PURPOSE:

All events filed in the Safety Reporting System (SRS) are reported under the attorney/client privilege and/or under the medical peer review and quality assurance programs of each entity and of Parkland Health & Hospital System. To ensure the security and appropriateness of access to safety events reports, the Vice President for Safety & Clinical Risk Management evaluates and provides oversight of the program. The reporting and review of safety events, concerns and good catches are used for the purpose of enhancing organizational learning in conformance with the Just Culture philosophy of reducing risk to patients, visitor and staff/providers by examining errors and potential errors and using that information to build systems that reduce the likelihood of harm at a future time. All reports are confidential within the attorney-client and peer review privileges. Reports should not to be copied, printed, or stored in locations outside of the electronic SRS system without permission of Legal Counsel. Event reports should only be forwarded to persons who have a responsibility to review and act on them. SRS event reports should not be referenced or included in the patient medical record.

This policy outlines and describes our organizational process for reporting, evaluating, and utilizing Safety Center event reports referred to as "Safety Posts".

SCOPE:

All Parkland Health & Hospital System ("Parkland") facilities, including but not limited to hospitals, ambulatory surgery centers, clinics, and all corporate departments/divisions.

DEFINITIONS OF EVENTS:

Patient Safety: Freedom from preventable harm

Just Culture: A safety-supportive system of shared accountability where healthcare institutions are accountable for the systems they have designed and for supporting the safe choices of patients, visitors, and staff. Staff and faculty/providers, in turn, are accountable for the quality of their choices – knowing that we cannot will ourselves to be perfect, but we can strive to make the best possible choices.

Harm: Temporary or permanent impairment of the physical, emotional, or psychological function or structure of the body and/or pain that may require intervention, use of an antidote, and increase length of stay by 1 or more days or result in vital signs, lab values, or effects outside of desirable parameters.

Event: Any event or risk not consistent with the standard of care of a patient or safety of

a patient, visitor, volunteer, staff or clinician, with or without injuries. Events are also known as incident reports or occurrences.

Good Catch Review: The process of reading, investigating, verifying and analyzing a safety report, includes determination of severity, notification of appropriate individuals or groups, designation of response actions, and documentation of the process.

Safety Reporting System (SRS): The online voluntary reporting mechanism used to report occurrences, risks, concerns and good catches involving patients, visitors, clinicians and employees. Vizient is the current vendor for the SRS.

Sentinel event: An event defined by The Joint Commission (TJC) as any unanticipated event in a healthcare setting resulting in death or serious physical or psychological injury to a patient or patients, not related to the natural course of the patient's illness. Sentinel events specifically include loss of a limb or gross motor function, and any event for which a recurrence would carry a risk of a serious adverse outcome.

Severity Rating Scale

1. Unsafe Condition (Non Event)
2. Good Catch: No Harm– Did not reach individual, caught by chance or because of action taken by caregivers/staff"
3. No Harm - Reached individual, no monitoring required, no effects
4. No Harm - Reached individual, monitoring required and/or intervention needed to prevent harm
5. Harm – Temporary
6. Harm - Temporary, escalation in level of care Needed
7. Harm – Permanent
8. Harm - Permanent, intervention required to sustain life
9. Death - Event contributed to or caused death

Adapted from National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) copyright 2001.

PRACTICE STATEMENT:

Safety is the responsibility of all employees, physicians and contracted staff. Therefore, Parkland Health & Hospital System (Parkland) expects that all will report any adverse events regardless of harm via a safety post in the Safety Center. The intent of reporting safety posts is to trend, learn and understand actions to reduce the likelihood of recurrence of same or similar events.

Parkland's appropriate and timely response to incident reports fosters concepts of high reliability to improve patient care. High reliability concepts include a focus on:

1) Safety is everyone's responsibility
2) Constant vigilance on reporting of events, especially non-harm and Good Catches
3) Reluctance to simplify
4) Pre-occupation with Failure
5) Using reported events as opportunities to learn across the enterprise

A focus on these elements will support Parkland's focus on improving safety, quality, and efficiency. It will also support the development of a culture of safety and accountability focused on processes that significantly reduce system failures and effectively responds when failures do occur which is the goal of high reliability thinking.

