MedStar Health Safety Principles

Overview & Executive Summary

Overview

MedStar Health has developed a national reputation as an innovator in safety, particularly based on our system-wide implementation of the HRO culture, the integration of system safety engineering and human factors approaches, and our innovative event review process. Consistency in our approach is critical to our safety culture.

This document outlines the fundamental principles which drive MedStar Health's safety program and serves as a leadership guidance in the expectations of the MedStar Health safety program. The accompanying handbook provides detailed guidance for the safety professionals and local operational leaders who are conducting these activities day to day.

These principles were approved by the MedStar Health Quality and Safety Oversight Committee on September 23, 2019.

MedStar Health Quality & Safety

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Background
In 2010, as part of the MedStar 2020 strategic plan, Medstar Health committed to a "highest quality and safety" transformation, with a goal of zero preventable serious safety events. Compared to other healthcare systems nationally, MedStar takes a progressive approach to safety. This innovative approach, incorporating key factors distinguishing a High Reliability Organization (HRO), has been shaped by safety scientists, human factors engineers, patient and family advocates, frontline associates and providers, and clinical safety experts leading safety across MedStar Health. The goal of the MedStar approach to safety and the event review process is to decrease the likelihood of any ***future*** risk to patients. **In order to optimize our safety culture, and to drive safety events to zero, it is essential that this approach be practiced consistently across the MedStar system**.

Purpose
This document defines the safety principles that are in place for all MedStar Health sites in order to execute MedStar's progressive approach to safety. These include principles which leaders must use to establish and maintain a safety culture that is essential to prevent adverse patient outcomes, as well as principles central to a robust response to serious unanticipated outcomes.

Defining Safety Philosophy: High Reliability Organization (HRO)
An HRO is an organization that succeeds in avoiding adverse events in an environment where normal accidents can be expected due to the complexity of the work and the inherent risk in the activity. Associates in successful HRO organizations are constantly searching for the smallest indication that the environment or a key process inadvertently contains a safety or quality issue that might lead to failure if action is not taken to resolve or eliminate the issue. They also feel empowered to take action to address these hazards. Uncovering safety concerns allows an organization to identify safety or quality problems before harm occurs.

Safety Principles

Principle 1: Establish and maintain a strong HRO safety culture in every local environment.
A strong safety culture is the foundation of our safety program and empowers our associates to own safety at every level, including raising awareness of ongoing safety risks and "stopping the line" when necessary.

A. Ensure all providers and associates receive HRO training.
B. Start all meetings with a *Safety Moment,* connecting the moment to HRO principles.
C. Report near misses and unsafe conditions in the Patient Safety Event Management System.
D. Approach serious unanticipated outcomes (SUOs) using the MedStar Event Review Process. An SUO is an unanticipated outcome involving a patient, visitor, or associate which could result in either temporary or permanent harm. If an SUO is determined to have caused moderate to severe harm because of a deviation in the standard of care, it is known as a serious safety event (SSE).
E. Maintain MedStar's Just Culture approach: Except in the rare case of consciously egregious behavior or irremediable competency, incidents and failures should be treated as opportunities to learn rather than to punish.

Principle 2: Notification of serious unanticipated outcomes (SUO) immediately upon discovery.
Early reporting allows for a standardized, empathetic response including immediate care for the patient, transparent and honest communication without delay with patient and family, care for our caregivers, and early, systems-focused learning. These four essential steps impact MedStar's local and systemwide safety culture, our ability to improve, and our reputation with patients, families, and associates. Our response to serious unanticipated outcomes begins immediately upon discovery and is not directly connected to the determination of whether the event was a Serious Safety Event (SSE) since that determination may take days or weeks following the event.

A. Local and system safety and risk management partners should be notified as soon as possible after any SUO is discovered by any associate.
B. Leaders must ensure that associates understand their responsibility to notify safety and risk leaders as soon as they discover a potential SUO.
C. Leaders and associates should not wait to determine if there has been a violation of the standard of care before reporting an SUO.

Principle 3: Patient and family must be supported immediately following an SUO, including disclosing potential harm associated with an SUO to the patient/family in partnership with risk management and the patient's attending physician.

Open, honest, and timely communication with patients and families is a key part of the MedStar Event Review Process and allows for early relationship building and information sharing. Ideally this will begin as soon as there is a perceived need and will almost always require ongoing contact with the patient and/or family.

