

Patient Safety Program Manual



California
Department of
Health Services



LAC+USC
Healthcare Network



KAISER PERMANENTE®



Huntington Hospital

A private/public collaboration between Kaiser Permanente, Huntington Memorial Hospital, Los Angeles County + University of Southern California Health Care Network and California's Department of Health Services.

Preface

This manual represents California's Patient Safety Improvement project for the 2004-05 Patient Safety Improvement Corps (PSIC). The Patient Safety Improvement Corps (PSIC) is a partnership between the Agency for Healthcare Research and Quality (AHRQ) and Veterans Administration (VA). The PSIC seeks to improve patient safety by providing knowledge and skills to teams of State field staff and hospital partners selected by States.

The manual is an attempt to assist health care facilities in developing an effective patient safety program by identifying and defining elements for consideration to be included in a patient safety program.

Acknowledgments

The California Patient Safety Improvement Team would like to give a special acknowledgement to the organizations for their dedication to patient safety by sponsoring the team members' participation in the training on patient safety and participation on this patient safety program manual. As stated in this manual, patient safety begins with leadership, and it is the commitment to patient safety from Kaiser Permanente, Huntington Memorial Hospital, Los Angeles County + University of Southern California Health Care Network and California's Department of Health Services that allowed this manual to come to fruition.

The California Patient Safety Improvement Corp Team consists of:

Loriann De Martini, Pharm.D. - Department of Health Services
Suzanne Graham, RN, Ph.D. – Kaiser Permanente
Gina Henning, RN, PHN – Department of Health Services
MaryRose Repine – Department of Health Services
Sunita Saxena, M.D. – Los Angeles County + University of Southern California
Health Care Network
Kari Strang – Huntington Memorial Hospital
Gregory Umeda, Pharm.D. – Department of Health Services

This manual would not have been possible without the dedication and hard work of the California PSIC team.

Finally, funding for the PSIC came from the Agency for Healthcare Research and Quality (AHRQ) and Veterans Administration (VA). The team extends a special thanks to AHRQ and the VA for providing such support and generously giving their time and expertise.

Contents

1. INTRODUCTION	3
Background	
Patient Safety	
2. PATIENT SAFETY PROGRAM – ELEMENTS	
Leadership	5
Culture of Safety	9
Adverse Events	
a) General	15
b) Reporting	18
c) Analysis	20
d) Feedback and Communication	23
e) Adverse Events Prevention	25
Patient Disclosure of Adverse Events	29
Science of Safety General	
a) Human Factors Engineering	34
b) Failure Mode and Effect Analysis	37
c) Technology	39
Evidence Based Medicine	42
The Patient Safety Committee	46
Patient Safety Officer	50
Education and Training	55
Patient Involvement	59
Environment of Care	62
External Influences	65
Future of Patient Safety	70
3. EXAMPLES OF PATIENT SAFETY PROGRAM PLANS	73
4. RESOURCES	74

Background

Modern healthcare is a highly complex, high-risk, and error-prone activity. Not surprisingly, adverse healthcare events are a leading cause of death and injury.¹ Despite remarkable advances in health care technology and delivery, too many patients die or are disabled as a result of adverse healthcare events. Adverse healthcare events occur in all health care settings: hospitals, clinics, nursing homes, urgent care centers and surgery centers.

The Institute of Medicine's report, To Err is Human, projected between 44,000 and 98,000 deaths annually secondary to preventable medical errors in our hospitals. The higher estimate of 98,000 deaths ranks medical errors as the fifth leading cause of death in the United States – higher than motor vehicle accidents (43,458), breast cancer (42,397), or AIDS (16,516).²

Preventable injury resulting from medical errors cost the economy from \$17 billion to \$29 billion annually, half of which are healthcare cost.³

One in five Americans (22%) reported that they or a family member has experienced a medical error of some kind. Nationally, this translates to an estimated 22.8 million people with at least one family member who experienced a mistake in a doctor's office or hospital.⁴

Of those experiencing a medical error, 10 percent reported that they or a family member had gotten sicker, and about half of those said the problem was serious. Nationally, this means that an estimated 8.1 million households reported a medical mistake that was very serious.⁴

Patient Safety

Patient safety is simply defined as “the prevention of harm to patients”.⁵ Patient safety is an integral part of the delivery of quality of care and a fundamental right of all Americans. Although simple in definition, the road to ensuring patient safety in health care facilities is complex and replete with obstacles.

Health care organizations should make patient safety a declared and serious aim by establishing comprehensive patient safety programs with defined executive responsibility, operated by trained personnel and in a culture of safety.

¹ Kizer K. Safe practices for better healthcare. National Quality Forum (NQF) 2003.

² Quality of Health Care in the United States: A Chartbook, Sheila Leatherman, Ph.D. and Douglas McCarthy, The Commonwealth Fund, April 2002.

³ Institute of Medicine (US). To Err is Human: Building a Safer Health System. Washington (DC): National Academy Press; 2000.

⁴ The Commonwealth Fund 2002 - http://www.cmwf.org/newsroom/newsroom_show.htm?doc_id=223607

⁵ Institute of Medicine (US). Patient Safety Achieving a New Standard for Care. Washington (DC): National Academy Press; 2004.

Patient safety programs should

- Provide strong, clear and visible attention to safety
- Implement a just system for reporting and analyzing errors within their organizations
- Incorporate well-understood safety principles (such as best practices)
- Establish interdisciplinary team training programs for providers that incorporate proven methods of team training such as simulation
- Identify and analyze system failures such as medical errors and near misses
- Proactive evaluation and redesign of systems to improve care processes to prevent future errors
- Involve participation of patients and their families and be responsive to their inquires
- Communicate findings throughout the organization in a consistent manner
- Provide education related to patient safety science

The information presented in this manual should be treated as a gateway and a tool kit. A gateway in that each element provides basic information which is then followed by resources (books, journal articles and websites) for further review or investigation. A tool kit in that there is no one right way in the development or evaluation of a patient safety program. Therefore take what is useful and applicable and leave what is not.

The information contained in this manual is provided as advisory and is not meant as an endorsement of any particular methodology or website, but only as a collection of resources for consideration and use.

Each element contains, at a minimum, the following:

- Purpose-explains how the element relates to a patient safety program
- Discussion-provides a brief overview of the element
- Resources-provides element-specific resource information

LEADERSHIP

PURPOSE

Improving patient safety should be among the highest priorities of health care leaders and managers.

In a consensus statement from the National Quality Forum, Dr. Kenneth Kizer stated, “There simply is nothing more important in overseeing a hospital or other health care facility than ensuring it is as safe as possible for the patients.”⁶

Leadership commitment is critical for the success of a Patient Safety Program.

"Patient Safety is Every Patient's Right and Everyone's Responsibility." This mantra of Kaiser Permanente's Patient Safety Program exemplifies that responsibility of patient safety does not exclude anyone and is the responsibility of all levels of the organization.

This discussion will focus on the roles and responsibilities of senior leaders including the Board of Directors and Senior Executive and Clinical leadership (e.g. CEOs/ Medical Directors and executives who report to them).

DISCUSSION

Since the release of the Institute of Medicine's Report, “To Err Is Human”, in 1999, significant progress has been made in patient safety. One of the remaining challenges is the need to continually improve the culture of safety. This is a long-term proposition, and one that is driven first and foremost by our leaders.

The culture of an organization begins with its leadership. It is the responsibility of senior leaders to direct patient safety efforts in their organizations and to foster the culture, commitment and resources that are necessary to address and resolve system issues related to medical errors that harm patients.

Organizational decision makers, such as a Board of Directors, should be involved in patient safety activities and apprised of all issues that come up so they may provide necessary oversight and resources. For example, reports that contain information on adverse events and other patient safety issues may influence decisions on capital, technology, and human resources.

