Organizational Structure

Name of Hospital: _____

Date: _____

Adapted from: Botwinick L, Bisognano M, Haraden C. *Leadership Guide to Patient Safety.* IHI Innovation Series white paper. Cambridge, Massachusetts: Institute for Healthcare Improvement; 2006. (Available on www.IHI.org.)

Always/ Yes	Sometimes	Never/ No	N/A	
				ORGANIZATION AND LEADERSHIP
				1. Leadership addresses strategic priorities, culture, and infrastructure:
☐	☐	☐	☐	a. Patient safety is established as a strategic priority.
☐	☐	☐	☐	b. Organizational culture is assessed.
☐	☐	☐	☐	c. A culture is established that supports patient safety.
☐	☐	☐	☐	d. Organizational infrastructure is addressed.
☐	☐	☐	☐	e. The governing board is actively and regularly engaged in the patient safety effort.
☐	☐	☐	☐	f. Progress in meeting patient safety goals is tracked, and demonstrated safety gaps are closed.
☐	☐	☐	☐	g. Risk management, quality assurance, quality improvement, credentialing, and other focused resources have been aligned and, where possible, integrated with the shared strategic aim of patient safety.
☐	☐	☐	☐	h. Leadership has been educated about patient safety and methods for improving it.
				2. Leadership engages key stakeholders.
☐	☐	☐	☐	a. It engages and captures the governing board's attention to patient safety.
☐	☐	☐	☐	b. It actively works with physician groups to improve safety.
☐	☐	☐	☐	c. It promotes and supports teamwork.
☐	☐	☐	☐	d. Patients and their family members are invited to collaborate with care providers in making clinical decisions.

Organizational Structure

Always/ Yes	Sometimes	Never/ No	N/A	
				3. Leadership communicates about and builds patient safety awareness:
☐	☐	☐	☐	a. It connects with front-line staff through programs such as IHI's WalkRounds™.
☐	☐	☐	☐	b. It has implemented safety briefings.
☐	☐	☐	☐	c. It has established a structured communication protocol (e.g., SBAR) to standardize discussions among caregivers to ensure that critical information about a patient's status is communicated effectively.
☐	☐	☐	☐	d. It has implemented crew resource management techniques.
				4. Leadership has established system-level aims, and it oversees and communicates them.
☐	☐	☐	☐	a. It has set quality and safety goals.
☐	☐	☐	☐	b. It uses adverse event tools to measure and track system performance and to establish, oversee, and communicate *system-level* aims for improvement.
				5. Leadership tracks, measures, analyzes, and improves performance.
☐	☐	☐	☐	a. It measures harm to patients over time as a system-level metric to identify targeted quality improvement projects.
☐	☐	☐	☐	b. It uses a variety of tools (e.g., Root Cause Analysis [RCA], Failure Mode and Effects Analysis [FMEA], and Agency for Healthcare Research and Quality [AHRQ] Patient Safety Indicators) to understand the underlying system properties that led to an error, and the system is redesigned to reduce the chance that the error will happen again.
☐	☐	☐	☐	c. There is an effective and easy-to-use reporting system for incidents.
				6. Staff and patients/families are supported when medical errors and harm affect them.
☐	☐	☐	☐	a. Mechanisms are in place to assist patients and families who are involved in a medical error.
☐	☐	☐	☐	b. Mechanisms are in place to assist physicians and staff who are involved in a medical error.
☐	☐	☐	☐	c. A disclosure and apology process is in place.
☐	☐	☐	☐	d. Leadership has provided systems and tools to keep staff safe.