A. In partnership with risk management, ensure open and honest communication occurs consistently and in a timely manner for every SUO at MedStar Health.
B. Ensure each local organization has access to trained Patient Communication Consult Service (PCCS) individuals who can assist in the event an SUO occurs.
C. Clinicians and leaders may consult the local PCCS for support and assistance. If entity specific PCCS experts are not available in the ambulatory setting or Baltimore hospitals, system PCCS resources may be contacted via the safety/risk hotline (833-MSH-SAFE).
D. Whenever there is an SUO, risk management will determine if bills should be put on hold. If there is suspicion of a violation of standard of care or if the patient or their family perceives there to be a violation, an initial bill hold should be placed by risk management. ***This does not require verification of SSE status and the bills may be released by risk management, at leadership discretion, once all of the facts and circumstances are known.*

Principle 4: Response to SUOs will include offering Care for the Caregiver.
MedStar's Care for the Caregiver (C4C) program provides immediate support of all associates affected by safety events. This supports associate wellness, reduces the chance of harmful long-term impact on the associate, and supports an ongoing safety culture essential for an HRO. C4C also reduces the likelihood of adverse outcomes for our associates, including in some cases the risk of suicide or other self-harm. C4C is not a one-time check-in session and usually requires additional follow-up as associates and clinicians process an event.

A. Ensure regular training in C4C principles occurs so that there are always members of your organization available to provide this service when it is needed.
B. Ensure associates involved in a SUO are offered C4C resources.
C. Associates directly involved with the SUO may be most at risk; those who decline formal C4C must receive a coordinated effort for continued attention, as warranted.
D. No corrective action or disciplinary stance will be taken in the immediate aftermath of an SUO, until proper learning and review has occurred (see Principle 6).

Principle 5: The MedStar Event Review Process will be followed for SUO reviews in which there is moderate to severe harm in order to identify systems factors and develop effective action plans. (See MedStar Event Review Process Handbook and the Healthcare Performance Improvement (HPI) Safety Event Classification (SEC) Levels of Harm)

Leadership response to an SUO heavily impacts both safety culture and the ability to properly mitigate risks and prevent recurrence of the event. The MedStar Event Review Process involves a robust review and development of appropriate and effective action plans.

A. Initial assessment, which includes one-on-one discussions with key stakeholders to garner a basic understanding of the event, must be **initiated within 24 hours and will generally be completed within 3 days for SUOs with significant injury or death.**
    - In some cases, it may be appropriate to use this assessment to generate the final action plan if the SUO is clearly found to not be a serious safety event (SSE) during this phase.
B. The MedStar Event Review Process will be used to guide a systems-focused event review with assistance from the system safety team as needed. **The review should be completed as soon as possible, ideally within 2 weeks, but within 30 calendar days from knowledge of the event. If completion of the review extends beyond this time due to extenuating circumstances, a member of the system safety team must be contacted.**
    - System resources, including trained event reviewers and safety engineers are available to assist with event reviews as needed.
    - Cases requiring significant safety science expertise, or which identify user interface design or technology implementation issues may benefit from consultation by experts from MedStar's Institute for Innovation's National Center for Human Factors in Healthcare. The system safety team should be contacted to determine if consultation is appropriate to assist the event review.
    - Sites will send the output from the event review to the safety team at the time the review is completed.
C. Patients and family who witnessed the progression of events or have collateral information must be included in the interviews, as they often have a unique and important perspective.
D. Action plans will include effective *and* sustainable solutions that are as rigorous as possible based on safety science principles. Follow-up plans must be included, and leaders are accountable for ensuring adoption of the planned action or a well justified optimization of the action as the actions are implemented. A process should be put in place to track the implementation of action plans, measure success, facilitate continuous improvement efforts, and report metrics to MedStar Quality & Safety through a single point of contact designated by the leader.
E. The system safety team will work collaboratively with local entities to share lessons learned and action plans from similar events at different entities.

F. The goal of the MedStar Event Review Process is to decrease the likelihood of any ***future*** risk to patients. Thus:
   i. When unrelated risks are uncovered during the review, these should be addressed and mitigated where appropriate.
   ii. Full event reviews should be considered on precursor events (near misses which did not cause patient harm by luck or intervention but that pose a high risk of serious harm to future patients) with the same attention to effective and sustainable action plans.

Principle 6: Corrective actions for associates in response to a safety event will be consistent with MedStar's commitment to a Just Culture (MedStar Health's fair, just, and accountable learning system approach to conduct).

The Just Culture approach supports identifying and understanding normal error, at-risk behavior, and systems factors versus consciously reckless or egregious behavior or irremediable competency issues. Just Culture aims to balance associate support and system changes with fair accountability for associate actions. This approach contributes to a strong safety culture because without it, associates are often afraid to discuss errors and near misses that could lead to patient harm in the future. Just Culture treats incidents and failures as opportunities to learn, not punish, except in cases where a proper event review determines the presence of consciously reckless or egregious behavior or irremediable competency issues.

A. Except in the rare case of consciously egregious behavior or irremediable competency, *no corrective action will occur in the immediate aftermath of an SUO* until a proper event review has been conducted in line with the MedStar Event Review Process. This review will include a full understanding of the environment, training, leadership precedent, and other contributing factors such as devices, technology, and team dynamics.
B. Corrective action of a disciplinary manner in response to a safety event requires deliberate and timely engagement of Human Resources, legal, and quality & safety leadership.
C. When appropriate, events should be referred for focused professional practice evaluation or the appropriate department to aid in determination of standard of care.
D. The MedStar Health Just Culture process should be followed, and system leadership should be consulted when there is ambiguity.

