

Policy Statement: The purpose of the Patient Safety Plan is to improve patient safety and reduce risk to patients through an environment that encourages:

- A culture of patient safety
- Recognition and acknowledgement of risks to patient safety and medical / health care errors.
- The initiation of actions to reduce these risks.
- The internal reporting of what had been found and the actions taken.
- A focus on processes and systems design and management by using Just Culture.
- Minimization of individual blame or retribution for involvement in a medical / health care error.
- Organizational learning about medical / health care errors.
- Support of the sharing of that knowledge to effect behavioral changes in itself and other health care organizations.
- Appropriate disclosure to patients, and when appropriate, their families, information regarding the outcomes of their care, including unanticipated outcomes, or when the outcomes differ significantly from the anticipated outcomes.

Key Definitions:

Adverse Event - Any injury caused by medical care. Identifying something as an adverse event does not imply, "error," "negligence", or poor-quality care. It simply indicates that an undesirable clinical outcome resulted from some aspect of diagnosis or therapy, not an underlying disease process.

Error - The failure of a planned action to be completed as intended (i.e., error of execution) or the use of an incorrect plan to achieve an aim (i.e., error of planning).

Human Error – Inadvertently doing other than what should have been done: a slip, lapse, or mistake.

Incident - An event, occurrence, or situation involving the clinical care of a patient in a medical facility which could have injured the patient but did not either cause an unanticipated injury or require the delivery of additional health care services to the patient.

Infrastructure Failure - An undesirable or unintended event, occurrence, or situation involving the infrastructure of a medical facility or the discontinuation or significant disruption of a service, which could seriously compromise patient safety. Infrastructure failures are reportable to the Pennsylvania Department of Health (DOH) under Act 13 and Chapter 51 of PA DOH Rules and Regulations, via PAPSRs.

Just Culture – a safety-supportive system of shared accountability in which management is accountable for good system design and responding to the behaviors of staff in a fair and just manner. In addition, staff members are accountable for the quality of their choices and for reporting errors, adverse events, and system vulnerabilities.

Near Miss - Any process variation which did not affect the patient outcome, but for which a recurrence carries a significant chance of a serious adverse outcome.

Patient Safety - Freedom from accidental injury while receiving health care services.

Root Cause Analysis (RCA) - A process for identifying the basic or causal factor(s) underlying variation in performance. An RCA focuses primarily on systems and processes, not individual performance. It progresses

from special causes in clinical processes to common causes in organizational processes and identifies potential improvements in processes or systems that would tend to decrease the likelihood of such events in the future.

Serious Event - An event, occurrence, or situation involving the clinical care of a patient in a medical facility (hospital, ambulatory surgery facility, or birthing center) resulting in death or compromising patient safety and resulting in an unanticipated injury requiring the delivery of additional health services to the patient. Serious events are reportable to the Patient Safety Authority and Department of Health, under Act 13 via PAPSRS.

Positions to Whom this Applies:

Board of Directors - The overall authority for the direction of the patient safety Plan rests with Board of Directors. The Board of Directors delegates its authority to implement and maintain the various components of the patient safety Plan to the President/Chief Medical Officer/Medical Director.

President/Chief Medical Officer/Medical Director - The President/Chief Medical Officer/Medical Director, in collaboration with administrative, managerial, medical, and clinical staff, ensures the patient safety Plan is implemented throughout the organization and integrated appropriately with other activities within the organization which contribute to the maintenance and improvement of patient safety, such as performance improvement, environmental safety, and risk management. The President/Chief Medical Officer/Medical Director will designate a qualified individual in the organization to manage the organization-wide patient safety plan/program.

Patient Safety Officer – Serving as a direct link to the facility President and Chief Medical Officer on all matters related to patient safety, this individual meets the qualifications of the Patient Safety Officer job description. This individual is responsible for the organization-wide patient safety Plan and is accountable to Board of Directors and President/Chief Medical Officer.

The patient safety officer shall:

1. Oversee the creation, review, and refinements to the patient safety plan/program.
2. Coordinate and prioritize the activities of the patient safety committee.
3. Act as the chairperson of the Patient Safety Committee
4. Develop and implement adequate information and management systems to support the activities of the patient safety Plan.
5. Identify and secure the necessary resources to fully implement the patient safety plan/program.
6. Ensure compliance with serious event, incident, and infrastructure failure reporting requirements as mandated by law/regulations or to meet accreditation standards.
7. Oversee the investigation of serious events and, as appropriate, identified incidents. In consultation with senior leaders, appoint teams to conduct RCAs as appropriate.
8. Determine whether an event constitutes an incident or serious event, as defined in Act 13, and outlined in the Plan Description, in collaboration with senior leaders and/or medical staff, when warranted. In the absence of the Patient Safety Officer, a designee will be appointed to perform this function.
9. Ensure disclosure of serious events to patients and/or families is carried out in accordance with organizational policy and law/regulations.
10. Take such action as is immediately necessary to ensure patient safety as a result of any investigation.
11. Report to the patient safety committee regarding any action taken to ensure patient safety as a result of any investigation.
12. Devise strategies to enlist medical staff, employee, and patient family input into the organization's patient safety plan.
13. Ensure the organization conducts proactive hazard analyses.
14. Serve as a member of the WellSpan Health Patient Safety Committee to assure coordination, optimum learning, and dissemination of information throughout WellSpan Health.