EQUIPMENT:

Safety Center electronic database

PROCEDURE:

1. Reporting of a Safety Event or Potential Risk:
    a. Except as noted below, all events, risks, concerns and good catches should be first entered into the Parkland Safety Event Reporting System (SRS) also known as Vizient. When this is not practical, the information may also be given telephonically, verbally or in writing directly to a member of the Patient Safety

Risk (PSR) Management team, however it is preferred that the communication begin in the SRS system.

1) For those events involving serious injury to a patient or visitor, the On Call PSR Manager shall be notified as quickly as possible by telephone or page, concurrent with the patient, visitor or employee receiving appropriate treatment/care. To PSR On call can be reached via SmartWeb.

   - For those events involving clinician and/or employee injury, refer to the Occupational Health Department policy for reporting guidance.

   - For those occurrences involving medical equipment, refer to the Clinical Engineering policies on equipment sequestration/management, The reporter should also ensure to include the following steps when reporting the event:

     (i) Settings - To the extent possible, maintain all settings when discontinuing use of the equipment. If the settings cannot be retained, document the settings in the SRS report and provide them to Clinical Engineering and Patient Safety & Clinical Risk Management.

     (ii) Sequester - Involved equipment will be sequestered and identified for return to Clinical Engineering. In the SRS report, include the location where the equipment can be found.

     (iii) Preservation of Accessories - Preserve all disposables including the packaging associated with any accessories that were used with the equipment so that the lot number can be determined if the manufacturer needs to initiate a recall.

     (iv) Contact - Notify Clinical Engineering about the occurrence involving medical equipment and reference the safety post number in the event report.

b) Note that Safety Posts involving medical or other equipment are not to be used as a substitute for a repair request. In the case of broken medical equipment, contact Clinical Engineering.

c) Safety Posts shall not be used for reporting personal disagreements or complaints, differences of opinion, or other concerns unless directly related to the safety of patients, visitors or clinicians/staff.
d) Safety Posts assigned a severity rating warranting consideration for designation as a sentinel event will be escalated to the appropriate department or operational leadership in addition to leaders in the Quality, Safety & Performance Improvement Department. Additional documentation of the case will be completed by the lead Patient Safety Risk Manager in the Quality, Safety and Performance Improvement 'QSPI' panel in the safety post.

e) Employees should never reference to the safety post or the number in the electronic medical record (EMR).

f) For questions related to safety posts, contact the Patient Safety & Clinical Risk Management Department for guidance.

g) Paper downtime forms are available for documentation when the SRS is offline and are available on Safety Center Intranet homepage.

REVIEWING OF SAFETY POSTS

All event investigation and analysis, including sentinel events, significant events, good catches and trend analysis, is confidential within the protections afforded the attorney/client privilege and the quality assurance/improvement and peer review functions.

A.All staff and providers are encouraged and expected to perform their duties in a safe manner. When conditions, processes, or systems, etc., make it difficult or prevent a staff member from performing safely or require work-a-rounds to provide safety, it should be reported.

B. Unexpected patient events or outcomes should be reported regardless of the associated level of harm and include but are not limited to, e.g., patient falls, return to surgery, use of reversal agents, procedures on the incorrect patient or site, unanticipated death, medication events , high risk elopements, Hospital Acquired Pressure Ulcers (HAPU), etc.

C. Events that are perceived to fall outside of normal operations or expected outcomes are expected to be reported.

D. Patient providers are to be notified of all clinical conditions that may require timely medical intervention. This process is separate from the safety event reporting process. Safety Post reporting must not interfere with the timely care of the patient.

E. Frontline supervisors/managers and the Nursing Administrative Officer (NAO) and/or Administrator On Call (AOC) should be notified of unsafe conditions, processes, patient conditions, etc. in a timely manner by the reporter. Unit/department managers are encouraged to escalate through their respective chain of command as appropriate.

F. Serious events defined by the administrative procedure, the Corporate Integrity Agreement (CIA) and by agreement with the Texas Department of State Health Services, shall be paged to the Patient Safety/Risk Manager on call via SmartWeb. An established escalation process is in place following the reporting of a serious event with identification of the issues and plans for next steps.