Principle 7: Following completion of the event review process, the MedStar Serious Safety Event Determination Process will be used to determine if an SUO meets criteria to be considered a Serious Safety Event (SSE).

The SSE rate is a key performance metric which MedStar Health has defined as the primary outcome metric to indicate our progress in improving safety. The goal is zero preventable harm.

A. The MedStar Health SSE Determination Process should be used to determine SSE status. This process includes using the Healthcare Performance Improvement (HPI) Safety Event Classification (SEC)* to determine SSE status, with the endorsement of system safety leaders in order to ensure consistency. **All final SSE determinations should be made as soon as possible but must be made within 30 calendar days from knowledge of the event. If completion of the review extends beyond this time due to extenuating circumstances, a member of the system safety team must be contacted as soon as possible.**

**When applying the SEC at MedStar, HPI's Generally Accepted Performance Standards (GAPS) is defined as the MedStar standard of care.*

B. The system Vice President Quality & Safety will administer a program to optimize consistency in the interpretation of these algorithms across entities. Cases that are unclear will be determined by a consensus process. Disagreements that cannot be resolved in the Vice President Q&S consensus process will be escalated to the Senior Vice President/Chief Nursing Officer and the Executive Vice President/Chief Medical Officer who will make the final determination.

C. An SUO determined not to be an SSE but rather a near miss or precursor safety event will be tracked for trending and learning. Abbreviated or full event reviews should be considered for these events, particularly when trends are noted.

Principle 8: At MedStar Health, in our relentless pursuit of zero harm, every associate owns safety from front line providers and associates to senior leaders.

Events that are determined to be SSEs will be presented to the MedStar Board of Directors at the Quality and Safety Professional Affairs Committee (QSPAC). The QSPAC has responsibility for ensuring safe care at MedStar Health. Case summaries, contributing factors, and action plans for each SSE are presented to the QSPAC and updates on action plans are provided subsequently. This helps to ensure the effectiveness and sustainability of action items critical to preventing the recurrence of safety events.

A. All SSEs will be reported to safety leadership stakeholders across the system in a weekly SSE report for the purposes of transparency and shared learning.

B. All SSEs (including case summaries, key findings, contributing factors, and action plans) will be presented to the MedStar Health Board via the QSPAC committee on a quarterly basis, and must be reported to each entity Board in similar fashion.

Principle 9: Safety hazards, near misses, unsafe conditions, serious unanticipated outcomes (SUOs), serious safety events (SSEs), and potentially compensable events (PCEs) will be consistently recorded in the Patient Safety Event Management System (PSEMS) and effectively addressed* by local leaders.

Frontline associates and providers have the greatest awareness of quality and safety issues and their feedback is essential to recognizing hazards, threats to safety, near misses, and barriers to executing best practice. Associates must understand how and when to report safety events and hazards or near misses and leaders must create an environment that encourages reporting and learning from events. Feedback to reporters improves future reporting and improves the safety culture.

A. Ensure that all associates (including physicians) have access and know how to report events through the Patient Safety Event Management System (PSEMS).

B. Each site or department will have a Safety File Manager responsible for reviewing and mitigating risks highlighted in PSEMS reports. This associate will have access to appropriate resources including training, automated reports, and dashboards.

C. Ensure that Safety File Managers understand how to identify contributing factors and develop potential action plans. Ideally, leaders will facilitate a mechanism for reviewing and addressing reviews at a departmental or entity level, such as a biweekly Patient Safety Event (PSE) review sessions with leaders.

D. Leaders should provide 1:1 feedback to associates who report significant cases through the PSEMS. Associates should be updated regarding review results and planned actions. Leaders may

provide global generalized feedback to associates for trends identified for lower risk reports, as it may not be necessary to respond to every report.

E. *Effectively addressing PSEs may involve trending of low frequency / low risk issues in lieu of a full individual resolution or action plan for each report.

Principle 10: Best practice guidelines set by MedStar clinical practice councils, nursing leadership, and other clinical leaders will be effectively communicated, implemented, and maintained.

MedStar Health clinical leaders often create and disseminate clinical best practices, guidelines, and protocols. Leadership engagement is needed to ensure implementation and consistent use of this guidance in order to improve safety.

A. Communicate best practice guidelines set by system level clinical leaders.
B. Ensure guidelines are effectively implemented and maintained in relevant areas.

Principle 11: Safety should be actively considered in selection of any medical device that carries clinical risk.

Safety is best managed in a proactive manner, avoiding hazards altogether or fixing them before they can injure a patient. Constant attention to safety is needed in the selection and implementation of new safety-critical medical devices in order to optimize patient outcomes.

A. Include a safety assessment when considering the selection of critical new devices, starting in the earliest stages of consideration.
B. Include a safety assessment during the implementation phase of safety-critical devices and technology.
C. When relevant, events or findings should be reported to external regulators via established mechanisms such as MedSun.