affected service lines to identify the root causes and develop and action plan with risk reduction strategies (RRS). The RRS 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 for review and approval of the RRS.

See *Risk Reduction Strategy and Action Hierarchy Levels and Categories* (**Appendix L**)

XIII. ~~ilPatient~~Variance Management Filter Council ("Filter")

The Council is a pavilion-based multidisciplinary group comprised of pavilion and system leadership as well as hospital quality personnel who provide guidance in determining the appropriate review process for all referrals relating to patient safety, quality of care, medical error, professionalism, grievances and other types of variances.

A. Objectives (Appendix M)

1. Create transparency and consistency in the review, investigation, and remediation process such that all participants will have confidence in an efficient, effective, and equitable management of variances or professionalism concerns.

2. Ensure that all components of the case related to system failures and process deficiencies are identified and remediated prior to focusing on individual performance.

3. Assist Office of Patient Safety and Risk Management in engaging stakeholders and key personnel to ensure timely and appropriate review and analysis of each case.

4. Filter and distribute cases to appropriate committees and venues for further analysis and/or remediation.

5. Track and trend incidents to provide longitudinal event analysis

~~XII.~~XIV. Patient Safety Collaborative ~~Committee~~

The Patient Safety Collaborative ~~Committee~~ is an interdisciplinary ~~Committee~~committee that aims to promote a culture of transparency to provide a multidisciplinary objective review and analysis of patient safety events and ~~functions as~~is a medical committee/medical peer review committee that acts at the direction of the ~~QGC~~BOT and regularly reports to the BOT Quality Committee. All functions of the Patient Safety Collaborative Committee are confidential, privileged and protected from disclosure pursuant to Chapter 161 of the Texas Health & Safety Code and Chapters 151 and 160 of the Texas Occupations Code~~.~~

The Patient Safety Collaborative Committee shall use a consistent scoring system to determine and/or approve the final severity level of patient safety events. The ~~workgroup~~committee will review and approve Serious Safety Event and High-Risk Event

root causes, recommendations, developed risk reduction strategies, and the severity level plus risk score determined in the One Harris Health Platform Risk Analysis Platform.

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 Committee meets bi-weekly (second and fourth Monday) and is comprised of system executive leadership, pavilion leadership, physician and nurse experts, physician residents, Risk and Patient Safety, Quality, Corporate Compliance, Accreditation, County Attorney's Office, and ad hoc members as applicable to specific safety events- *Refer to The Patient Safety Collaborative Committee Charter*~~:~~ *in* Appendix N

~~XIV.~~XV. 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 Collaborative Committee.

The VP of Patient Safety and Risk Management and Patient Safety~~/ Patient Safety~~ Officer (or designee) 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~~a reviewed and approved ~~Leapfrog~~ Culture of Safety ~~Culture survey~~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.

~~XV.~~XVI. 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."

~~XVI.~~XVII. References/Bibliography:

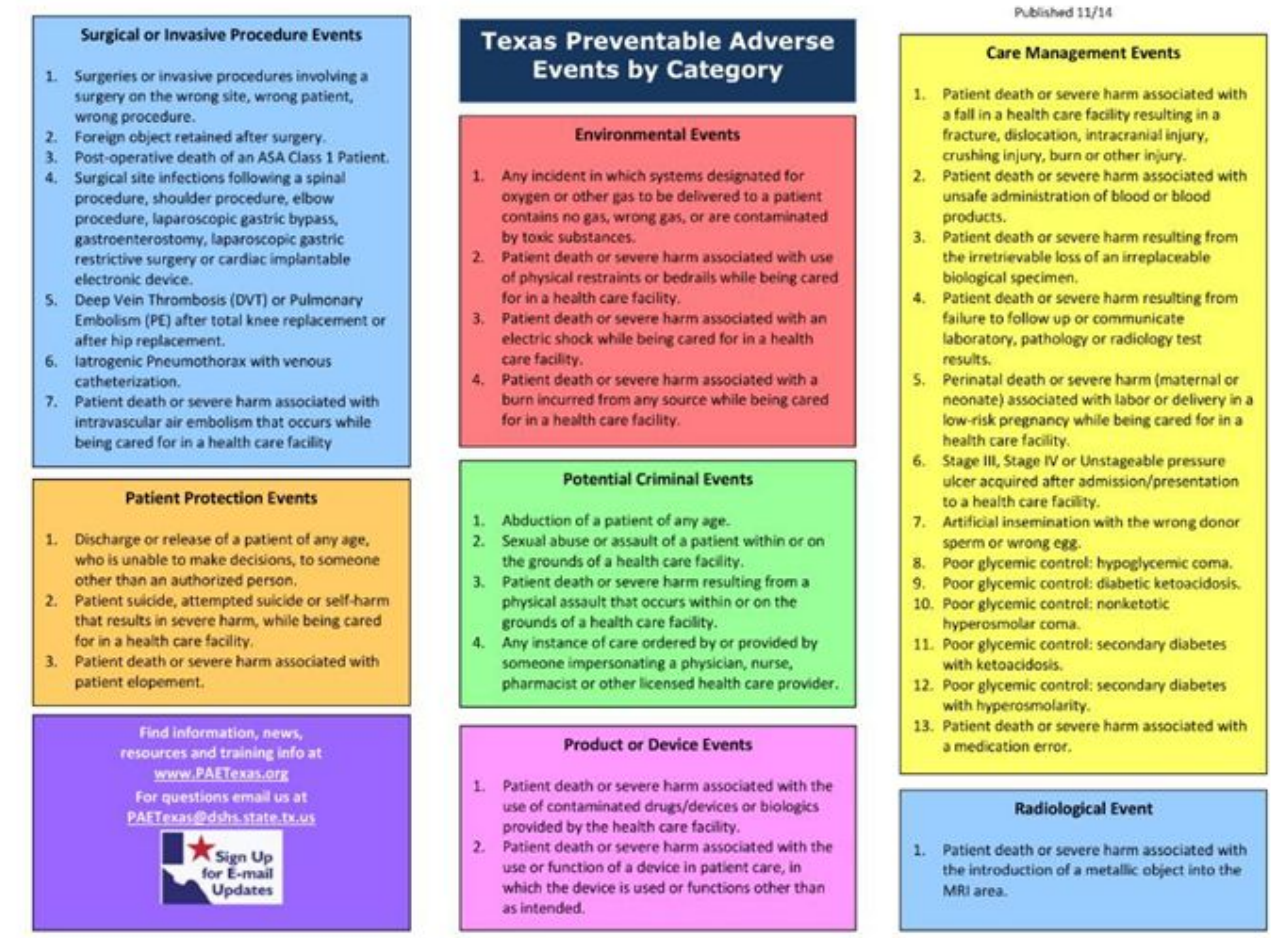
Harris Health System Quality Manual
National Quality Forum- http://www.qualityforum.org/topics/sres/serious_reportable_events.aspx
25 Tex. Admin. Code § 133.48
Texas Health & Safety Code § 161.
Texas Occupations Code § 151 and 160.
DNV Standard QM.8 Patient Safety System.
Harris Health Policy 3.63, "Incident 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

~~XVII.~~XVIII. 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.)
5/1/2016		5/1/2016	Approved by Harris Health System Patient Safety Committee
4/11/2019		04/11/2019	Approved by Harris Health System Quality Governance Council
5/30/2019		5/30/2019	Approved by Harris Health System Board of Trustees

3/10/2020		3/10/2020	Approved by Harris Health System Quality Governance Council
3/10/2020		3/12/2020	Approved by Harris Health System Board of Trustees
5/17/2022		5/17/2022	Approved by Harris Health System Quality Governance Council
6/23/2022		6/23/2022	Approved by Harris Health System Board of Trustees

APPENDIX A
PREVENTABLE ADVERSE EVENTS



APPENDIX B
SERIOUS REPORTABLE EVENTS

SURGICAL OR INVASIVE PROCEDURE EVENTS

1. Surgery or other invasive procedure performed on the wrong site;
2. Surgery or other invasive procedure performed on the wrong patient;
3. Wrong surgical or other invasive procedure performed on a patient;
4. Unintended retention of a foreign object in a patient after surgery or other invasive procedure;
5. Intraoperative or immediately postoperative/post procedure death in an ASA Class 1 patient.