Organizational Structure

Always/ Yes	Sometimes	Never/ No	N/A	
				7. System-wide activities and incentives are aligned.
☐	☐	☐	☐	a. The daily work of employees is organized to support deployment of strategies, and improvement projects are chosen because of their direct impact on system-level measures or support of strategic objectives.
☐	☐	☐	☐	b. Safety and quality measurements are incorporated into compensation plans for organization leaders and employees.
				8. Systems are redesigned to improve reliability.
☐	☐	☐	☐	a. Processes are designed to increase standardization, incorporate redundancies, and reduce the effect of human error.
☐	☐	☐	☐	b. Rapid response teams have been implemented.
☐	☐	☐	☐	c. Simulation is used to teach staff to recognize problems and understand the effects of their responses in preparing for error-prone, high-risk, or unusual situations.
☐	☐	☐	☐	d. A computerized provider order entry (CPOE) system has been implemented.
				9. Leadership provides the governing body with patient safety reports at least quarterly. The reports include patient safety initiatives and metrics.
☐	☐	☐	☐	a. The governing body, administration, and the leaders of the medical staff communicate regularly on issues of patient safety.
☐	☐	☐	☐	b. The governing body, administration, and the leaders of the medical staff communicate regularly on issues of performance improvement.
☐	☐	☐	☐	10. The hospital maintains a system to assure that National Patient Safety Goals and initiatives (or similar goals, such as National Quality Forum safe practices) are achieved. (Please include a brief overview with comments describing the goals your organization has adopted.)
☐	☐	☐	☐	11. There is a system in place to coordinate activities and share results between patient safety, compliance, risk management, and performance improvement.
☐	☐	☐	☐	12. There is a mechanism in place to periodically review and update all hospital-wide and department-specific policies and procedures.

Organizational Structure

Always/ Yes	Sometimes	Never/ No	N/A	
				13. The administrative policy and procedure manual addresses the following topics:
☐	☐	☐	☐	a. Incident reporting and near misses.
☐	☐	☐	☐	b. General and special consents (photographs, blood transfusions, HIV testing, blood alcohol, minors, etc.).
☐	☐	☐	☐	c. It requires that staff refer all inquiries by media, attorneys, or others seeking sensitive information to a specific person within the hospital (e.g., administrator, risk manager, public relations).
☐	☐	☐	☐	d. Patient confidentiality/security of information, including:
☐	☐	☐	☐	i. releasing information,
☐	☐	☐	☐	ii. transmitting information to physician offices (by fax, etc.), and
☐	☐	☐	☐	iii. using e-mail for communication with patients.
☐	☐	☐	☐	e. Retaining records.
☐	☐	☐	☐	14. Legal counsel provides review and oversight for information posted to the organization's Web site.
				15. Policies and procedures on informed consent include and are consistent with Centers for Medicare and Medicaid requirements.
☐	☐	☐	☐	a. Procedures require evidence of informed consent.
☐	☐	☐	☐	b. Informed consent is obtained.
☐	☐	☐	☐	c. There are guidelines for action if the patient is not able to give consent.
☐	☐	☐	☐	d. There are guidelines for action when consent is withheld or refused.
				16. The governing body, medical staff leadership, and administration collaborate:
☐	☐	☐	☐	a. to address and manage conflict among the groups and
☐	☐	☐	☐	b. to modify medical staff bylaws and rules and regulations.
☐	☐	☐	☐	17. The organized medical staff is accountable to the governing body.