⁶ Kizer K. Patient safety: a call to action – National Forum for Health Care Quality Measurement and Reporting (NQF).

Organizational decision makers can take a leadership role in patient safety by including patient safety goals/requirements for organizational leadership and staff. Requirements could include:

- Education/Training in patient safety (e.g. patient safety science, human factors, communication and teamwork, etc.)
- Developing and implementing programs related to responsible reporting and accountability ("just culture")
- Organizational assessments in areas such as medication safety (including requirements for implementing action plans based on the assessment and follow-up measurement of the success of the action plans)
- Specific information to be provided to organizational decision makers related to patient safety (e.g. structure, process, and outcome measures)

In order to lead in the area of patient safety, leaders must understand the principles of patient safety and keep current with new developments in the field of patient safety. Leadership must also be continually attuned to the level of patient safety within their organization.

There are multiple ways that senior leaders can keep abreast of patient safety issues at their organization. One way of doing this is through assessments of the organizational culture. This is further discussed in the culture section of this document. Another leadership tool is patient safety executive walkrounds. The objectives of patient safety walkrounds are to:

- visibly demonstrate to clinicians and staff the commitment of leadership to patient safety
- clearly articulate leadership commitment to developing the infrastructure necessary to ensure responsible reporting
- identify opportunities for improvement based on issues identified during the walkrounds
- implement changes based on systems issues identified

RESOURCES

Tool Kits:

<http://www.hospitalconnect.com/hospitalconnect/index.jsp> - The American Hospital Association has several tools in their Strategies for Leadership series. This includes topics such as improving the culture of safety, doing Failure Mode Effect Analysis (FMEA), the role executives should play in patient safety, and many others.

Kaiser Permanente has developed an Executive Walkrounds Tool kit based upon its experience in implementing this leadership-based initiative. *(To request a copy, please contact the Patient Safety Department, Kaiser Permanente, at (510) 987-2820, as this material is copyright protected.)*

<http://www.ihl.org/IHI/Topics/LeadingSystemImprovement/Leadership/Tools/> - The Institute for Healthcare Improvement has developed a compendium of tools related to leadership in patient safety. The compendium contains tools in the leadership area of information gathering, culture of safety, set-up, and measurement and feedback.

<http://www.premierinc.com/all/safety/publications/11-05-full-txt.jsp#story-06> - A leadership guide offering eight steps for senior health care leaders to help their organizations achieve patient safety and high reliability is available from the Institute for Healthcare Improvement (IHI). "The Leadership Guide to Patient Safety: Resources and Tools for Establishing and Maintaining Patient Safety" introduces the concept of "reliability," defined as patients getting the intended tests, medications, information, and procedures at the appropriate time and in accordance with their values and preferences. Strategies for redesign of healthcare systems are presented using examples that IHI has gleaned from its experience in guiding organizations in improving patient safety

Major Centers/Programs:

http://www.npsf.org/html/pressrel/leadership_fellowship.html - The National Patient Safety Foundation and the Health Forum (AHA) offers a Patient Safety Leadership Fellowship. Fellows learn leadership skills in the context of patient safety science.

<http://www.npsf.org/congress/leadershipday.html> - The National Patient Safety Foundation also includes a Leadership Day at its annual Patient Safety Congress meeting. The tagline for the curriculum is, "Patient Safety Doesn't Just Happen ... It Requires a Leadership Team."

Articles:

Cohen MM, Eustis MA, Gribbins RE. **Changing the Culture of Patient Safety: Leadership's Role in Healthcare Quality Improvement.** Joint Commission Journal on Quality and Safety. 2003;29(7):329-335.

In this article, the authors describe the positive results of a Missouri community hospital's initiative to change the patient-safety culture from one of blame and punishment to a culture in which a large team of key personnel shares accountability for the development and outcomes of safety initiatives.

Frankel A, Graydon-Baker E, Neppel C, Simmonds T, Gustafson M, Gandhi TK. **Patient Safety Leadership WalkRounds.** Jt Comm J Qual Saf. 2003;29(1):16-26.

This article details the Leadership WalkRounds project implemented at the Partners Healthcare System in Boston, MA, which includes the Brigham and Womens Hospital and Massachusetts General.

Weingart SN. **Implications for practice: challenges for healthcare leaders in fostering patient safety.** Quality & Safety in Health Care. 13 Suppl 2:ii52-ii56, December 2004.

This article was written to help the reader understand the challenges facing hospital and health system executives.

Mohr JJ, Abelson HT, Barach P. **Creating Effective Leadership for Improving Patient Safety.** Quality Management in Health Care. 11(1):69-78, Fall 2002.

The authors of this article describe the importance of leadership addressing errors systemically to allow individual and organizational learning to occur.

Frankel A, Grillo SP, Baker EG, Huber CN et al: **Patient safety leadership walkrounds at partners healthcare: Learning from implementation.** Jt Comm J on Quality and Patient Safety 2005;31:423-437.

CULTURE OF SAFETY

PURPOSE

“All health care settings should establish comprehensive patient safety programs operated by trained personnel within a culture of safety.”⁶

DEFINITION

Culture of Safety - “Can be defined as an integrated pattern of individual and organizational behavior, based on shared beliefs and values that continuously seek to minimize patient harm that may result from the process of care delivery.”⁶

The key elements of a culture of safety include:

- (1) a shared belief that although health care is a high-risk undertaking, delivery processes can be designed to prevent failures and harm to participants
- (2) an organizational commitment to detecting and analyzing patient injuries and near misses
- (3) an environment that balances the need for reporting of events and the need to take disciplinary action

DISCUSSION

An organization’s culture is reflected by what it does - its practices, procedures, and processes - rather than what it claims to espouse or believe in. A safety culture is the set of assumptions and practices necessary for health care organizations to provide optimal care.

James Reason says that a safety culture has several characteristics:⁷

- 1) It is informed - leaders understand the technical, organizational, environmental, and human factors that impact error
- 2) It is just - trust pervades the organization so people report safety concerns and errors and know what constitutes unsafe practice
- 3) It values reporting - staff and leaders know the importance of accurate data and reward reporting of errors and near misses
- 4) It is flexible - responsibility for addressing immediate safety situations is given to front-line experts

⁷ Reason J. Managing the risks of organizational accidents. England: Ashgate Publishing; 1997.

It's a learning culture - organizations learn from their safety data and act on needed change solutions.

The current healthcare culture has developed in ways that do not always support a culture of safety. Although the intent of the healthcare culture is to help improve healthcare, it can lead to error-medicine and has become a high-risk industry.

Examples of healthcare culture developments include:

- Technological changes have now made medicine a high tech business. - high tech can have risks.
- Specialization can lead to fragmentation in the delivery of care, which can lead to error. Even on a single unit, care can be fragmented between multiple providers; changes in shifts, etc.
- New treatments, medications, and information is discovered every day and no one person can retain all of this information and knowledge.
- Pressures to be more productive and make better use of healthcare resources.
- Training is discipline specific and does not support communication and teamwork.
- Professionals are trained to be perfect and people who make errors are punished.

As we move toward an environment that supports and sustains a culture of safety we must consider the above as well as other factors that are discussed below and in other parts of this document. We must also recognize that changing culture is not easy and it takes time. There are certain steps that need to be taken when embarking on a culture change. These include:

- WHY? - it is important to discuss why we must change and set up the "burning platform" so there is a felt need for change
- TO WHAT? - it is important to discuss what we are changing to and set up a clear vision for change
- HOW? - need to discuss clear initial steps - how are we going to get to the change and is it achievable
- WIIFM (What's in it for me/patient)? - need to clearly articulate how changing will make the practitioner, staff and patients' life better

This discussion will focus on:

- Assessing the culture
- Responsible reporting and accountability - creating a "just culture"
- Human factors and communication and teamwork

Assessment: Prior to embarking on developing a culture of safety it is important to assess the current safety environment. This will provide a baseline that can be used to determine where efforts should be focused. There are many ways in which this can be done including interviews, focus groups, observation, attitudinal surveys etc. Performing an assessment will also allow an organization to determine what to measure after interventions are put in place to determine whether or not the intervention has had an impact on improving the perceptions of the safety environment.