PRODUCT OR DEVICE EVENTS

1. Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting;
2. 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;
3. Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a healthcare setting.

PATIENT PROTECTION EVENTS

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

CARE MANAGEMENT EVENTS

1. 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);
2. Patient death, serious injury, or close call associated with unsafe administration of blood products;
3. Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting;
4. Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy;
5. Patient death or serious injury associated with a fall while being cared for in a

healthcare setting;

6. Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission/presentation to a healthcare setting;
7. Artificial insemination with the wrong donor sperm or wrong egg;
8. Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen;
9. Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test reports.

ENVIRONMENTAL EVENTS

1. Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in a healthcare setting;
2. 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.
3. 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;
4. Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a healthcare setting.

RADIOLOGIC EVENTS

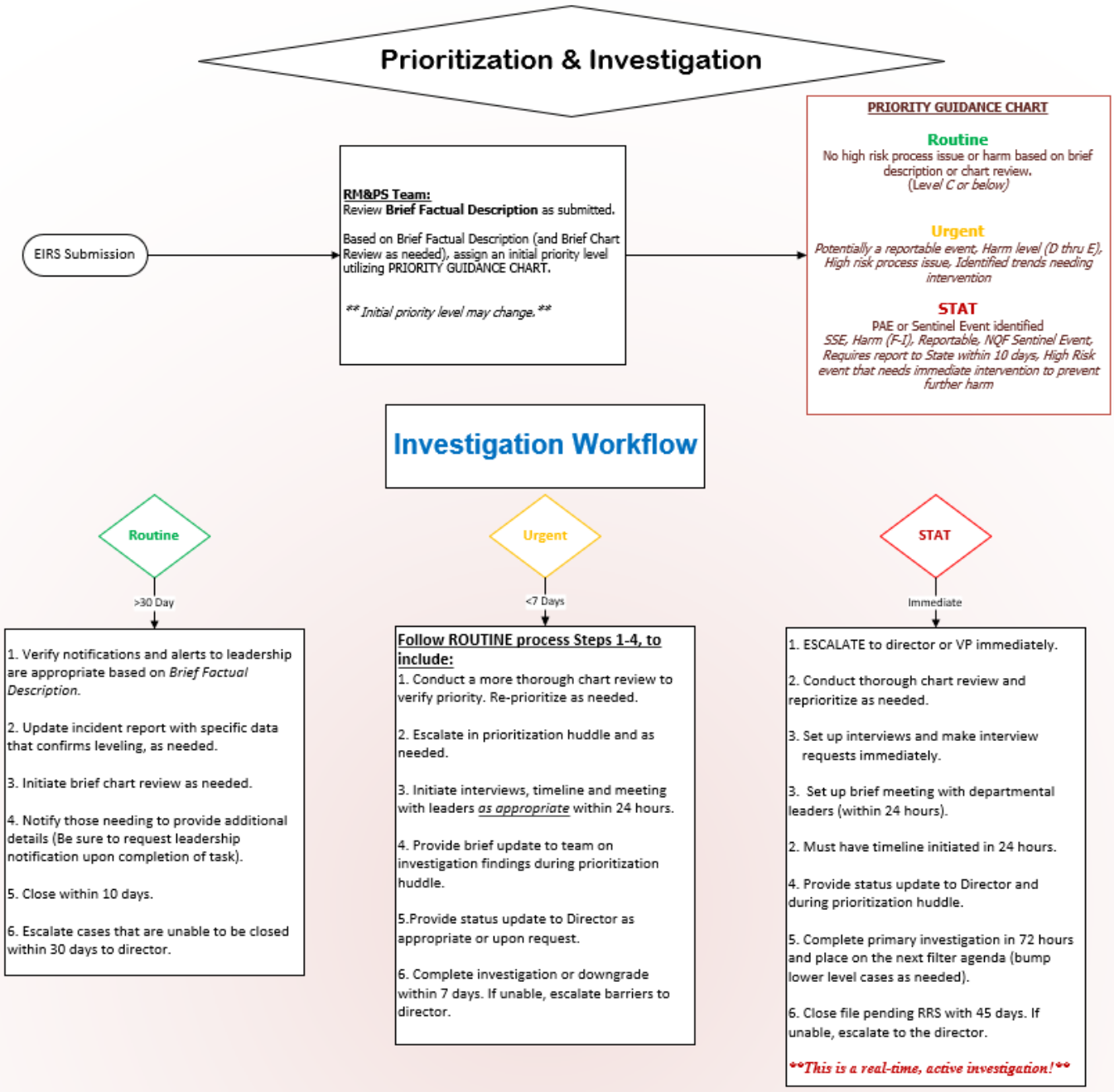
1. Death or serious injury of a patient or staff associated with the introduction of a metallic object into the MRI area.

POTENTIAL CRIMINAL EVENTS

1. An instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider.
2. Abduction of a patient/resident of any age;
3. Sexual abuse/assault on a patient or staff member within or on the grounds of a healthcare setting;
4. 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.