Organizational Structure

Always/ Yes	Sometimes	Never/ No	N/A	
				PATIENT SAFETY
☐	☐	☐	☐	18. There is a board policy indicating a formal commitment to provide resources and support for patient safety.
☐	☐	☐	☐	19. There is a designated leader of patient safety.
☐	☐	☐	☐	a. The patient safety leader reports to the CEO, COO, chief medical officer, or other C-level executive.
☐	☐	☐	☐	b. The patient safety leader has the authority to work across all areas of the organization and carries the full support of the CEO in matters relating to patient safety.
☐	☐	☐	☐	c. The patient safety leader understands patient safety and has knowledge of effective tools and improvement methodologies.
☐	☐	☐	☐	20. There is an established and active patient safety committee.
☐	☐	☐	☐	21. There is a formal patient safety program.
				The written plan includes the following elements:
☐	☐	☐	☐	a. It addresses organizational structure and goals.
☐	☐	☐	☐	b. It outlines processes for proactive and preventive patient safety analyses:
☐	☐	☐	☐	i. risk assessment (failure mode effects analysis) on high-risk and problem-prone areas to evaluate for possible failures and to find ways to prevent failures from occurring;
☐	☐	☐	☐	ii. reporting, tracking, and evaluating incidents and near misses; and
☐	☐	☐	☐	iii. root cause analysis or other process on sentinel events.
☐	☐	☐	☐	c. It includes a process for reporting and addressing patient complaints.
☐	☐	☐	☐	d. There is a process for investigating incidents.
☐	☐	☐	☐	e. It includes a list of federal, state, and local laws and regulations monitored by the patient safety committee for compliance (OSHA, EPA, ADA, ++SMDA, EMTALA, HCQIA, etc.).
☐	☐	☐	☐	f. It includes periodic surveys or inspections for potential hazards (risk surveys of hospital clinical departments, the physical plant, etc.).
☐	☐	☐	☐	g. It outlines educational programs for orientation of new staff and continuing education for current staff.

Organizational Structure

Always/ Yes	Sometimes	Never/ No	N/A	
☐	☐	☐	☐	22. The patient safety leader or a committee conducts an annual review to determine the effectiveness of the department.
☐	☐	☐	☐	a. It reviews actions taken and documents the results.
☐	☐	☐	☐	b. It reviews hospital departments' compliance with policies that address patient safety/risk issues.
☐	☐	☐	☐	23. The patient safety committee includes representatives of administration, nursing, medical staff, performance improvement, ancillary departments, and physical plant and maintenance.
				24. The committee reviews:
☐	☐	☐	☐	a. incident and near-miss report summaries;
☐	☐	☐	☐	b. potentially compensable events;
☐	☐	☐	☐	c. hazardous materials and waste management program;
☐	☐	☐	☐	d. disaster plans and drills;
☐	☐	☐	☐	e. security plans and audits;
☐	☐	☐	☐	f. equipment policies, including preventive maintenance, repair, lock out/tag out, and user error; and
☐	☐	☐	☐	g. issues related to patient safety.
☐	☐	☐	☐	25. Risk management, patient safety, and performance improvement functions are integrated. For example:
☐	☐	☐	☐	a. Pertinent information is shared between performance improvement, patient safety, and risk management.
☐	☐	☐	☐	b. Each committee has a representative from the other disciplines.
☐	☐	☐	☐	26. The patient safety leader reviews all committee meeting minutes to identify possible patient safety and risk issues.

Organizational Structure

Always/ Yes	Sometimes	Never/ No	N/A	
				RISK MANAGEMENT
☐	☐	☐	☐	27. There is a designated risk manager.
				28. The incident reporting policy includes the following elements:
☐	☐	☐	☐	a. The risk manager reviews all incident reports, including medication error reports.
☐	☐	☐	☐	b. Incidents are reported to the risk manager within 48 hours. Serious patient injuries are reported as soon as possible.
☐	☐	☐	☐	c. All departments report incidents to risk management.
☐	☐	☐	☐	d. Incident trends are identified.
☐	☐	☐	☐	e. Frequency, severity, and causes of adverse patient care occurrences are reported to the board at least every six months.
☐	☐	☐	☐	f. Occurrence screens identify events that must be reported (e.g., unscheduled return to the OR, AMA discharges, unexpected deaths).
				29. The following statements are true with regard to the incident report form:
☐	☐	☐	☐	a. No corrective actions are documented on the incident report form.
☐	☐	☐	☐	b. The reports are confidential, and statutory protection language is used.
☐	☐	☐	☐	c. Reports are not photocopied.
☐	☐	☐	☐	30. There is a policy/practice of documenting in the medical record the facts surrounding an incident.
☐	☐	☐	☐	a. This documentation is reviewed by either the risk manager or supervisory staff to assure adequate documentation of the incident.
☐	☐	☐	☐	b. Medication errors are included in the policy.
☐	☐	☐	☐	c. The policy clearly states there will be no documentation placed in the medical record that an incident report was written or submitted for review.
☐	☐	☐	☐	d. No copies of or references to incident reports are included in the medical record.
☐	☐	☐	☐	31. The organization does not give copies of incident reports to patients, family, visitors, or employees.