For the purposes of this discussion, the focus will be on attitudinal assessments. Why attitude as a measurement? Attitudes are reliably assessed through validated research instruments and attitude predicts performance and outcomes. Additionally, attitude is malleable and while personality is fixed, training that targets attitude improves subsequent performance. Attitude and culture are linked to observed behavior and performance, and when we aggregate attitude scoring, this reflects the climate of a clinical area/organization. There are several tools available to perform an organizational attitudinal assessment to collect data across the organization. According to Sexton and Thomas,⁸ by looking at the attitudes in the aggregate, one can not only get a snapshot of the safety climate in the organization but also use the data to:

- Diagnose organizational strengths and weaknesses
- Evaluate the effects of organization changes
- Improve communication with employees
- Provide context for important organizational variables such as absenteeism and turnover
- Develop targeted interventions

Responsible Reporting and Accountability: Despite constant and committed efforts to provide safe health care, from time to time, patients are harmed due to a medical error. Because most medical errors involve multiple factors including problematic systems and processes, strategies aimed at punishing clinicians that make errors are misguided and result in severe under-reporting. This, in turn, results in an organizational inability to learn, improve, and prevent further errors. As a result, it is essential that we create a non-punitive reporting system. This requires that leadership and management are responsible for creating and sustaining an environment in which staff and physicians are able to report without fear of punishment. However, discipline should be considered in certain circumstances – see following boxed text. When an error or near miss occurs, it is the responsibility of staff/physicians to report the event through established mechanisms. It is also the responsibility of leaders, staff, and physicians to take action to address the root cause and prevent the error from happening again. Reporting should include both actual errors and near misses.

⁸ Sexton B, Thomas E. Measurement: assessing a safety culture. In Leonard M, Frankel A, Simmonds T, Vega K. Achieving Safe and Reliable Healthcare Strategies and Solutions, ACHE Management Series, Health Administration Press, 2004.

The IOM report on Patient Safety Achieving New Standard of Care states the following: “Protection is not granted for criminal behavior (e.g., a physician treating a patient while inebriated) or for active malfeasance (e.g., a nurse who purposely violated safety polices or short-circuits built-in protections)” HealthCare organizations are including wording such as this in Policies and Procedures related to Responsible Reporting. Kaiser Permanente policy states that "Punitive discipline is indicated when the employee is under the influence of drugs or alcohol; has deliberately violated rules or regulations; specifically intended to cause harm; or engaged in reckless behavior". The Veteran's Administration Handbook <http://www.patientsafety.gov/psic/s1/rcatools/handbook.pdf> points out that “The only exception to this protection would be in the case of an intentionally unsafe act as defined as a criminal act: a purposefully unsafe act; an act related to alcohol or substance abuse by an impaired provider and/or staff; or events involving alleged or suspected patient abuse of any kind”.

Reporting should not stop with errors that cause harm. It should also include errors that do not result in harm, as well as near misses. The following definitions are provided:

1. Errors that cause harm - those errors that reach the patient and injury or death occurs as a result of the error. Example: patient receives transfusion meant for another patient and has a hemolytic transfusion reaction resulting in transfer to the ICU.
2. Errors that do not cause harm - an error that has occurred, but resulted in no actual harm although harm could have resulted from the error. Lack of harm may be due to robust physiology or pure luck. Example: patient receives transfusion meant for another patient but had no reaction because there was no blood incompatibility.
3. Near Miss - a near miss is “a commission or omission that could have harmed the patient but did not cause harm as a result of chance, prevention, or mitigation.”⁵ Another way of saying this is that the error was trapped before it reached the patient. Example: Blood is about to be hung on the wrong patient, but, when nurses double check, they recognize that the name on the unit of blood does not match the patient’s identification wrist band.⁹

Although it is important to review errors and develop action plans to prevent occurrences, near misses provide us with far greater information because systems can be put in place to prevent an actual error from taking place.

Human Factors and Communication and Teamwork: Human factors is a broad science that deals with many factors influencing human performance. These factors include the physical environment, task characteristics, individual characteristics and organizational or management systems. A key strategy in this area is communication and teamwork.

⁹ Van der Schaff T, Near Miss Reporting in the Chemical Process Industry (dissertation). Eindhoven. The Netherlands Eindhoven University of Technology, 1992.

"Creating an environment centered around effective communication and teamwork offers several benefits for an organization including the following:

- Contributes to the consistent delivery of patient care
- Managing the complexity of patient care in a setting that often exceeds the capabilities of the individual physician
- Supports staff safety
- Allows staff to learn from mistakes rather than place blame
- Provides a more satisfying and rewarding work environment for staff
- Fosters an environment in which healthcare organizations can retain critically important employees such as nurses, pharmacists, and physicians."¹⁰

RESOURCES

<http://ihi.org/IHI/Topics/PatientSafety/SafetyGeneral/Tools/> - Institute of Healthcare Improvement (IHI) – provides tools to help organizations to accelerate their work to improve patient safety and develop a culture of safety. This website includes the AHRQ assessment and the University of Texas Safety Climate Survey.

www.ahrq.gov/qual/hospculture - AHRQ Hospital Survey on Patient Safety Culture

http://www.uth.tmc.edu/schools/med/imed/patient_safety/survey&tools.htm - Safety Climate Survey--University of Texas

http://www.mers-tm.net/support/Marx_Primer.pdf - Medical Event Reporting System for Transfusion Medicine. Patient Safety and the “Just Culture”. A Primer for Health Care Executives. April 17, 2001

Articles:

Leonard M, Graham, S, Taggart, B, **The Human Factor: Effective Teamwork and Communication in Patient Strategy** Achieving Safe and Reliable Healthcare, ACHE Management Series, 2004 (37-63).

Leonard M, Graham S, Bonacum D, **The Human Factor: The Critical Importance of Effective Teamwork and Communication in Providing Safe Care Quality & Safety in Health Care**, AHRQ. October 2004 (85-90).

Graham S, Monroe M, **Safety Across High-Consequence Industries** Proceedings of the conference, March 9-10, 2004. Parks School of Engineering and Aviation, School of Public Health, St. Louis, MO.

¹⁰ Leonard M, Graham S, Taggart W. The human factor: effective teamwork and communication in patient safety. In Leonard M, Frankel A, Simmonds T, Vega K. Achieving Safe and Reliable Healthcare Strategies and Solutions, ACHE Management Series, Health Administration Press, 2004.

Monroe M, Graham S, **Application of Human Factors Concepts in the Healthcare Industry**, HealthBeat, Publication of the American Society of Safety Engineers Healthcare Practice Specialty, Spring 2004.

Manuscript on **Patient Safety Executive Walkarounds** accepted for publication in AHRQ Advances in Patient Safety.

Uhlig PN, Brown J, Nason A, Camelio A, Kendall E, **John M Eisenberg Patient Safety Awards. System Innovation: Concord Hospital**, Joint Commission Journal of Quality Improvement, 2002; 28 (12): 666-72.

Tool Kits:

Human Factors - Communication and Teamwork

Kaiser Permanente has developed a Communication and Teamwork Tool kit based on its experience in implementing SBAR. SBAR is an effective and efficient way to communicate. This tool closes the gap between physician and nurse communication styles. SBAR offers a simple way to help standardize communication and allows parties to have common expectations related to what is to be communicated and how the communication is structured.

S=Situation (a concise statement of the problem)

B=Background (pertinent and brief information related to the situation)

A=Assessment (analysis and considerations of options - what you found/think)

R=Recommendation (action requested/recommended - what you want).