15. Elevate, in conjunction with the Administrator-on-Call, serious events to the system level following approved escalation standard work.
16. Ensure relevant information is elevated to and discussed at required entity committees, such as Quality Council, Medical Executive Committee, Board of Directors, etc.

Management Staff – Managers will ensure the patient safety plan/program is given high priority and will support the program.

Managers shall:

1. Assure allocation of adequate resources for organizational and departmental patient safety initiatives.
2. Assign staff to participate in risk reduction activities.
3. Ensure sufficient time is available for staff participation in patient safety activities at both the department and organizational level.
4. Reinforce reporting expectations.
5. Establish a Just Culture to encourage reporting, in which events are evaluated for both system design and behavioral choices. Staff are treated fairly – consoled for human error, coached regarding at-risk behaviors, and sanctioned for reckless choices, knowledge, and purposeful behaviors.
6. Make sure staff members complete all required patient safety education programs.
7. Supplement mandatory education programs with other patient safety education and training relating directly to the jobs performed by employees in that area of the organization.
8. Ensure safe practice by all staff through observation and use of other appropriate evaluative processes.
9. Review and investigate all safety reports for their area(s) and take appropriate actions to prevent recurrence as warranted.
10. Provide appropriate support for those involved in a serious event, including Employee Assistance Program referral when indicated.
11. Refrain from any behavior that would intimidate or in any way prevent a fellow health care worker, patient, or visitor from reporting any potential or actual incident or serious event.
12. Use the Just Culture algorithm to assess and manage events.
13. Provide applicable follow-up and close safety events reported from their department.

Medical Staff and Employees – Medical staff and employees are responsible for participating actively in the patient safety plan/program.

An active participant shall:

1. Assume responsibility for identifying processes or systems potentially leading to errors and adverse events.
2. Know and follow organizational and departmental policies and procedures applicable to assigned duties.
3. Avoid taking shortcuts; discourage others in the organization from taking shortcuts of established policies and procedures as a means of facilitating patient care. Assume accountability of their own choices.
4. Inform patients and families about care, medications, treatments, and procedures; encourage them to ask questions and participate with caregivers in the development of their treatment plan.
5. Use sound judgment and awareness of potential hazards before taking action.
6. Participate in required organizational and departmental patient safety education programs and other activities designed to improve departmental and organizational patient safety.
7. Promptly report patient safety concerns, near misses, adverse events and serious events to supervisor or the Patient Safety Officer. Enters reports into the safety reporting system as appropriate.
8. Assume responsibility for one's own professional development and education to improve individual performance and promote patient safety.
9. Refrain from any behavior that would intimidate or in any way prevent a fellow health care worker, patient, or visitor from reporting any potential or actual incident or serious event.

10. Make suggestions to improve safety.

Volunteers – Volunteers are responsible for actively participating in the WellSpan’s patient safety program/plan.

An active participant shall:

1. Know and follow organizational and departmental policies and procedures applicable to assigned duties.
2. Avoid taking shortcuts; discourage others in the organization from taking shortcuts of established policies and procedures as a means of facilitating patient care. Assume accountability of their own choices.
3. Inform patients and families about activities; encourage them to ask questions of the staff.
4. Maintain awareness of potential hazards before taking action. Refrain from any activity for which instruction has not been given.
5. Promptly report serious events and incidents in accordance with established hospital policy and procedure.
6. Make suggestions to improve safety.

Patients and Families –Each WellSpan entity recognizes patients, and their families play a critical role in ensuring patient safety. In particular, the patient and family can often serve as the final checkpoint to avoid an error or adverse outcome. As such, each WellSpan entity will provide appropriate education to patients and families to encourage patients and families to:

1. Disclose relevant medical and health information to caregivers to facilitate appropriate care delivery.
2. Report unexpected changes in a patient’s condition or perceived risks to the patient’s health and well-being to responsible caregivers.
3. Question any variation in medications, treatment, or plan of care from what the patient or family was informed to expect.
4. Complete questionnaires related to satisfaction, quality, or patient safety.