Organizational Structure

Always/ Yes	Sometimes	Never/ No	N/A	
☐	☐	☐	☐	32. The risk manager manages claims for the hospital.
				a. If not the risk manager, who manages claims? _____
☐	☐	☐	☐	b. There are procedures in place for setting up claim files.
☐	☐	☐	☐	c. Claim files include date of loss, date the file was opened, dates for hearings, deadlines, all claim activity, claim documents, correspondence with the insurance carrier and defense counsel, and the resolution of the claim.
☐	☐	☐	☐	d. There is a method for securing medical records against tampering or unauthorized use.
☐	☐	☐	☐	e. All information is kept in a locked file or is locked electronically.
☐	☐	☐	☐	f. The risk manager maintains a current claims history.
☐	☐	☐	☐	g. The risk manager has authority to secure the medical record or lock the electronic HR record in the event of potentially compensable events, claims, or suits.
☐	☐	☐	☐	h. The risk manager has the authority to settle claims up to a specified amount. (If yes, the amount is documented in the hospital policy.)
☐	☐	☐	☐	33. The hospital has a policy related to the write-off of patient charges (waiver of charges, waiver of co-pay insurance, etc.) for patient injuries or patient complaints.
☐	☐	☐	☐	a. The policy is consistent with Medicare regulations and state law.
☐	☐	☐	☐	b. There is coordination with other providers (ED physicians, radiologists, surgeons, etc.), who may withhold their bills for charges related to an incident when there has been a patient injury.
☐	☐	☐	☐	34. As a courtesy, visitors who are injured on hospital property are offered the opportunity to be evaluated in the emergency department for an initial assessment.
☐	☐	☐	☐	a. Physician charges are also waived (ED physician charges, radiology charges, etc.).
☐	☐	☐	☐	b. Visitors who are injured on hospital property are given the name of a person to contact if they have additional concerns.
☐	☐	☐	☐	c. If the injury is due to unsafe practices or hazards on the premises, there is a policy to ensure immediate inspection of the area to protect others from harm.
☐	☐	☐	☐	d. Incident reports are completed for visitor injuries.

Organizational Structure

Always/ Yes	Sometimes	Never/ No	N/A	
☐	☐	☐	☐	35. There is a designated person for handling patient, family, or visitor complaints (a patient representative, risk manager, etc.).
☐	☐	☐	☐	a. There is a system for patients to communicate their concerns, and there is a mechanism for a hospital response.
☐	☐	☐	☐	b. The risk manager is notified of complaints.
☐	☐	☐	☐	c. The response to complaints is coordinated with the risk manager.
☐	☐	☐	☐	36. The risk manager is notified by the medical records department of all requests for medical records from attorneys and of requests that raise suspicion that there is a potential claim.
☐	☐	☐	☐	37. There is a hospital medical record policy on making late entries, correcting errors, or inserting an addendum.
☐	☐	☐	☐	a. Late entries that are made after the end of the shift are approved by a supervisor.
☐	☐	☐	☐	b. Late entries made after the patient's discharge are also reviewed by the risk manager/patient safety officer.
☐	☐	☐	☐	c. Late entries and addenda are prohibited from being made after notification of a claim or a legal action.
☐	☐	☐	☐	d. The policy addresses the proper format for late entries, corrections, or addenda to the record.
☐	☐	☐	☐	38. The risk manager reviews a list of patient names to be sent for bill collection and determines if potential claims exist.
☐	☐	☐	☐	39. The billing department forwards patient complaints to the risk manager.
				40. The risk manager or hospital attorney reviews hospital contracts for the following elements:
☐	☐	☐	☐	a. A description of each party's duties and responsibilities.
☐	☐	☐	☐	b. The contractor's responsibility to carry liability insurance, to provide a certificate of insurance, and to notify the hospital of changes in coverage.
☐	☐	☐	☐	c. A hold-harmless clause.
☐	☐	☐	☐	d. A statement that the contractor is not an agent, servant, or employee of the hospital.
☐	☐	☐	☐	e. A statement allowing the hospital to access the contractors' books and records related to regulatory requirements.