(To request a copy, please contact the Patient Safety Department, Kaiser Permanente, at (510) 987-2820, as this material is copyright protected.)

Videos:

Do No Harm

www.p4ps.org

Beyond Blame

www.bridgemedical.com

Josie King

www.JosieKing.org

ADVERSE EVENT GENERAL

PURPOSE

Errors are infrequently the result of one individual, but rather, are the result of a complex series of system-related problems.

An error is an event that may or may not result in an adverse outcome. The primary purpose of capturing information about adverse events is to learn from them and to prevent future occurrences. In other words, an adverse event is an event, the full benefit of which has not yet been turned to your advantage.

Proactive reporting of adverse events or near misses with systematic analysis promotes a philosophy of designing safety into processes of care.

DEFINITION

Error - “The failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.”³

Errors depend on two kinds of failure:³

- The correct action does not proceed as intended. (Referred to as error of execution)

OR

- The original intended action is not correct. (Referred to as an error of planning)

Adverse Event – “an event that results in unintended harm by an act of commission or omission rather than by the underlying disease or condition of the patient.”⁷

Near Miss - “an act of commission or omission that could have harmed the patient but did not cause harm as a result of chance, prevention, or mitigation.”⁷

Near misses are also synonymous with potential adverse events and close calls.

Sentinel Event –a type of adverse event, defined by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) as an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injuries specifically include a loss of limb or function.

DISCUSSION

An effective adverse event system incorporates the following components:

- Comprehensive adverse event detection system that incorporates both actual adverse events and near misses.
- Detection system fosters a non-punitive philosophy to reporting events.
- Effective, consistent adverse event analysis process that identifies process and/or systems that could be changed, altered, or eliminated to prevent a recurrence of the identified near miss or adverse event.
- Feedback of information and outcomes to staff.
- Commitment and support of the entity's leadership to event reporting and implementing proposed changes to the entity's operational, philosophical and cultural structure.

Errors can happen in all stages in the process of care, from diagnosis, to treatment, to preventive care.

Many, but not all, adverse events are preventable. Those that are, are considered medical errors.

A medical error may or may not result in adverse events, and adverse events may or may not be the result of errors.¹¹

Example:

New antibiotic is administered to a patient who subsequently has a severe allergic reaction. This case could be the result of a medical error, or it could be an unavoidable adverse reaction. If the medical record shows a prior allergic reaction to the type of antibiotic, or the health care team failed to ask the patient whether he or she had any allergies to medications, the adverse event (i.e., the allergic reaction) would have resulted from medical error. If, on the other hand, the patient was asked about allergic reactions and it was clear there was no history of allergy to this type of medication, the result would be an adverse event that was not the result of a medical error.

Near miss events are much more common than adverse events – as much as 7-100 times more frequent – reporting systems for such events are much less common. Incorporation of near misses into the adverse detection system provides a greater number of reports promoting meaningful statistical analysis and the opportunity to correct faulty systems before an actual adverse event occurs.⁵

¹¹ Youngberg BJ, Hatlie M. The Patient Safety Handbook.

There are several advantages to collecting and analyzing data on near misses:

- Near misses occur more often than adverse events, thus generating more data for analysis
- There are fewer barriers to reporting (shame, reprisal concerns)
- Recovery procedures can be useful in devising prevention strategies
- Reduced hindsight bias

Given the advantages, a reporting system for actual adverse events would benefit from the inclusion of near misses data.^{5,7,11}

ADVERSE EVENT REPORTING

PURPOSE

To develop a reporting system that collects data on adverse events and near misses in a proactive, non-punitive manner within a just culture. The objective is to learn from such events and identify trends that may reveal organizational, operational, cultural, systemic, and environmental problems. The more data, the greater the ability of an entity to prevent future occurrences.

DISCUSSION

To facilitate adverse event and near miss reporting the following concepts should be considered in the development or evaluation of the reporting system:

- Do not rely solely on incident or voluntary reporting. Literature has demonstrated this method as a minimally effective way to detect such events.⁵
- Sources to identify adverse events may include, but are not limited to:
 - Anonymous reporting.
 - Licensure/accreditation survey reports.
 - Infection control surveillance.
 - Legal complaints and suits.
 - Performance improvement data.
 - Retrospective clinical record review.
 - Review of complaint data.
 - Patient satisfaction surveys.
 - Automated surveillance of patient treatment data that may be a response to a patient injury.
 - Establishment of patient signals that trigger a concurrent clinical review. Examples may include unanticipated return to surgery cases or administration of reversal agents such as Romazicon or Narcan.
- Establish a non-punitive just culture environment and systems for reporting adverse events or near misses. Focus should be on fixing the system rather than fixing the blame.
- Leadership commitment to encourage and expect all employees to be alert to threats to patient safety and to feel that their contributions and concerns are respected³.
- Reporting mechanisms should encompass all staff, departments and settings.

Adverse Response Teams

Some entities have established an adverse response team as a means to facilitate data collection and maintain a culture of support. After any adverse event, members of the response team take prompt action: they keep the atmosphere in the unit calm, they do whatever is possible to mitigate harm to the patient and prevent further harm, they curtail any undue punitive action, they review what happened, and they support the family, staff and physicians. A trained response team for adverse events demonstrates commitment to a culture of support rather than a culture of blame.

Sentinel events and JCAHO accredited facilities

The sentinel event policy is designed to improve patient safety in organizations that experience serious adverse events in patient care. The policy encourages the self-reporting of medical errors to the Joint Commission that enables it to learn about the relative frequencies and underlying causes of sentinel events and to share "lessons learned" with other health care organizations, thereby reducing the risk of future sentinel events in other organizations.

RESOURCES

Program for incident and near miss reporting

University HealthSystem Consortium (UHC) <https://www.uhc.edu>

UHC is an alliance of academic health centers situated mainly in the United States. UHC provides a program for incident reporting under its patient safety net resources. UHC is a fee based membership organization.

Adverse Event Response Team

Institute for HealthCare Improvement (IHI)

<http://www.ihl.org/IHI/Topics/PatientSafety/MedicationSystems/Changes/IndividualChanges/Create+an+Adverse+Event+Response+Team.htm>

Examples of facilities with Non-Punitive Reporting Policies

Luther Midelfort – Mayo Health Systems, Wisconsin

<http://www.ihl.org/IHI/Topics/PatientSafety/SafetyGeneral/Tools/Non-Punitive+Reporting+Policy+Luther+Midelfort.htm>

Wentworth- Douglass Hospital, New Hampshire

<http://www.ihl.org/IHI/Topics/PatientSafety/SafetyGeneral/Tools/Non-Punitive+Reporting+Policy+Wentworth+Douglass.htm>

ADVERSE EVENT ANALYSIS

PURPOSE

The aim of adverse event analysis is to identify ways to improve the delivery of health care. Accomplishing this objective involves defining the adverse events to investigate, establishing methods for the detection of such events, and identifying the data needed for analysis purposed.⁵

DISCUSSION

When an adverse event or near miss occurs, the entity assesses the appropriate course of action and then determines the level of analysis and action that would be required.

Given volume of actual and potential adverse events the entity should have a systematic method to determine which events should be analyzed based on the facts and evaluation of each event(s).

Some entities utilize the Veteran's Affairs National Center for Patient Safety (VA NCPS) prioritizing scoring methodology known as the Safety Assessment Code (SAC) as a means of systematically evaluating which events warrant a thorough evaluation. See www.va.gov/ncps/matrix.html

This scoring methodology uses numerical measures for severity and probability that drives the level of analysis required.

Once a decision is made to analyze an event(s) the system utilized should be applied consistently throughout the entity.

A tool that has been used for years in other industries for the investigation of adverse events is Root Cause Analysis (RCA).