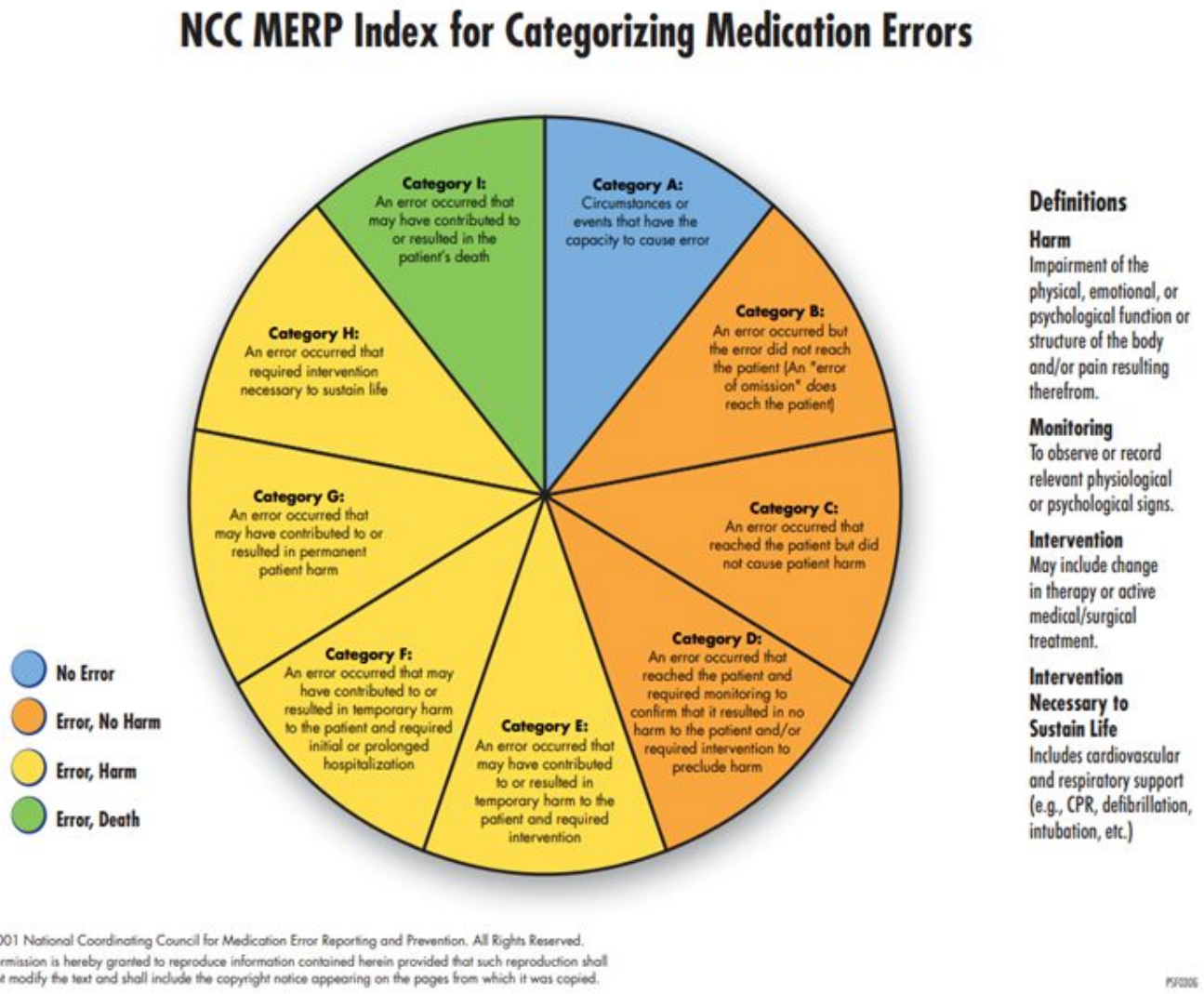
APPENDIX C

Incident Reporting, Prioritization, and Investigation



APPENDIX D

NCC MERP Index

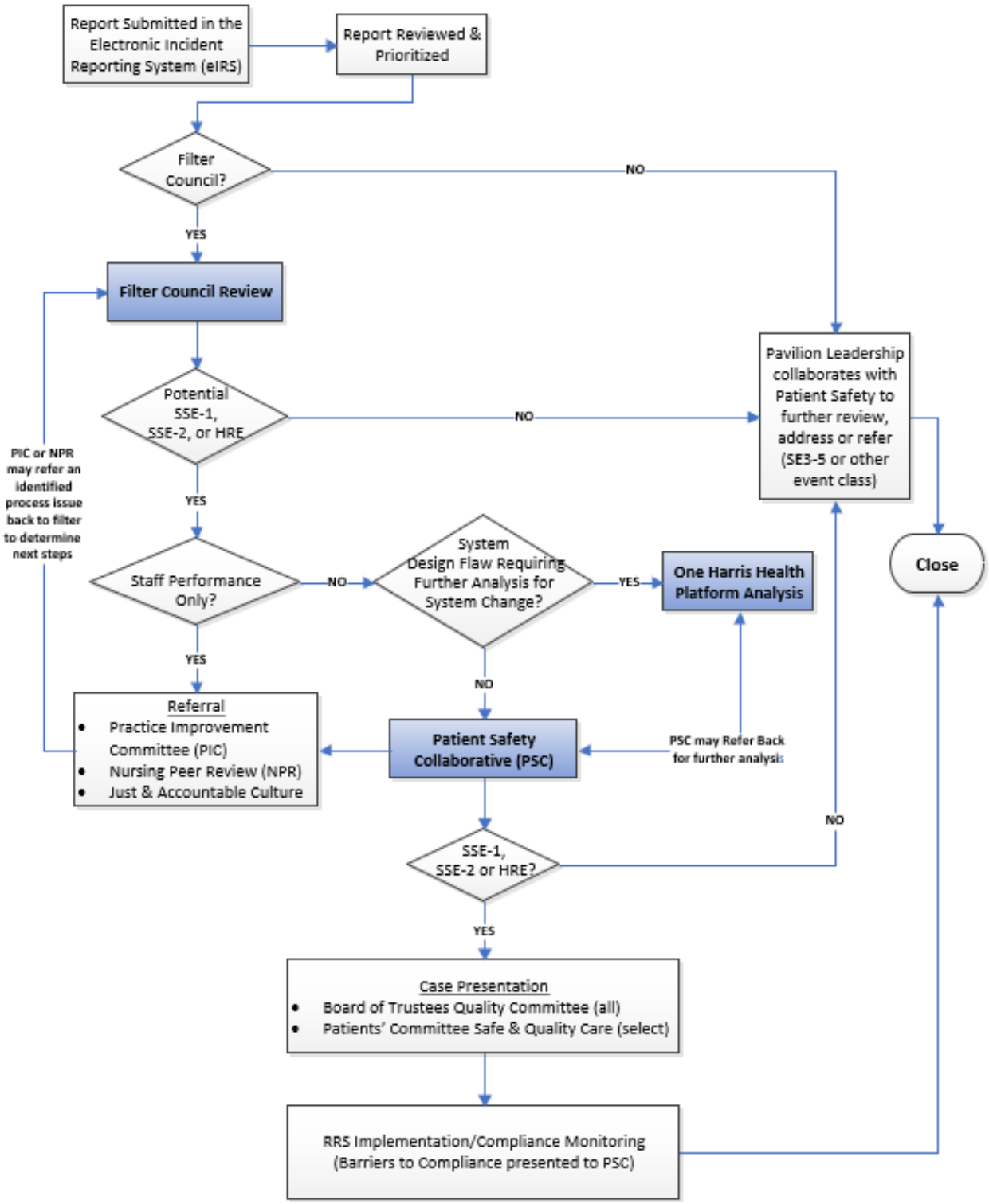


APPENDIX E

Red Alert Post-Event Notification	Red Alert Actions
A serious safety or high-risk event has occurred that requires immediate leadership awareness and/or timely decision support / action to prevent / mitigate harm and recurrence. (*Never Event, Sentinel Event, Reportable Event, Serious Safety Event*)	