Patient Safety Committee

Composition – The Patient Safety Committee (“The Committee”) is an interdisciplinary committee required by the MCARE Act of 2002. The Committee is comprised of individuals with organizational responsibility for quality, safety, and risk management, and representatives from various clinical departments and from other committees where patient safety is of vital importance.

The committee will be composed of a minimum:

1. Patient Safety Officer
2. Ambulatory surgical centers will be composed of at least one community representative residing in the service area. Inpatient hospitals will be composed of at least two community representatives residing in this service area. Other WellSpan Health departments will be composed of at least one community representative residing in the service area. They shall not be employed by WellSpan Health.
3. Ambulatory surgical centers will be composed of at least one healthcare worker of the facility. Inpatient hospitals will be composed of at least three health care workers of the facility. Other WellSpan Health departments will be composed of at least one health care worker.
 - * No more than one member of the committee will be a member of the Board of Directors. The board member will not be counted as one of the community members.
 - * All community members of the committee will be required to sign a confidentiality attestation, which outlines their responsibilities related to sharing or discussing information addressed in the committee.

Frequency of Meetings – Ambulatory surgical centers will meet at least quarterly. Inpatient hospitals will meet at least monthly. Other WellSpan Health departments will meet at least quarterly. Attendance and minutes will be maintained at each meeting.

Responsibilities

1. Provides oversight and management of the patient safety program/plan. This includes making recommendations to organization leaders and the Board of Directors about the adequacy of resources allocated to support patient safety activities.
2. Guides the development and revision of organization-wide and departmental-specific patient safety policies and procedures to ensure compliance with law, regulation, and accreditation and professional practice standards, and to foster a non-punitive environment for error reporting.
3. Establishes and maintains processes for the reporting, tracking, and trending of incidents and other risk management investigations and activities.
4. Establishes appropriate mechanisms for the review and analysis of incidents, near misses, serious events, and infrastructure failures including the appointment of teams to conduct root cause analysis.
5. Establishes and maintains a systematic accountable process to ensure implementation of approved recommendations from RCA teams including measures of success.
6. Reviews summaries of all serious event RCAs to determine if the review has been thorough and credible and ascertained the causal factor(s). Recommends process improvements resulting from these reviews and analyses.
7. Receives and reviews reports from the patient safety officer and other internal reports from health care providers, as well as reports from the Patient Safety Authority.
8. Recommends process improvements resulting from review and analysis related to any type of event to appropriate hospital and medical staff committees.
9. Reviews entity patient safety and performance data.
10. Supports a healthy culture of safety within the hospital.
11. Conducts activities that improve the safety and quality of patient care and are conducted in the entity patient safety evaluation system.
12. Reports to the administrative officer and board of directors the number of serious events and incidents and its recommendations to eliminate future serious events and incidents.

Event Management and Reporting

Upon identification of a Serious Event, Incident, or Infrastructure Failure or any event that may cause harm to a patient, staff involved with care of the patient should:

1. Take appropriate steps to care for the patient and minimize negative outcomes.
2. Contact the patient's attending physician and other providers as appropriate to report the error, incident, or event and implement any additional therapy or treatment as ordered by the provider.
3. As appropriate, implement steps to eliminate or reduce the risk to others.
 - a. Preserve any information or evidence that may be helpful in analyzing the error, incident, or event. This includes physical evidence such as preservation of IV tubing, fluid bags, equipment such as pumps, the unit of blood, or medication labels.
 - b. Report serious events immediately to the staff member(s) immediate manager(s).
4. Complete the required incident report using the online safety reporting system or a paper-based report of the incident if Safety1st is not readily available. If a paper-based report is provided, it is the responsibility of the involved department manager to assure a computerized report is made using the online reporting system within a short period of time (no more than 72 hours).
5. Rapidly escalate all serious safety and workplace violence events to the Administrator on Call (AOC) to determine the need for a WSH Safety Event Notification Call.
 - a. Safety Event Notification Call is determined by the standard work on the Patient Safety SharePoint, on the INET.

6. Obtain appropriate support for staff members involved in the error, incident, or event as needed.

A. Internal Reporting- WellSpan Health utilizes a web-based patient safety reporting system. Every employee or staff member will utilize their WellSpan username and password to access the reporting system which is easily accessible from every PC device throughout WellSpan. Each employee or staff member will undergo training in the use of the reporting system.

* WellSpan focuses first and foremost on system process improvements and will not blame the individual(s) involved in the event or seek retribution against them or seek retribution against the individual for reporting the event. WellSpan entities will accept anonymous reports when submitted.

B. Analysis- An analysis may be conducted based on the needs of the patient safety program/plan. This review may include, but is not limited to, near misses, medication errors, patient falls, and other events or situations deemed appropriate. High-risk processes may be selected for risk assessment and hazard analysis. Selection will be based on internal needs and information published by authoritative bodies that identifies the most frequently occurring types of serious events.