Root Cause Analysis (RCA) is a structured process for retrospectively identifying the basic or contributing causal factors that underlie variations in performance associated with adverse events or near misses.

Root Cause Analysis is based on the principles of human factors engineering and therefore focuses on weaknesses in systems and processes that may have diminished human performance. The primary objective of the analysis is to find ways of redesigning systems and processes in order to reduce the likelihood of error and to enhance human performance.

Characteristics of RCA¹²:

- The review is interdisciplinary with involvement of those knowledgeable about the processes involved in the event.
- The analysis focuses on systems and processes rather than individual performance.
- The analysis keeps asking “what” and “why” until all aspects of the process are reviewed and contributing factors are considered.
- The analysis identifies changes that could be made in systems and processes through either redesign or development of new processes, or systems that would improve performance and reduce the risk of the adverse event or close call recurrence.
- Some events that are similar in nature can be aggregated to facilitate efficient use of resources.

For entities accredited by the Joint Commission for Accreditation of Healthcare Organizations (JCAHO) there is an expectation to complete a thorough and credible root cause analysis, implement improvements to reduce risk and monitor the effectiveness of those improvements.

Another system for adverse event analysis includes the London protocol which may be accessed using the resource link listed below.

RESOURCES

Root Cause Analysis

www.patientsafety.gov - Veteran’s Affairs National Center for Patient Safety

Gano, D. Apollo Root Cause Analysis (2nd ed), Apollonian Publications, Yakima (WA), 2003

Nelms, C. What You Can Learn From Things That Go Wrong: A Guidebook to the Root Causes of Failure, Failsafe Network, Montebello (VA), 1994

<http://www.apollorca.com/> - Apollo - specializes in root cause analysis training, root cause analysis consulting, and root cause analysis software.

<http://www.failsafe-network.com/> - Failsafe Network – provides on-site, public, and web-based training and consulting to address the root causes of its failures.

<http://www.patientsafety.gov/psic/s1/rcatools/handbook.pdf> - VA Patient Safety Handbook

¹² Department of Veterans Affairs – VHA Handbook 1050.1 Transmittal Sheet – January 30, 2002

Adverse Event Analysis Tool

<http://www.ihl.org/IHI/Topics/PatientSafety/SafetyGeneral/Tools/SystemsAnalysisofClinicalIncidentsTheLondonProtocol.htm> - London Protocol - Incident Decision Tree—
United Kingdom

FEEDBACK AND COMMUNICATION

PURPOSE

Feedback to the front-line staff is a critical component of demonstrating a commitment to safety and ensuring that staff members continue to report safety issues.

DISCUSSION

Human beings, by their nature, learn from the experiences of others. Teaching others by our experiences, however, requires us to be willing to share our mistakes as well as our successes.¹³ If leadership acts upon suggestions, staff members should know their voices are heard. Additionally staff should be recognized for their contributions, especially when leadership's response would otherwise be invisible from the front lines. Maintaining a consistent flow of information from senior leadership affirms that every safety initiative is important and not a fleeting idea of the month.

Communication and Feedback Pearls¹⁴

- During the start-up period, create an environment that permits frank and open dialogue between stakeholders, even if it means keeping the groups small.
- Promote frequent communications between key parties to build trust and credibility.
- Use patient safety leadership “walkrounds” as an opportunity to provide feedback to staff, as well as to hear staff suggestions and ideas.
- Ensure that the feedback system reaches all staff members, including those who work on alternate shifts, weekends, or intermittently.
- Develop a newsletter for communicating safety information, or add a page or column to an existing newsletter. Make sure some messages come directly from senior leaders.
- Recognize and thank staff members in front of their peers for their suggestions.
- Give feedback about each suggestion even if you can't act on it: make sure the staff member who made the suggestion knows it was investigated and explain why you could not take action.
- Make responses timely, as failure to provide prompt feedback will make staff members think you don't listen or take action.

¹³ Cohen M. Medication errors. Sudbury (MA): Jones and Bartlett Publishers; 2000.

¹⁴ National Academy for State Health Policy May 2002

Communication about the importance of patient safety must be well conceived, repeated, and consistent across the entire organization. In its communication, with physicians, managers, employees, and patients, the organization should stress that safety problems are quality problems and that all persons must be involved in identifying deficiencies in current care delivery processes and in designing and executing solutions needed to create safer systems. Communicated messages must be supported by organizational behavior that reinforces the priority the organization places on patient safety to ensure that the communication is believable and, in turn, promotes the desired behavior of those practicing, working, and being cared for within the organization.

ADVERSE EVENT PREVENTION

PURPOSE

A goal of an entity's patient safety program is to prevent adverse events through proactive actions.

Those actions may include but are not limited to:

- Proactive assessment of processes to identify potential system failures using assessment tools such as Failure Mode Effects Analysis (FMEA).
- Internal surveillance to identify problem prone procedures/processes.
- Evaluation of best practices for possible incorporation.
- External surveillance such as response to external alerts.
- Education of staff on patient safety.

DISCUSSION

Failure Mode and Effects Analysis (FMEA) is a systematic, proactive method for evaluating a process to identify where and how it might fail and to assess the relative impact of different failures, in order to identify the parts of the process that are most in need of change.

Entities use FMEA to evaluate processes for possible failures and to prevent them by correcting the processes proactively rather than reacting to adverse events after failures have occurred.¹⁵

Internal Surveillance is a means to proactively monitor those procedures or processes that might be problem prone. Surveillance systems are designed to actively monitor for deviations in care processes. Use of surveillance systems in high risk processes/procedures provides a means to yield substantial reduction in potential and actual adverse events.

Best Practices includes incorporating use of evidence based medicine, technology and recommendations from advisory associations or regulatory organizations.

¹⁵ Institute for Healthcare Improvement

- Evidence Based Medicine (EBM) or practice is a means to assure systematic decisions and approaches to patient care. Decisions that are based solely on clinical instinct or experience in the absence of a consideration for scientific evidence pose risk to the system of care. EBM serves as an educational tool on which guidelines, checklists, and outcome plans can be based. Therefore, EBM allows for a standardized method to update and educate all involved health care staff. It avoids reliance on the instincts and experiences of individuals and the potential resultant conflict in decision making when opinions differ. For further information see section on Evidence Based Medicine.
- Technology – All technology has the potential to increase adverse events. Ideally, principles of human factors research, usability testing, and workflow impact should all be considered before products are released into the workplace.

Examples of current advances that have been identified to potentially reduce adverse events include but are not limited to:

- Computerized Physician Order Entry and decision support (CPOE)
- Automated medication dispensing systems
- Bar coding technology to promote accuracy of medication administering

- National Quality Forum (NQF) – “Safe Practices for Better Healthcare – A Consensus Report” 2003. The NQF, established in 1999, is a private, nonprofit corporation whose mission is to improve the American healthcare system. The NQF report details 30 healthcare practices that should be universally utilized in applicable clinical care settings to reduce the risk of harm to patients. The safe practices is not intended to capture all activities that might reduce adverse healthcare events, it has been carefully reviewed and endorsed by a diverse group of stakeholders.
- National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) – is an independent body comprised of 23 national organizations including but not limited to: American Hospital Association, American Medical Association, Food and Drug Administration, American Nurses Association and American Society of Health-System Pharmacists. The NCCMERP has developed council recommendations to promote medication error reporting and prevention. Examples of council recommendations include: “recommendations to reduce errors related to administration of drugs” and “recommendations to reduce errors due to labeling and packaging of drug products and related devices.
- Agency for Healthcare Research and Quality (AHRQ) – Medical Errors and Patient Safety website provides documents on practices to promote patient safety and reduction of medical errors such as; “30 Safe Practices for Better Health Care: fact sheet”, “Reducing Medical Errors in Health Care: fact sheet”, “Improving Health Care Quality: fact sheet” and “Five steps to safer health care”

- Joint Commission on Accreditation of Healthcare Organizations (JCAHO) National Patient Safety Goals (NPSGs) – The goals address problematic areas in health care and provide expert-based solutions to these problems.