Criteria:
1. Injury, Morbidity or Mortality
• Concern for unexpected death or cardiac arrest
• Required significant additional treatment (ICU, major surgery/invasive procedure)
• Significant loss of function (movement, vision, wrong site major surgery)
• Wrong surgery OR procedure involving wrong site, wrong patient OR performing an A list procedure without consent
• Retained foreign object requiring re-operation or additional surgical procedures
• Patient death or severe harm as a result of:
  o An irretrievable loss or irreplaceable biological specimen
  o Failure to follow up or communicate laboratory, pathology or radiology test results
  o A medication error
  o A fall
  o The use or function of a device in patient car in which the device is used or functions other than as intended
  o The introduction of a metallic object into the MRI area
• Maternal or infant death in a low-risk pregnancy
• Patient death or severe injury associated with unsafe administration of blood products
• Actual or potential patient harm from contaminated drug, device, or biologics
• Suicide attempt or self- harm of a patient resulting in serious harm
• Patient or staff allegation of abuse (physical or sexual), neglect, exploitation, or unprofessional conduct by a Harris Health Staff member or another patient within any Harris Health Facility or facility where Harris Health workforce are employed **(Page Forensic Nursing Immediately for sexual assault or rape)**
• Serious staff or visitor related safety event (Staff injury or assault or visitor creating a disturbance including potential damage to facility)
• Significant threats of violence or harm by a patient, visitor, or workforce member that requires immediate intervention by the pavilion and system
2. Significant Regulatory, Compliance, Legal Risk:
• Death while in restraints or seclusion, OR within 24 hours of removal of 4-point restraints or seclusion, OR within 7 days of removal of restraints or seclusion if restraint is determined to be the contributing factor of the death
• Concern for EMTALA violation
• Patient Elopement without Decision Making Capacity
• Unsafe Discharge of a patient of any age who is unable to make decisions
• Abduction of a patient of any age
• Any morgue related issue where human bodies or fetal remains are mismanaged and/or released inappropriately (i.e., wrong entity, wrong temperature storage). Includes complications related to autopsies (or autopsy orders)
• Impersonation of a Health Care Provider
3. Unanticipated Internal / External Disaster Events
4. Serious concern for imminent negative media, social media or regulatory party exposure
	Once Escalated
	***(See Appendix A)*:**
	Department Leadership:
	1. Notify House Supervisor who will notify AOC and Pavilion Exec Team
	2. Notify Patient Safety/Risk Management (if not already aware)
	3. Call for a Safety Huddle as needed (See Safety Huddle instructions in orange column).
	4. Report in Tier 3
	Pavilion Exec Team:
	1. Place WebEx Alert and notify system leader
	2. Call for a Safety Huddle (as needed)
	3. Report in Tier 4
	Patient Safety/Risk Management:
	1. Create an SBAR for Pavilion and System Leaders
	2. Verify appropriate notifications (i.e. Compliance, Legal)
	3. Initiate an immediate investigation (in collaboration with department leaders)
	4. Follow the High-Level SSE Event Process (Appendix B & C)

High Level SSE/HRE Review Flow



APPENDIX F
Harris Health Leadership Event Notification and Escalation Guidelines

Red Alert Post-Event Notification	Red Alert Actions
A serious safety or high-risk event has occurred that requires immediate leadership awareness and/or timely decision support / action to prevent / mitigate harm and recurrence. (*Never Event, Sentinel Event, Reportable Event, Serious Safety Event*)	

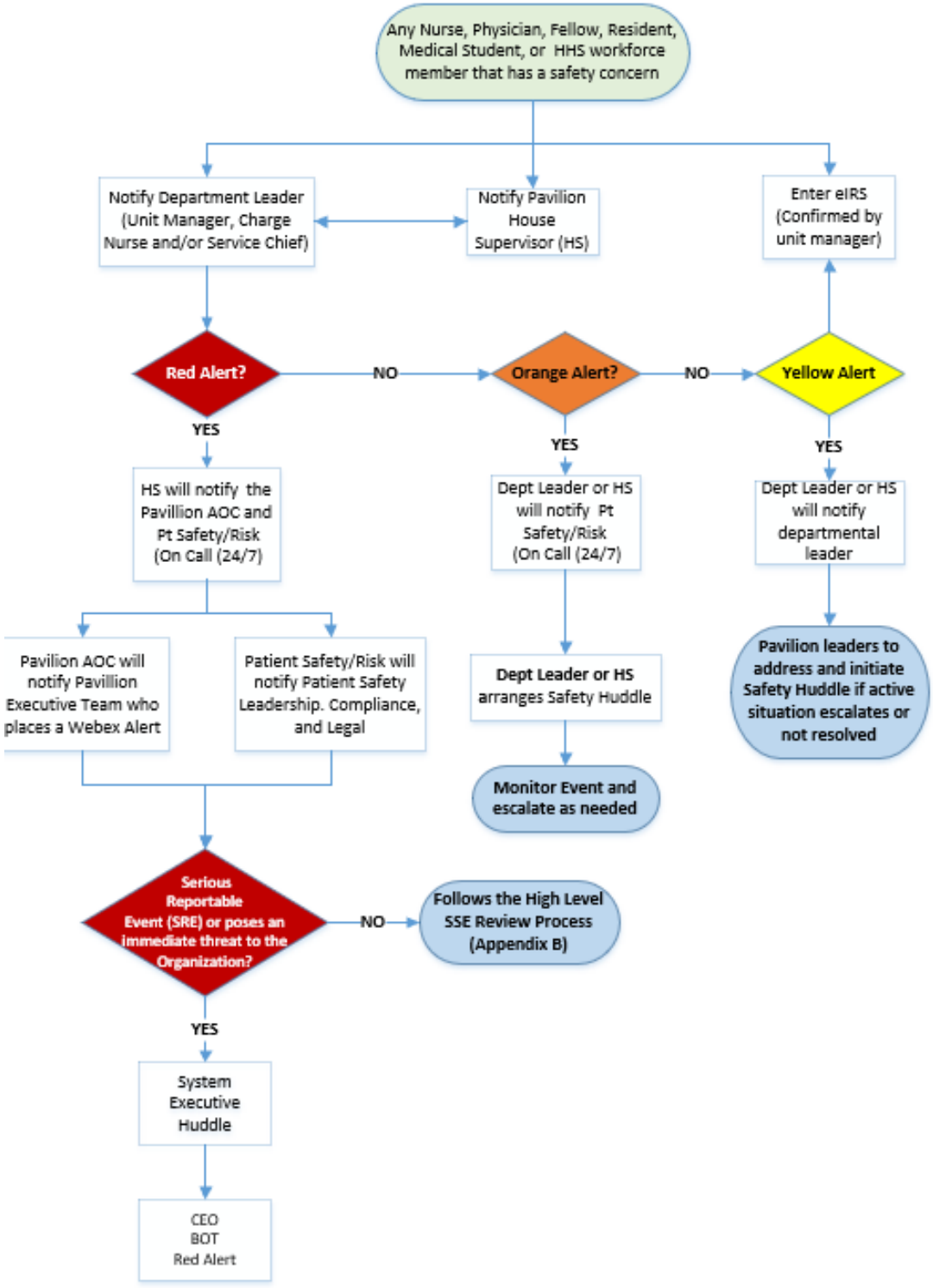
Criteria:
1. Injury, Morbidity or Mortality
• Concern for unexpected death or cardiac arrest
• Required significant additional treatment (ICU, major surgery/invasive procedure)
• Significant loss of function (movement, vision, wrong site major surgery)
• Wrong surgery OR procedure involving wrong site, wrong patient OR performing an A list procedure without consent
• Retained foreign object requiring re-operation or additional surgical procedures
• Patient death or severe harm as a result of:
  o An irretrievable loss or irreplaceable biological specimen
  o Failure to follow up or communicate laboratory, pathology or radiology test results
  o A medication error
  o A fall
  o The use or function of a device in patient car in which the device is used or functions other than as intended
  o The introduction of a metallic object into the MRI area
• Maternal or infant death in a low-risk pregnancy
• Patient death or severe injury associated with unsafe administration of blood products
• Actual or potential patient harm from contaminated drug, device, or biologics
• Suicide attempt or self- harm of a patient resulting in serious harm
• Patient or staff allegation of abuse (physical or sexual), neglect, exploitation, or unprofessional conduct by a Harris Health Staff member or another patient within any Harris Health Facility or facility where Harris Health workforce are employed **(Page Forensic Nursing Immediately for sexual assault or rape)**
• Serious staff or visitor related safety event (Staff injury or assault or visitor creating a disturbance including potential damage to facility)
• Significant threats of violence or harm by a patient, visitor, or workforce member that requires immediate intervention by the pavilion and system
2. Significant Regulatory, Compliance, Legal Risk:
• Death while in restraints or seclusion, OR within 24 hours of removal of 4-point restraints or seclusion, OR within 7 days of removal of restraints or seclusion if restraint is determined to be the contributing factor of the death
• Concern for EMTALA violation
• Patient Elopement without Decision Making Capacity
• Unsafe Discharge of a patient of any age who is unable to make decisions
• Abduction of a patient of any age
• Any morgue related issue where human bodies or fetal remains are mismanaged and/or released inappropriately (i.e., wrong entity, wrong temperature storage). Includes complications related to autopsies (or autopsy orders)
• Impersonation of a Health Care Provider
3. Unanticipated Internal / External Disaster Events
4. Serious concern for imminent negative media, social media or regulatory party exposure
	Once Escalated *(See Appendix A)*:
	Department Leadership:
	1. Notify House Supervisor who will notify AOC and Pavilion Exec Team
	2. Notify Patient Safety/Risk Management (if not already aware)
	3. Call for a Safety Huddle as needed (See Safety Huddle instructions in orange column).
	4. Report in Tier 3
	Pavilion Exec Team:
	1. Place WebEx Alert and notify system leader
	2. Call for a Safety Huddle (as needed)
	3. Report in Tier 4
	Patient Safety/Risk Management:
	1. Create an SBAR for Pavilion and System Leaders
	2. Verify appropriate notifications (i.e Compliance, Legal)
	3. Initiate an immediate investigation (in collaboration with department leaders)
	4. Follow the High-Level SSE Event Process (Appendix B & C)