C. Disclosure-

* **For WellSpan Health facilities that are subject to PA Act 13, all adverse events that meet criteria as Serious Events will result in written disclosure to the patient from the facility's Patient Safety Officer or designee per requirements of the Act.**

1. Primary responsibility for disclosure of medical errors and events is with the Medical Staff member. In cases where a difference of opinion regarding disclosure arises, the appropriate administrator will make the final decision.
2. Verbal disclosure should be made as soon after the event as is reasonably possible. Speculation should be avoided, and focus placed on what is known at the time of discussion. Answer questions and provide assurance that unanswered questions will be investigated further. Contact information should be provided as the patient/family may wish additional information.

D. External Reporting-

* **For WellSpan inpatient hospitals and ambulatory surgical centers, only.**

1. **MCARE ACT**

- a. Incidents: Minor injuries involving only first aid treatment or requiring diagnostic testing which is negative. will be considered "incidents". Incidents will be reported by using the web-based reporting tool, safety reporting system. Incidents will be sent to the Patient Safety Authority via the PA Patient Safety Reporting System (PA PSRS).
- b. Infrastructure Failures: Infrastructure Failures will be reported to the Department of Health via the PA Patient Safety Reporting System (PA PSRS) within 24 hours of the confirmation of the Infrastructure Failure.
- c. Serious Event: Serious Events will be reported to the Patient Safety Authority and Department of Health via the PA Patient Safety Reporting System (PA PSRS) within 24 hours of the confirmation of the Serious Event. This report will not be delayed for peer review of other quality investigation activities.
 - i. Additional Health Care Services – The term additional health care services, as used in this Patient Safety Plan, does not include minor first aid such as the application of a band aid or steri-strip, the application of a small amount of topical ointment, or the administration of non-prescription medication.

- 2. PA Act 52** Healthcare associated infections (HAI) as defined in Pa Act 52 will be reported as required to the National Health Safety Network (NHSN) by the Department of Infection Control. Infection Control will provide written notification to patients and/or families within seven days of such identification. HAIs that do not meet the CMS definition for NHSN reporting are still required to be reported as Serious Events by Patient Safety via PA-PSRS with written disclosure within seven days of confirmation.

CMS/DOH Deaths Associated with Restraint/Seclusion: The Patient Safety Office will report the following information to CMS Regional office by telephone or electronically, no later than the close of business on the next business day following knowledge of the patient's death.

a. For restraint/seclusion other than soft wrist restraint:

- i. Each death that occurs while a patient is in restraint or seclusion.
- ii. Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion.
- iii. Each death known to the hospital that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death, regardless of the type(s) of restraint used on the patient during this time. "Reasonable to assume" in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing or asphyxiation.
 - * The date and time of reports will be noted in the medical record.
 - * The Patient Safety Officer or her designee will also enter a PA PSRS report as an infrastructure failure for numbers 1 and 2 above, and a Serious event for number 3 above.

When no seclusion has been used and when the only restraints used on the patient are those applied exclusively to the patient's wrist(s), and which are composed solely of soft, non-rigid, cloth-like materials, this will be tracked.

- iv. Any death that occurs while a patient is in such restraints.
- v. Any death that occurs within 24 hours after a patient has been removed from such restraints.
- vi. Each entry will be made not later than seven days after the date of death of the patient.
- vii. Each entry in the restraints log will note the patient's name, date of birth, date of death, name of attending physician or other licensed independent practitioner who is responsible for the care of the patient, medical record number, and primary diagnosis(es).
 - * The date and time the death is recorded in an internal log and must be recorded on the patient's medical record.

Program/Plan Review

Together with the committee, the Patient Safety Officer will review and update the Patient Safety Plan on a yearly basis. Employees shall be notified of updated Patient Safety Plan, with an electronic version stored for all employees to view.

Confidentiality

This Patient Safety Program/Plan reviews and evaluates patient safety work product in a confidential manner. Records, data, and knowledge collected by or for the Patient Safety Committee to review shall be maintained within the entity patient safety evaluation system. Unauthorized disclosure is absolutely prohibited. Unauthorized disclosure of information by a committee member may result in discipline including loss of committee membership or termination of employment or corrective action including loss of committee membership, reprimand, or non-reappointment for any Medical Staff member.

References: *Portions of the following resources may have been consulted as part of the development of this policy. These resources are not authoritative.*

Pennsylvania Act 13 of 2002, Medical Care Availability and Reduction of Error Act

AHRQ

National Quality Forum

Submitted By: WSH Corporate Patient Safety

Document History

Version #	Approved by/Date	Published Date/ Initials	Description of Revision(s)
1	AHSC Patient Safety Committee April 26, 2023	April 26, 2023 AK	None