External Surveillance – the use of information obtained from external sources to promote internal patient safety activities.

- Patient Safety Net - is a national web-based resource featuring the latest news and essential resources on patient safety. The site offers weekly updates of patient safety literature, news, tools, and meetings and a vast set of carefully annotated links to important research and other information on patient safety.
<http://psnet.ahrq.gov>
- Web based Morbidity and Mortality - online journal and forum on patient safety and health care quality. This site features expert analysis of medical errors reported anonymously and, interactive learning modules on patient safety.
<http://webmm.ahrq.gov>
- Food and Drug Administration (FDA) MedWatch Program –provides concise timely information about drugs and devices and clinically important medical product safety alerts through an E-list automated message delivery system.
www.fda.gov/medwatch/elist.htm
- Institute for Safe Medication Practice (ISMP) – a nonprofit healthcare agency comprised of pharmacists, nurses and physicians. The organization is dedicated to learning about medication errors, understanding their system-based causes, and disseminating practical recommendations that can help healthcare providers, consumers, and the pharmaceutical industry prevent errors. www.ismp.org

Education of staff on Patient Safety

Education and training of staff on patient safety is an important process in the success of a facility's patient safety program.

Education and training includes; curriculum development, staff orientation and staff evaluations. Additionally, facilities should consider safety briefings.

Safety briefings are a tool that front-line staff can use to share information about potential safety problems and concerns on a daily basis. Safety briefings help increase staff awareness of patient safety issues and create an environment in which staff shares information without fear of reprisal.

The Institute for Healthcare Improvement (IHI) provides access to a Safety Briefing tool on their website.

RESOURCES

<http://www.ahrq.gov/qual/30safe.htm> - National Quality Forum - “Safe Practices for Better Healthcare – A Consensus Report” – The NQF-endorsed set of 30 safe practices can be found at ARHQ website

www.nccmerp.org - National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP)

www.ahrq.gov/qual/errorsix.htm - Agency for Healthcare Research and Quality (AHRQ) – Medical Errors and Patient Safety

www.jcaho.com/accredited+organizations/patient+safety/05+npsg/intro.htm - Joint Commission for Accreditation for Healthcare Organizations (JCAHO) – National Patient Safety Goals

www.fda.gov/medwatch/elist.htm - FDA MedWatch Program - E-List automated message delivery system

www.ismp.org - Institute For Safe Medication Practices (ISMP)

<http://www.ihl.org/IHI/Topics/PatientSafety/SafetyGeneral/Tools/Safety+Briefings+%28IHI+Tool%29.htm> - Institute for Healthcare Improvement (IHI) – Safety Briefings (IHI Tool)

PATIENT DISCLOSURE OF ADVERSE EVENTS

PURPOSE

To ensure patients are informed of an unanticipated outcome that is injurious or potentially injurious as a result of care or treatment rendered.

Disclosure of adverse events or unanticipated outcomes of care compels an entity to examine the relationship between clinician and patient as it plays out within the medical, legal and ethical domains. It brings to the forefront the fundamental rights and responsibilities of all parties involved and forces reexamination of the accepted standards of general conduct when such events occur during the clinical process.

DISCUSSION

Dispelling Fallacies

Fallacy #1: Disclosure has limited value

Disclosure can have significant positive value. It can serve to enhance both individual clinician and overall institutional learning around error prevention, particularly if the disclosure process feeds into a quality improvement process. Since most errors arise from multiple systems shortcomings, discovery of their root causes could lead to significant improvements in patient care practices in multiple levels of the organization.¹⁶ Disclosure enables the patient to obtain timely and appropriate treatment, to better understand the situation and any future health concerns that may stem from an injury that has occurred, to be better informed about probable outcomes, and to be an active partner in making healthcare decisions.¹⁶ Research also points to the therapeutic value of disclosure to the clinician as a venue for expressing regret and for receiving forgiveness.¹⁶ On an organizational level, supporting an open disclosure policy speaks to the institution's integrity, which is demonstrated by a willingness to take ownership of its systems weaknesses and to deal with them in a constructive manner.

Fallacy #2: Disclosure always leads to litigation

Based on the results of a study of one Department of Veterans Affairs facility that had actively engaged in full disclosure over a period of several years; it was found that disclosing medical errors and unanticipated outcomes of care does not result in an increase in litigation.¹⁶ Research in this area indicates that the risk of litigation substantially increases if patients and families believe they are being deceived or

¹⁶ University of Michigan Health System Patient Safety Toolkit

mistreated by a clinician and a breach of trust has occurred. Litigation is often pursued because it is perceived as the only means of uncovering facts that weren't revealed and of obtaining an apology. Generally speaking, the weaker the relationship is between clinician and patient, and the more inadequate the communication and delivery of information is on the part of the clinician, the greater the chance that the patient or family will consider pursuing litigation. Research also suggests that in addition to obtaining a better understanding of what went wrong and an apology, what patients and families often seek is an assurance that something has been done to lessen the likelihood of the same thing happening again to others. Many patients and their families have a strong desire to see constructive changes in clinical practice as a result of what they went through, so that valuable lessons will be learned from the experience.

Fallacy #3: Error always equates to negligence.

Clinicians may believe that most medical errors or unanticipated outcomes will be perceived as negligent acts, the disclosure of which will increase their legal risk. While it is true that the manner in which a disclosure conversation plays out may enhance or minimize legal risk; if done properly, neither the disclosure of the error nor the error itself necessarily create liability. This is reinforced in the Ethics Manual of the American College of Physicians- American Society of Internal Medicine, which states; "Errors do not necessarily constitute improper, negligent, or unethical behavior..." Past studies have examined the relationship between patient injuries and malpractice claims. One major study conducted at Harvard evaluated 280 medical charts that pointed to patients being injured due to probable negligence. Their findings determined that only 47 of these actually resulting in the filing of claims against the clinician.

Method of Disclosure

The overwhelming consensus around disclosure is that it is the right thing to do. The critical question is, "At what level of error should disclosure occur?" Most organizations discover that a gray area emerges when attempting to translate, "what the right thing to do is", into actual practice. Developing and implementing criteria that clearly determine whether or not specific types of incidents should be disclosed may be challenging.

Guidelines offered by professional organizations differ around the minimum event criteria for disclosure. For example:¹⁶

- The American College of Physicians – American Society of Internal Medicine suggests disclosing if it is "material" to the patient's well being.
- The American Medical Association advises disclosing when there are "significant" medical complications.
- The Joint Commission's minimum event criterion is any "unanticipated outcome".
- The National Patient Safety Foundation bases the disclosure threshold on the occurrence of an injury.

Each institution must decide what criteria it will use in determining the threshold for disclosure.

What to Disclose?

It is recommended that disclosure take place in a timely manner following the occurrence of an incident and includes the following elements:

- Acknowledgement of the adverse event
- What happened
- How it happened
- Why it happened (To the best of your knowledge)
- What the professional or facility is going to do to assist the patient and family
- What steps have been or will be taken to reduce the likelihood of this happening in the future
- How the adverse event will affect patient care and actions taken to treat the patient
- A statement that full analysis will take place
- An expression of concern, sympathy, compassion
- Inform the patient and/or legal/surrogate representative that social services are available to the patient and family to deal with the unfavorable outcomes, including adverse outcomes

How to Disclose?

The process of disclosure involves numerous considerations that need to be made before, during and after the disclosure conversation. These include:

- Who should deliver the information
- The best timing for disclosure
- How it should be articulated
- How to remediate injury
- Ascertaining the probable causes of the negative outcome
- Sensitivity to patient's ethnic and cultural characteristics

Ethical Principles

Many professional organizations have developed Codes of Ethics and Statements of Principles urging their members to be open about disclosing errors to patients.