Orange Alert Escalation For Safety Huddle	Orange Alert Actions
A serious safety event may occur if an identified unsafe condition or hazard is not urgently escalated.	
Criteria: 1. **Potential for Injury, Morbidity or Mortality (clinically significant care concerns or delays)** • Care delay needing immediate intervention • Complex care decision support to prevent harm to patient, visitors and/or workforce members • Decision-making capacity concern • Time sensitive transfer delay • Time sensitive safe discharge concern • Time Sensitive OR Unresolved Issues (despite dept/pavilion internal escalation) 2. **Delay in or potential disruption in care or operations related to:** • Unanticipated high risk equipment failure • Time Sensitive Equipment or Medication Recall 3. **Regulatory, Compliance or Legal Risk:** • Concern for or awareness of complaint to State/CMS • Concern for or awareness of complaint or other state agency (Disability Rights, Elderly Advocacy) • Concern for negative media exposure o Patient or patient's representative raises concern claiming or intimating that they will report to the media o During a sensitive event (i.e., CIT, CPR) a patient, visitor or staff appears to have recorded some or all of the event. • Concern for a significant deviation from an existing Harris Health policy or procedure ***IMPORTANT NOTE:*** **A Safety Huddle may be called for any concern and is not limited to the above criteria.**	**Need For Safety Huddle Has Been Identified:** **Departmental Leadership:** 1. Notify Patient Safety and Risk Management (24/7 on call) as well as additional departments involved of the situation and proposed time of safety huddle 2. Arrange a Safety Huddle by following the below: a. Create a Webex meeting b. Choose below pavilion email group from address book (includes pavilion triad, legal, risk, corporate compliance) • *Safety Huddle- BT* • *Safety Huddle- LBJ* • *Safety Huddle- ACS* c. Add to invite all of the below who are involved or key decision makers: • Nursing, Provider, and/or Ancillary Department Leaders • Involved Provider and Nurse who can best speak to the situation (if applicable) • House Supervisor • Specialty Service (i.e., Psychiatry, Forensic Nursing) • Security • Social Work d. Send invite

Yellow Alert Pre or Post Event	Yellow Alert Actions
A safety event has occurred that requires leadership awareness *OR* a safety event that may occur if an identified unsafe condition or hazard is not escalated and resolved (*does not meet any of the red alert criteria*).	
Criteria: 1. **Injury, Morbidity or Mortality** • High Risk Red Rule Violation • Any care management event that results in minor to moderate harm • Suicide or self-harm attempt (no harm) 2. **Delay in or potential disruption in care or operations related to:** • Treatment, admission, consultation (unable to reach), ancillary services, transfer, administrative approval • Unanticipated staff shortage (call in or illness mid-shift) • Interpersonal or professional issues that interfere with the delivery of care (i.e., incivility, retaliation) 3. **Regulatory, Compliance or Legal Risk:** • Concern for or awareness of complaint to State/CMS • Concern for or awareness of complaint or other state agency (Disability Rights, Elderly Advocacy) • Patient or patient representative has sought or is seeking legal council • Patient, visitor or other party is injured in or near HH property • Significant deviation from an existing Harris Health policy or procedure 4. **High Risk Events Requiring Reporting** • Ambulatory Surgery Center (ASC) transfer of any patient to a higher level of care • Suspected drug diversion by patient, visitor, or workforce • Suspected impairment by workforce member, medical provider, or third parties that participate in care, supervision, transport or escort of Harris Heath patients (EMS, Law enforcement, shared ride drivers) • Suspected controlled substance overdose • Death from communicable disease or infection 5. **Concern for negative media exposure** • Patient or patient's representative raises concern claiming or intimating that they will report to the media • During a sensitive event (i.e., CIT, CPR) a patient, visitor or staff appears to have recorded some or all of the event. 6. **Unanticipated equipment failure**	**Once Escalated (See Appendix A):** **Pavilion Departmental Leadership:** • Enter eIRS • Notify departments who need to be involved in addressing/resolving the issue (i.e. Human Resources, Pharmacy, etc.) • Work with pavilion leaders to address/resolve • Report in Tier 3 Huddle **Pavilion Executive Team:** 1. Call for a Safety Huddle if there is an active situation that is escalating or not resolved 2. Report in Tier 4 **Patient Safety/Risk Management:** 1. Review eIRS for leadership resolution and action items.

APPENDIX G

Harris Health Leadership System Event Notification and Escalation Flow Chart

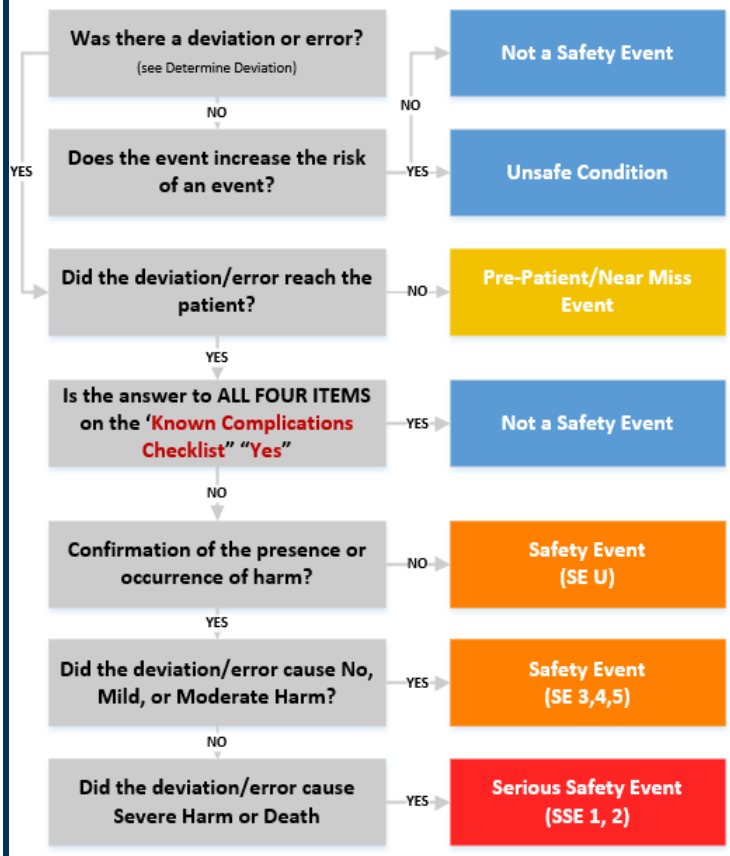


APPENDIX H
Scale for Harm Classification

Safety Event Class	Level of Harm	Code	Patient Outcome
Serious Safety Event (Reaches the patient)	**Death**	**SSE-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 the incident.
	Severe **Permanent or Temporary Harm**	**SSE-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 (impact), 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**	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**	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**	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**	Unknown if harm reached a patient
Pre-Patient Event/Near Miss (Does not reach the patient)	**Almost Happened**	**PPE**	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.