Organizational Structure

Always/ Yes	Sometimes	Never/ No	N/A	
☐	☐	☐	☐	41. The risk manager participates in reviewing policies and procedures for credentialing, re-credentialing, and/or delineating privileges for both the medical staff and allied health staff.
☐	☐	☐	☐	42. The risk manager verifies that hospital policy requires adequate medical malpractice insurance coverage for members of the medical staff and allied health staff.
☐	☐	☐	☐	43. The information from an investigation of a physician incident is included in the credentialing/peer review file for that physician.
☐	☐	☐	☐	44. The risk manager participates in the selection and purchase of hospital insurance policies.

PERFORMANCE IMPROVEMENT

☐	☐	☐	☐	45. There is a designated leader for performance improvement.
☐	☐	☐	☐	46. There is a formal process of gathering and analyzing internal data to identify potential areas of high organizational risk.
☐	☐	☐	☐	47. When adverse trends are identified, an investigation takes place, an action plan is developed and implemented, and the results are evaluated.
				48. At a minimum, the hospital collects and analyzes data on:
☐	☐	☐	☐	a. operative or other procedures that place patients at risk of disability or death,
☐	☐	☐	☐	b. significant discrepancies between preoperative and postoperative diagnoses,
☐	☐	☐	☐	c. adverse events related to moderate or deep sedation or anesthesia,
☐	☐	☐	☐	d. use of blood and blood components,
☐	☐	☐	☐	e. all reported and confirmed transfusion reactions,
☐	☐	☐	☐	f. results of resuscitation,
☐	☐	☐	☐	g. behavior management and treatment,
☐	☐	☐	☐	h. use of restraints and seclusion,
☐	☐	☐	☐	i. significant medication errors,
☐	☐	☐	☐	j. significant adverse drug reactions,
☐	☐	☐	☐	k. patient perception of the safety and quality of care, and
☐	☐	☐	☐	l. staffing effectiveness.

Organizational Structure

Always/ Yes	Sometimes	Never/ No	N/A	
				49. The hospital collects data on:
☐	☐	☐	☐	a. staff willingness to report adverse events, and
☐	☐	☐	☐	b. staff perception of the organization's culture (AHRQ Survey of Patient Safety Culture).
☐	☐	☐	☐	50. The hospital evaluates the effectiveness of fall-reduction activities.
☐	☐	☐	☐	51. The hospital collects and evaluates data on the effectiveness of its response to changes in or deterioration of patient condition.
☐	☐	☐	☐	52. The hospital compiles data in usable formats.
☐	☐	☐	☐	53. The hospital identifies the frequency for data analysis.
☐	☐	☐	☐	54. The hospital uses statistical tools and techniques to analyze and display data.
☐	☐	☐	☐	55. The hospital analyzes and compares data over time to identify levels of performance, patterns, and trends.
☐	☐	☐	☐	56. The hospital compares data with external sources.
☐	☐	☐	☐	57. The hospital analyzes data from core measures that, over three or more consecutive quarters, show the hospital as a negative outlier.
☐	☐	☐	☐	58. The hospital uses the results of data analysis to identify improvement opportunities.
☐	☐	☐	☐	59. Opportunities for improvement are prioritized by leaders.
☐	☐	☐	☐	60. The hospital takes action when it does not achieve or sustain planned improvements.

This interactive guide is not a standard of care. Any guidelines suggested here are not rules, do not constitute legal advice, and do not ensure a successful outcome. The ultimate decision regarding the appropriateness of any action or treatment must be made by each health care practitioner in light of all circumstances prevailing in the individual situation and in accordance with the laws of the jurisdiction in which the care is rendered.