In its Ethics Manual, the American College of Physicians - American Society of Internal Medicine (ACP-ASIM) states: "...physicians should disclose to patients information about procedural or judgment errors made in the course of care if such information is material to the patient's well-being. Errors do not necessarily constitute improper, negligent, or unethical behavior, but failure to disclose them may."

The American Medical Association's Council on Ethical and Judicial Affairs advocates that: "It is a fundamental ethical requirement that a physician should at all time deal honestly and openly with patients. Patients have a right to know their past and present

medical status and to be free of any mistaken beliefs concerning their conditions. Only through full disclosure is a patient able to make informed decisions regarding future medical care.”

There are principles that outline standards for other professions as well. The Code of Ethics for pharmacists states, "A pharmacist has a duty to tell the truth and to act with conviction of conscience." The Code of Ethics for nurses states, "The nurse owes the same duties to self as to others, including the responsibility to preserve integrity and safety."

The National Patient Safety Foundation issued a Statement of Principle strongly encouraging: "When a health care injury occurs, the patient and the family or representative is entitled to a prompt explanation of how the injury occurred and its short and long-term effects. When an error contributed to the injury, the patient and the family or representative should receive a truthful and compassionate explanation about the error and the remedies available to the patient. Health care professionals and institutions that accept this responsibility are acknowledging their ethical obligation to be forthcoming about health care injuries and errors."

Accreditation Standards – As of July 2001, the Joint Commission on Healthcare Organizations (JCAHO) requires that information related to "unanticipated outcomes" of care be disclosed to patients. The new disclosure language resides in the chapter on Patient Rights. JCAHO Standard RI.1.2.2 states that: "Patients and, when appropriate, their families are informed about the outcomes of care, including unanticipated outcomes." The intent of the standard reflects that: "The responsible licensed independent practitioner or his or her designee clearly explains the outcome of any treatment or procedures to the patient and, when appropriate, the family, whenever those outcomes differ significantly from the anticipated outcomes."

RESOURCES

The American Society for Healthcare Risk Management has a three part series on disclosure title, “Disclosure: What works now and what can work even better.”

<http://www.hospitalconnect.com/ashrm/resources/files/Disclosure.Pt1.pdf>

<http://www.hospitalconnect.com/ashrm/resources/files/DisclosurePart2.Policy.pdf>

<http://www.hospitalconnect.com/ashrm/resources/files/Disclosure.Part3.0204.pdf>

<http://www.npsf.org/html/statement.html> - National Patient Safety Foundation – “Talking to patients about health care injury; Statement of Principle”

Tool kits

<http://www.med.umich.edu/PATIENTSAFETYTOOLKIT/disclosure.htm> - University of Michigan Health System Patient Safety Tool kit – Disclosure Chapter

Articles

Kraman, Steve S. and Hamm, Ginny, **Risk Management: Extreme Honesty May Be the Best Policy**, Annals of Internal Medicine, 131 (12) December 21, 1999, p.963-7.

Medical Mistakes: Tell Patients, Families Say Risk Managers in National Survey, QRC Advisor, 16 (11) September 2000, p.12.

Perspective on Disclosure of Unanticipated Outcome Information. Chicago, IL: American Society for Healthcare Risk Management, April 2001, 20pp.

Wu, Albert W., **Handling Hospital Errors: Is Disclosure the Best Defense?**, Annals of Internal Medicine, 131 (12) December 21, 1999, p.970-2.

Wu, Albert W, et al., **To Tell the Truth; Ethical and Practical Issues in Disclosing Medical Mistakes to Patients**, Journal of General Internal Medicine, 12(12) December 1997, p 770-5.

SCIENCE OF SAFETY GENERAL

PURPOSE

The science of safety recognizes the inherent role that safety must play in the design and daily operations of an organization. Safety should be an integral and natural part of all operations.

DISCUSSION

Three focus areas will be discussed:

- Human factors engineering.
- Failure mode and effects analysis.
- The relationship of technology to safety.

Although this discussion will treat these topics individually, it is acknowledged that they are inseparably linked.

RESOURCES

<http://www.mihealthandsafety.org/icu/1.htm> - Michigan Health and Safety Coalition has developed a science of safety tool kit for Intensive Care Units.

HUMAN FACTORS ENGINEERING (HFE)

PURPOSE

Human Factors Engineering is one of the basic sciences that support the practice of patient safety.

DEFINITION

Human Factors Engineering (HFE) has been described in several ways. It is often used interchangeably with User Interface Design or Human-Computer Interface. For the purpose of this discussion, HFE will apply to a systematic approach to the design process focusing on the interaction of the human and the system.

DISCUSSION

Human Factors Engineering is not limited to the healthcare industry. It has its roots in industries such as aviation and large scale manufacturing. Applications are varied but a fundamental feature is inclusion of the entire system when designing components of the system. Healthcare, in the majority, is delivered in a context of complex systems. Because of this, the importance of designing devices, instructions, interfaces, etc. that are cognizant of the complexity is paramount. Ill-designed labeling, the absence of information, or confusing policies and procedures, for example, can lead to serious consequences for the patient.

Attached are web links to presentations from the Patient Safety Improvement Corps relating to HFE.

<http://www.patientsafety.gov/psic/s2/resources/07a-HFEoverview.ppt>

<http://www.patientsafety.gov/psic/s2/resources/07b-Heuristics.ppt>

<http://www.patientsafety.gov/psic/s2/resources/07c-usability.ppt>

RESOURCES

<http://www.fda.gov/cdrh/humfac/1497.html> provides guidance for pre-market and design control reviewers for medical device use safety. Many of the principles can be applied in various settings.

http://www.2-sir.com/Human_Factors/ is an effort that provides links to human factors and ergonomic resources. The site lists the definition of human factors, human factors organizations, societies, handbooks, and publications.

<http://hfec.vt.edu/> is the Human Factors Engineering and Ergonomics Center (HFEEC), which is comprised of nine research laboratories and supporting facilities and is a major international center for excellence of research in human factors engineering and ergonomics.

<http://hfetag.dtic.mil/> is the Department of Defense's Human Factors Engineering Technical Advisory Group. This website contains a breadth of information on various human factors engineering subjects.

http://www.va.gov/ncps/NEWS/NCPSBg/bg_HFE.PDF - is the VA Web site for information on human factors engineering.

<http://www.usernomics.com/human-factors.html> - is a portal to research efforts as varied as: The International Journal of Man-Machine Studies to NASA.

Additionally, two websites that are special interest (medical device design and computer-person interaction) are as follows:

<http://www.devicelink.com/mddi/archive/02/05/004.html> and <http://sigchi.org>

Articles

Rogerson WT, Tremethick M.J. **Turning the tide on medical errors in intensive care units: a human factors approach**, *Dimens Crit Care Nurs*. 2004 Jul-Aug; 23(4):169-75.

Weigner MB, Slagle J. **Human factors research in anesthesia patient safety**. *Proc AMIA Symp*. 2001; 756-60.

FAILURE MODE AND EFFECTS ANALYSIS (FMEA)

PURPOSE

Failure Mode and Effects Analysis, or FMEA, is a method for determining product and process shortcomings before they occur. Conversely, it also represents an opportunity for product and process improvement.

DEFINITION

Failure Modes and Effects Analysis (FMEA) is a systematic, proactive method for evaluating a process to identify where and how it might fail and to assess the relative impact of different failures, in order to identify the parts of the process that are most in need of change. FMEA includes review of the following:

- Steps in the process
- Failure modes (What could go wrong?)
- Failure causes (Why would the failure happen?)
- Failure effects (What would be the consequences of each failure?)