APPENDIX I
One Harris Health Risk Analysis Platform

Patient Safety & Risk Management Safety Event Classification



DETERMINE DEVIATION

- Internal policies, procedures, or protocols
- Nationally recognized best practices and standards of care
- Industry-imposed practice mandates and requirements
- Professional practice standards
- Objective review by other experts
- Organization obligation to best protect the patient from harm

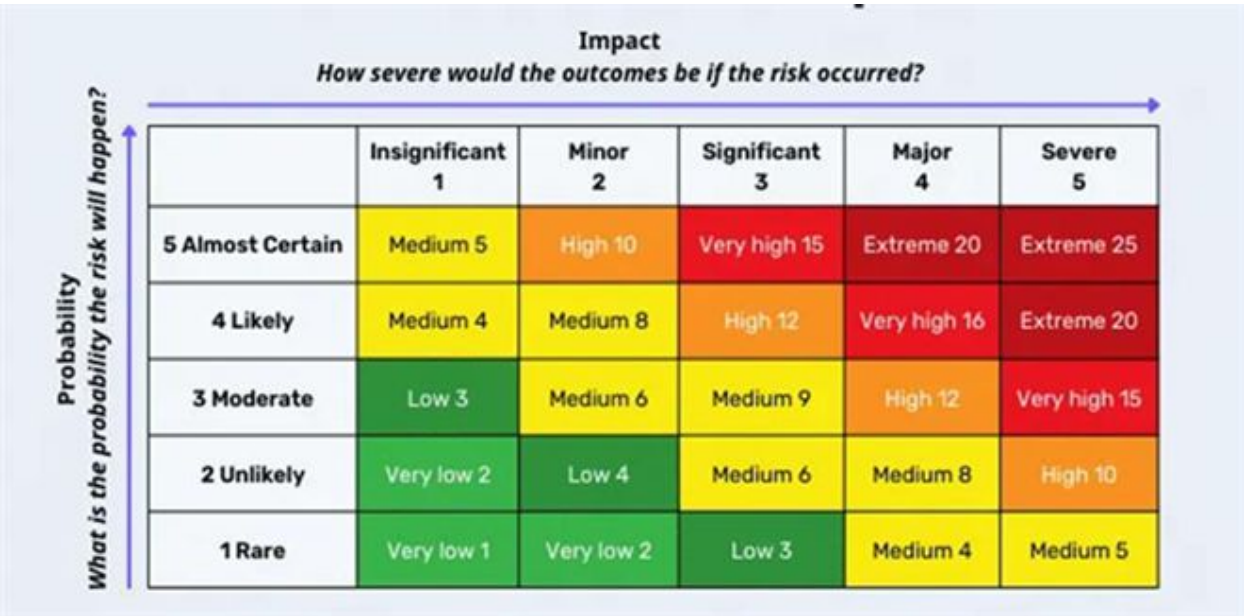
If any of the above are answered YES, proceed with safety events classification

KNOWN COMPLICATION CHECKLIST

1. Was the procedure, treatment, or test appropriate and warranted based on nationally recognized standards of care?
2. If patient experienced a "complication": Was the complication a known risk AND it was anticipated AND the care team planned ahead to take steps to prevent it?
3. Was the complication identified in a timely manner?
4. Was the complication treated according to evidence based standards in a timely manner?

REMINDER TO VIEW FROM THE PATIENT'S PERSPECTIVE:
WOULD WE HAVE EXPECTED OR WANTED THIS LEVEL OF CARE FOR OURSELVES OR OUR LOVED ONE?

APPENDIX J
Risk Matrix



	Insignificant 1	Minor 2	Significant 3	Major 4	Severe 5
5 Almost Certain	Medium 5	High 10	Very high 15	Extreme 20	Extreme 25
4 Likely	Medium 4	Medium 8	High 12	Very high 16	Extreme 20
3 Moderate	Low 3	Medium 6	Medium 9	High 12	Very high 15
2 Unlikely	Very low 2	Low 4	Medium 6	Medium 8	High 10
1 Rare	Very low 1	Very low 2	Low 3	Medium 4	Medium 5

Impact

Also called severity or consequences, the Impact (y-axis) aims to determine the level of effects that the hazard can cause to workplace health and safety.

While a 5×5 risk matrix can be tailored to the needs of an organization, the following represent the general terms used to describe the 5 levels to determine the risk's impact:

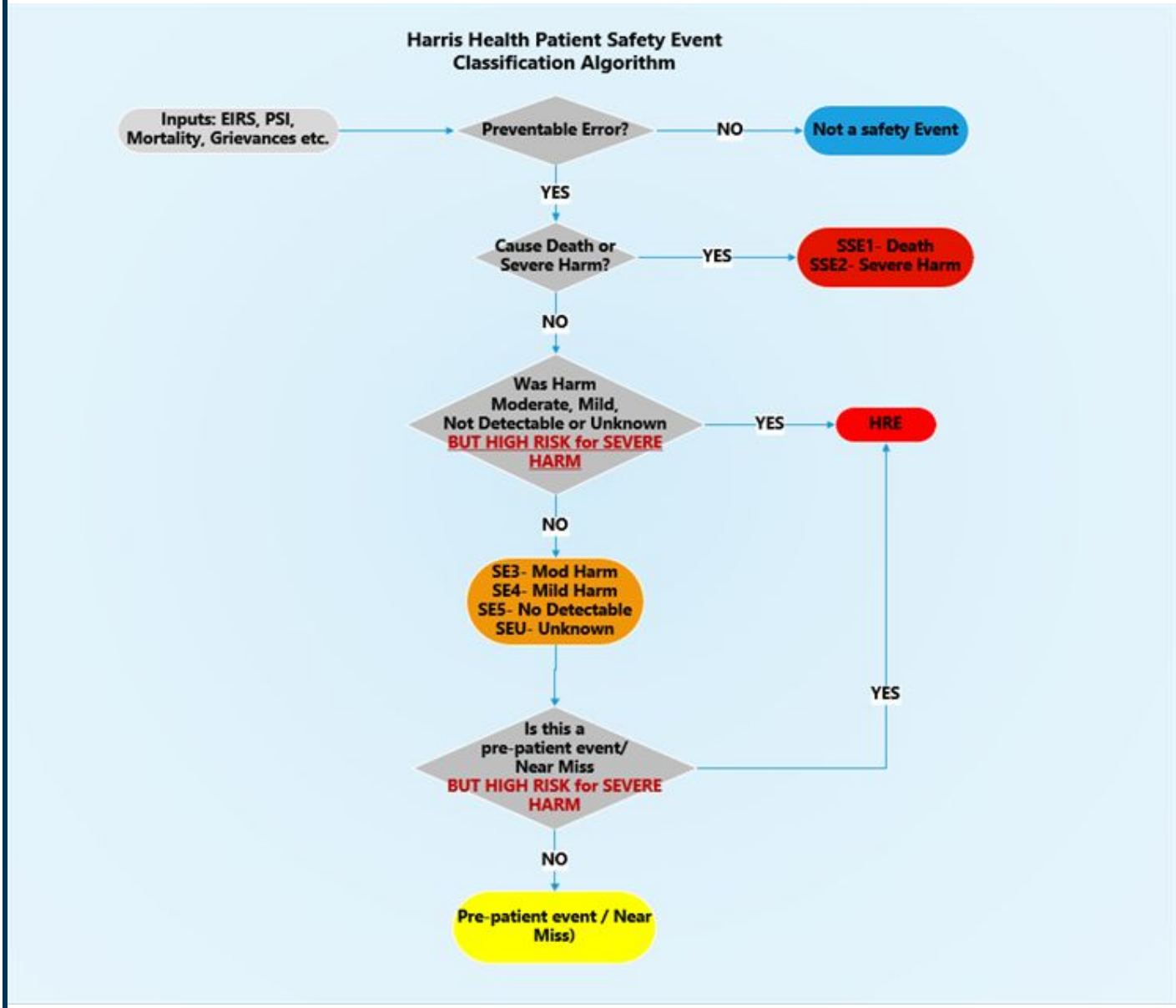
1. **Insignificant** – won't cause serious injuries or illnesses
2. **Minor** – can cause injuries or illnesses, only to a mild extent
3. **Significant** – can cause injuries or illnesses that may require medical attention but limited treatment
4. **Major** – can cause irreversible injuries or illnesses that require constant medical attention
5. **Severe** – can result in fatality