G. Completion of the Safety Posts should be done by the individual closest to the event as soon as possible after the event, or upon the identification of the unsafe condition. Entry of the post should not be delegated.

H. Safety Posts may be made anonymously, although investigation and follow up on the post is aided by the ability to talk with the person completing the report. Parkland has a no retaliation policy for staff or others reporting in good faith.

I. If there is a question on behalf of the reporter as to report or not, the reporter is encouraged to enter the Safety Post and/or page the on call Patient Safety Risk Manager for guidance.

J. The Safety Center is found on the front page of the Parkland Intranet by selecting “Parkland Safety Center”

2. Management of Safety Posts:

A. Primary Reviewers are local Managers who oversee the safety posts assigned to their oversight location. Responsibilities include:

1) Documentation within the post of reviews and consults for timely awareness and action, as appropriate, to minimize recurrence.

2) Documentation within the post of appropriate investigation and follow up which shall include actions taken to address the issue, the dates of the actions taken or other information as appropriate.

3) Escalation to their respective chain of command/NAO as appropriate.

4) Facilitate closure on posts within 10 business days and move to “Completed”.

B. Quality/Safety Reviewer is the Patient Safety and Clinical Risk Managers who are responsible for:

1) Review the Safety Center Posts within one business day and are the overall gatekeepers for the data. Responsibilities include but are not limited to:

- Taxonomy event type or harm score modifications
- Appropriate department attribution and/or clinical service thus enabling distribution to the appropriate responsible manager.
- Consulting of others within the Safety Post to ensure all areas involved in a Safety Post have electronic access to review and provide follow up.
- Bill Hold placement according to established procedures for severe harm or other related cases:
- Launch more intense investigations for those cases that meet the sentinel event criteria, or meet the definition of events to be reported to external authorities under Parkland’s obligations while under the obligations of Corporate Integrity Agreement (CIA).
- Escalation of significant events to Patient Safety Leadership who will inform Executive and Operational Leadership.

- Conduct additional investigations as directed by the Director of Patient Safety & Clinical Risk Management, Vice President of Safety & Clinical Risk Management, Chief Quality & Safety Officer, Executive Leadership, the Board of Managers, and/or any of their designees.

- Management of a serious event will be driven by the Patient Safety/Clinical Risk Management Department with knowledge to Executive Leadership. The Patient Safety & Risk Department shall collaborate with other areas as needed to include but are not limited to: Pastoral Care, Patient Financial Services, Medical Staff Office, and Clinical Areas. Arrangements will be made for the appropriate peer support for reported events.

    - Event investigation and behavior management will incorporate 'Just Culture and High Reliability' principles into of the management of event (such as console, provide education, and address at risk behaviors).

2) The Patient Safety and Clinical Risk Manager will be responsible for closure of Safety Posts after review and investigation. Managers will notify Patient Safety & Clinical Risk Management regarding access needs or changes. Patient Safety & Clinical Risk Management can reopen a Safety Post upon request.

AGGREGATE & TREND REPORTING FOR ORGANIZATIONAL IMPROVEMENT

A. The Quality, Safety & Performance Improvement (QSPI) Division will oversee SRS data analysis and reporting. In addition, the QSPI shall assist with:

1) Access management will be under the direction of the Safety Center Data Group and monitor appropriate assigned users.

2) Ensure divisions and departments are aware of the top event trends in their areas on at least an annual basis including event types, event harm scores, event locations, and Good Catches/Near Misses.

a. Aggregate reports will be developed and distributed upon request or scheduled, with information de-identified.

b. Assist providers and medical staff leaders with data requests data trending for committees or departmental meetings.

c. Executive Leadership and Committees will be provided the necessary reports needed for review, trending, peer review, and performance improvement initiatives at routine intervals.

REFERENCES:

The Joint Commission list of Sentinel Events & Sentinel Policy and SE List of Events/www.jointcommission.org

Texas State Department of Health Services (TSDHS) Patient Adverse Event Listing/dshs.texas/gov 2017

National Quality Forum Serious Reportable Event List/www.qualityforum.org 2011