Probability

Also called likelihood, the Probability (x-axis) pertains to the extent of how likely it is for the risk to occur. The 5 risk rating levels under this component are as follows:

1. **Rare** – unlikely to happen and/or have minor or negligible consequences
2. **Unlikely** – possible to happen and/or to have moderate consequences
3. **Moderate** – likely to happen and/or to have serious consequences
4. **Likely** – almost sure to happen and/or to have major consequences
5. **Almost certain** – sure to happen and/or have major consequences

APPENDIX K
Patient Safety Collaborative Revised Healthcare Performance Improvement Safety Event Classification (SEC) Levels of Harm for Standardized Scoring



Appendix L
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.

APPENDIX M
Variance Management Filter Council Leadership ~~Guidance~~Guidelines

HARRISHEALTH SYSTEM

Filter Council

The Filter Council is a pavilion based multidisciplinary patient safety meeting with leaders and system colleagues that provides for the transparent initial review of safety and quality of care events or trends to collectively determine next steps for further analysis and/or remediation (i.e., follow-up to the Filter Council, a One Harris Health Platform (OHHP) or Pavilion RCA, or a referral to another committee such as PIC or nursing peer review).

General Safety Event Review Process

- Always initiate an immediate investigation when your unit experiences a potential error that may have reached a patient, caused harm, OR is high risk for harming a patient if the event were to a recur.
- Patient Safety will support and collaborate with your investigation. We may reach out to speak to staff members involved. Please ensure workforce members understand that if a patient safety representative would like to speak with a workforce member, it is because we are looking for ways to improve the process to better support all workforce members (human factors) and prevent a recurrence.
- As part of the investigation into the event, an individual performance issue may be identified and will be referred to the departmental leadership to make recommendations for additional review including peer review.

Filter Council Preparation Instructions

The Patient Safety Team will notify you when a specific event is scheduled to present to the Filter Council. ***The following are next steps:***

- Use the filter template provided in the notification email.
- All involved departments/service lines should contribute to the presentation (i.e., radiology, social work, guest transportation).
- The format helps you communicate your analysis by utilizing an SBAR technique (examples follow below).
  - The **SITUATION** is a simple overview of the care concern.
  - The **BACKGROUND** is a timeline of the event.
  - The **ASSESSMENT** is where you will be introduced you to the "5 whys." You do not have to get this perfect or even reach 5 whys. This is simply a great tool to help you as a leader think at a deeper level to identify holes in the process (Swiss cheese) to identify the most possible root cause to your care concern (what occurred). We have placed several examples of utilizing 5 whys below. Please note, this is an initial 5 why exercise. If this case goes to an OHHP analysis, Patient Safety will lead a deeper analysis to determine causal factors, 5 whys, root causes, and contributing factors. See video Example of "5 Whys"- Watch VIDEO- https://www.youtube.com/watch?v=N7cR2gArCFE
    - During your investigation, if it is identified that a process or expected performance was not followed, please make further attempts to determine the ***why*** behind the staff member failure. This will help in identifying whether there are opportunities in the process or obstacles/barriers that may impact other staff members.
  - The **RECOMMENDATIONS** should address your root causes. (Recommendations by strength plus examples are provided below)
    - Recommendations should include an owner and targeted completion date
- The filter presentation **will be due to Patient Safety 48 hours prior to Filter (Monday by 2:30 pm).** If not submitted, an escalation email will be sent to the one up leadership. Please note the 48 hours is an expectation set by your pavilion leadership as it allows for review and opportunity for additional support if needed. We are here to partner with you!

Appendix N
Patient Safety Collaborative Charter

Harris Health System's Board of Trustees ("BOT") & the Board of Trustees – Quality Committee ("BOT-QC"), through the Quality Manual, has authorized the formation of the Patient Safety Collaborative ("The Collaborative

Title: Harris Health System Patient Safety Collaborative (the "Collaborative")

Purpose: The Patient Safety Collaborative Committee is an interdisciplinary Committee that aims to promote a culture of transparency to provide a multidisciplinary objective review and analysis of patient safety events and functions as a medical committee/medical peer review committee at the direction of the QGC. All functions of the Patient Safety Collaborative Committee are confidential, privileged and protected from disclosure pursuant to Chapter 161 of the Texas Health & Safety Code and Chapters 151 and 160 of the Texas Occupations Code. The Patient Safety Collaborative is an interdisciplinary team that consists of system and pavilion leaders that collaborate to review events related to patient safety. The goal of the Collaborative is to partner together to achieve zero harm at Harris Health System.

RESPONSIBILITIES

The Collaborative has the following broad sets of responsibilities:

- Supports the overall mission, vision, and values of Harris Health System.
- Review safety events and all risk reduction strategy development to reduce harm and improve patient safety outcomes within the organization.
- Score safety events brought forth for review using the Harris Health approved Serious Safety Event Classification System.
- Conduct data analysis using performance indicators, the Patient Safety Event Rate, Incident Reporting Data, etc. as it may deem necessary or appropriate.
- Monitor risk reduction strategy development.
- Deliberate, discuss, and approve recommendations from the Patients' Collaborative for Safe & Quality Care
- Provide physician and nursing peer review recommendations when applicable.
- Make recommendations related to patient safety and quality that pertains to policy and procedure development.

OVERSIGHT: The Harris Health System Board of Trustees and the Harris Health System Board of Trustees Quality Committee

MEMBERSHIP

Membership for the Collaborative is based on roles, not individuals. Co-chair of the Collaborative will be the Associate Chief Medical Officer/Senior Vice President Quality and Patient Safety and Vice President of Patient Safety and Risk Management. Each member of The Collaborative shall be appointed for a one-year term. The Collaborative members may be removed and/or replaced by the Chair.

Membership on The Collaborative will broadly include the following workforce member's roles:

System	Pavilion
Board Member	Executive Vice President
Chief Executive Officer	Chief Medical Officer
Chief Quality & Patient Safety Officer	Chief Nursing Officer
Chief Operating Officer	Vice President, Operations
Chief Compliance & Risk Officer	Administrative Director of Nursing
Chief Medical Executive	Director, Patient Safety
Chief Nursing Executive	Director, Quality & Patient Safety
Chief Pharmacy & Laboratory Officer	Patient Safety Specialist
Chief Strategy & Integration Officer	Senior Patient Safety Specialist, Controlled
Senior Vice President, Medical Affairs & Utilization	Substances
Senior Vice President, Transitions & Post-Acute Care	Chief of Staff
Senior Vice President, Nursing Affairs & Support Services	Baylor Physician

Senior Vice President, Human Resources Vice President, Transformation & Operational Excellence Vice President, Risk Management & Patient Safety Vice President, Quality Programs Medication Safety Officer Administrative Director, Pharmacy System Operations Administrative Director, Nursing Strategic Initiatives Director, Nursing Quality & Patient Safety Director, Medical Peer Review Director, Lean Six Sigma Program Consultant, Harris County District Attorney	UT Physician

MEETINGS

The Collaborative strives to meet bimonthly and/or at such times, it deems appropriate. Special meetings may be convened, as the Collaborative deems necessary. When additional expertise is needed, Harris Health Workforce Members may be invited by the Patient Safety and Risk Management Department to address specific issues.

PROCEDURE

The Collaborative meetings will have a standard agenda, which will include:

- Confidentiality Statement
- Old Business/Unresolved Issues
- Patient Safety Priorities
- Patient Safety Performance Indicators
- Risk Reduction Strategy and Monitoring Tracking
- Event Summary

A patient safety event summary will include at a minimum:

- Case Summary
- Root Causes
- Incidental Findings (If Applicable)
- Contributing Factors
- Risk Reduction Strategy Table, which will include at a minimum:
    - Strategy
    - Associated Root Cause/Contributing Factor
    - Owner
    - Measurement Strategy
    - Implementation Deadline

The following entities/ roles may refer events for the Collaborative to review:

Role	Entity
Board Member Chief Executive Officer Chief Quality & Patient Safety Officer Chief Medical Executive Chief Compliance & Risk Officer Chief Nursing Executive Executive Vice President Pavilion Triads	Variance Management Filter Council

Events will be scored using Harris Health System's approved Serious Safety Event Classification System, which is adapted from the HPI Safety Event Classification & Serious Safety Event Rate Patient Safety Measurement System.

When deemed necessary and at its discretion, the Collaborative may review a previously scored event to update a patient safety event summary or score that may not have been identified during the original case presentation or to change the score

on a previously reviewed patient safety event when additional information is presented that suggests a change or update is warranted.

As often as is necessary or appropriate in its judgment, the Collaborative shall report a patient safety summary, as applicable, at each scheduled BOT-QC meeting.

RECORDS

The Collaborative decisions and actions are documented through minutes as recorded by Patient Safety and Risk Management Department. The meeting minutes are disseminated within ten business days from the meeting.

Meeting minutes are reviewed and approved by the Collaborative members. Agendas and meeting minutes are retained by the Patient Safety and Risk Management Department and approved by all members.

QUORUM

Includes a minimum of one operational and nursing executive (or their appointed delegate) from Ben Taub, Lyndon B Johnson, and the System. Ambulatory Care Services and Hospital at Home will require an executive leader (or their delegate) to be present when a summary from their pavilion is presented. The Collaborative may take no action without the consent of a majority of the members.

REPORTS

The Collaborative will report to the BOT-QC routinely to include:

- Data derived from the electronic Incident Reporting System (eIRS)/Patient safety event analysis/trending.
- Progress on Risk Reduction Strategies
- Event Summary
- Patient Safety Event Rate

SUBCOMMITTEE

Subcommittees may be established by the Collaborative. Any subcommittee shall be composed of members of the Collaborative (or the designees of such members) and a minimum of three patients or family members of patients. A subcommittee charter will be included as a sub-section of the Collaborative Charter. The subcommittee will require the same quorum requirement as the Collaborative. The subcommittee will report recommendations and advice to the Collaborative for deliberation and discussion. The Collaborative will document the subcommittee's recommendations and advice and present them to the BOT-QC.

Title: The Patients' Committee for Safe & Quality Care

The Patients' Committee for Safe & Quality Care is a subcommittee of the Patient Safety Collaborative. The purpose of the Patients' Committee for Safe & Quality Care is to provide awareness on patient safety events and quality of care concerns to promote patient involvement, input, and engagement in preventing future harm. The Patients' Committee for Safe and Quality Care, as a subcommittee of the Collaborative, is a medical committee/medical peer review committee that functions at the direction of the Collaborative and the QGC. All functions of the Patients' Committee for Safe and Quality Care are confidential, privileged and protected from disclosure pursuant to Chapter 161 of the Texas Health & Safety Code and Chapters 151 and 160 of the Texas Occupations Code.

RESPONSIBILITIES

The Patients' Committee for Safe & Quality Care has the following broad sets of responsibilities:

- Supports the overall mission, vision, and values of Harris Health System.
- Review safety events and quality of care issues
- Provide recommendations on strategies and/or process improvements to prevent harm and improve quality of care delivery.
- Provide recommendations related to patient safety and quality that pertains to policy and procedure development.

MEETINGS

The Patients' Committee for Safe & Quality Care strives to meet quarterly. Special meetings may be convened, as deemed necessary. When additional expertise is needed, Harris Health Workforce Members may be invited by the Risk & Patient Safety Department to address specific issues.

PROCEDURE

1. The Committee's meetings will have a standard agenda, which will include:
    - Confidentiality Statement
    - Old Business/Unresolved Issues
    - Patient Safety and Quality of Care Concerns
    - Strategy and Process recommendations
    - Open Forum
2. Meeting will be held virtually.
3. The chair shall create the meeting agenda. The agenda is distributed electronically to members at least two days in advance of scheduled meetings. PCSQC members may request that items be considered for the agenda by contacting the chair.
4. Members should confirm attendance prior to meetings.

MEMBERSHIP

The PCSQC shall be comprised of the following:

- Chair: Vice President for Patient Safety & Risk Management
- Minimum of three patients
- Patient Relations
- Minimum of three Harris Health workforce members
- Ad hoc/quest members as needed/appropriate

The Committee shall review and assess the adequacy of this charter periodically and recommend any proposed changes to the BOT.

BOARD OF TRUSTEES

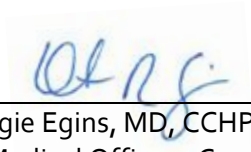
Quality Committee

HARRISHEALTH

Tuesday, May 6, 2025

Executive Session

Report Regarding Harris Health Correctional Health Quality of Medical and Healthcare, Pursuant to Tex. Occ. Code Ann. §§151.002, 160.007 and Tex. Health & Safety Code Ann. §161.032 to Receive Peer Review and/or Medical Committee Report.



O. Reggie Egins, MD, CCHP-CP
Chief Medical Officer - Correctional Health

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BOARD OF TRUSTEES
Quality Committee

HARRISHEALTH

Tuesday, May 6, 2025

Executive Session

Report Regarding Quality of Medical and Healthcare, Pursuant to Tex. Occ. Code Ann. §§151.002, 160.007 and Tex. Health & Safety Code Ann. §161.032, to Receive Peer Review and/or Medical Committee Reports in Connection with the Evaluation of the Quality of Medical and Healthcare Services, Including Report Regarding Harris Health Quality Review Councils.

Yashwant Chathampally, MD, MSc
Associate CMO & SVP, Quality & Patient Safety

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