Teams use FMEA to evaluate processes for possible failures and to prevent them by correcting the processes proactively rather than reacting to adverse events after failures have occurred. This emphasis on prevention may reduce risk of harm to both patients and staff. FMEA is particularly useful in evaluating a new process prior to implementation and in assessing the impact of a proposed change to an existing process.

DISCUSSION

FMEA has been used for approximately 40 years in various industry settings. The focus is on preventing a failure rather than responding to an incident that has already occurred. The tool kits below provide an introduction to the process with accompanying examples.

RESOURCES

www.va.gov/ncps/SafetyTopics/HFMEA/HFMEAIntro.doc - The Department of Veterans Affairs, National Center for Patient Safety, has developed a health care oriented FMEA process.

<http://www.ihl.org/IHI/Topics/PatientSafety/SafetyGeneral/Tools> - Institute for Healthcare Improvement (IHI) - Failure Modes and Effects Analysis (FMEA) Tool.

<http://www.fmeainfocentre.com> - FMEA Info Centre - is a non-commercial web-based inventory dedicated to the promotion of Failure Mode and Effect Analysis. Resources listed on the site include books, publications and downloads, plus updates on research and news related to FMEA in all industries.

Tool Kits:

Kaiser Permanente has a tool kit entitled “System Safety for Healthcare Professionals: A Foundation for FMEA.” For copies of this material, please contact the Patient Safety Department, Kaiser Permanente, at (510) 987-2820.

Articles:

Apkon M, Leonard J, Probst L, DeLizio L, Vitale R. **Design of a safer approach to intravenous drug infusions: failure mode effects analysis.** Qual Saf Health Care. 2004 Aug;13(4):265-71.

Isrealski EW, Muto WH, **Human factors risk management as a way to improve medical device safety: a case study of the therac 25 radiation therapy system.** Jt. Comm J. Qual Saf. 2004 Dec;30(12):689-95.

Krouwer JS, **An improved failure mode effects analysis for hospitals.** Arch Pathol Lab Med. 2004 Jun;128(6):663-7.

Uslan MM, Burton DM, Chertow BS, Collins R. **Accessibility of insulin pumps for blind and visually impaired people.** Diabetes Technology Therapy. 2004 Oct;6(5):621-34.

Duwe R, Fuchs BD, Hansen-Flaschen J. **Failure mode and effects analysis application to critical care medicine.** Crit Care Clin. 2005 Jan; 21(1):21-30, vii.

Spath PL. **Using failure mode and effects analysis to improve patient safety.** AORN J. 2003 July;78(1):16-37; quiz 41-4.

Wehrli-Veit M., Riley JB, Austin JW. **A failure mode effects analysis on extracorporeal circuits for cardiopulmonary bypass.** J Extra Corpor Technol. 2004 Dec;36(4):351-7.

Saxena S, Kempf R, Wilcox S, Shulman IA, et al. **Critical Laboratory Value Notification * A Failure Modes, Effects, and Criticality Analysis (FMECA).** Jt Comm J on Quality and Patient Safety 2005;31:495-506.

TECHNOLOGY

PURPOSE

Technology can enhance human performance to the extent that human plus technology is more powerful than either is alone. Technology integrated into care process has the capacity to discover and recover from both actual and potential medical errors.

DEFINITION

Technology can be broadly defined in healthcare as: “techniques, drugs, equipment and procedures used by health care professionals in delivering medical care to individuals and the systems within which such care is delivered.”¹⁷ The broadness of this definition is outside the scope of this document. Therefore, the discussion section which follows will outline the narrowed focus of this section.

DISCUSSION

The Agency for Health Care Research and Quality (AHRQ) sponsors evidence reports and technology assessments to improve the quality of health care. In May 2003 research¹⁸, a summary of several technology implementations were presented. These included: clinical decision support systems and nosocomial infection; dosing of nephrotoxic medications; computer enhanced laboratory assessments; computerized physician order entry; decision support features that include alerts and reminders; using decision support features that demonstrate error reduction in prescribing; and use of technology in chronic disease management and in preventive care. The state of the science in these applications is still evolving.

It should be noted that technology is not immune to creating new forms of error and failure^{19,20,21}. As mentioned in the AHRQ review, cited above, other disciplines including the military, the aviation industry, and the nuclear industry have demonstrated that caution is needed in the deployment of information systems technology. Human performance research has demonstrated, for example, the need for understanding the

¹⁷ Institute of Medicine (US). Assessing Medical Technologies. Washington (DC): National Academy Press; 1985.

¹⁸ U.S. Department of Health and Human Services, Public Health Service, AHRQ, Evidence Report/Technology Assessment. 2003 May;74. Available at: www.ahrq.gov.

¹⁹ Bottles J, Keyes M. Technology and patient safety; a two-edged sword. *Biomedical Instrumentation and Technology* 2002;36(2):84-88.

²⁰ Cook R. Safety technology: Solutions or experiments? *Nursing Economics* 2002; 20(2):80-82.

²¹ Evans CC. Healthcare technology project ownership. *J Healthc Inf Manag* 2005 Winter;19(1):34-8.

underlying process first, prior to computer automation. The complexities that arise when technology is added to the existing circumstances must then be given consideration.

The technology must be appropriately designed, introduced and monitored to ensure the expected benefits will be realized. Human factors engineering solutions can often provide guidance in enhancing the likelihood for usefulness and usability of introduced technology²².

There are several major initiatives in healthcare that are technology based. Many solutions in this scope focus on the larger issue of the use of technology for patient identification. Others seek to exploit information technology by integrating decision support software in the delivery systems. Yet others focus on technology in training applications. This discussion will focus on two subset technologies in these larger focus areas: bar coding and the use of technology in training applications.

Bar coding: This technology is being deployed for a range of applications. Two discussed in this section are transfusion therapy^{23,24,25} and prescription drug products^{26,27}.

In the case of transfusion safety, this technology is used to avoid patient misidentification. Results indicate success with the technology.

In drug applications, the use can either be for avoidance of errors at the point of care, administration of medication, or in bar coding medication at the dispensary station. Bar coded enabled point of care systems are a valuable tool for helping to ensure that the right medication reaches the right patient at the right time through the matching of the patient's ID bar coded wrist band with the bar code on the medication packages.

The Veteran's Health Administration (VHA) has been a leader in developing and using bar coded medication administration system. The VHA has developed 15 best practices²⁸. Sutter Hospital in Sacramento, California has found bar code point of care technology easy to implement in a short time frame with immediate benefits²⁹.

²² Kargh BT. Beyond usability: designing effective technology implementation systems to promote patient safety. *Qual Saf Health Care* 2004 Oct;13(5):388-94.

²³ Dzik WH, Corwin H, Goodnough LT, Higgins M, Kaplan H, Murphy M, Ness P, Shulman IA, Yomtovian R. Patient safety and blood transfusions; new solutions. *Transfusion Medication Review* 2003 July;17(3):169-80.

²⁴ Murphy MF, Kay JD. Bar Code Identification for transfusion safety. *Curr Opinion Hematol* 2004 Sep;11(5):334-8.

²⁵ Turner CL, Casbard AC, Murphy MF. Barcode technology: its role in increasing the safety of blood transfusion. *Transfusion* 2003 Sep;43(9):1200-9.

²⁶ May EL. The case for bar coding: better information, better care and better business. *Healthcare Executive* 2003 Sep-Oct;18(5):8-13.

²⁷ Anderson S, Wittwer W. Using bar-code point of care technology for patient safety. *J HealthC Qual* 2004 Nov-Dec;26(6):5-11.

²⁸ Patterson ES, Rogers ML, Render ML. Fifteen best practices recommendations for bar-coded medication administration in the Veteran Health Administration. *Jt Comm J Qual Saf* 2004 July;30(7):355-65.

²⁹ Johnson VR, Hummel J, Kinninger T, Lewis RR. Immediate steps toward patient safety. *Healthc Finance Manager*. 2004 Feb;58(2):56-61.

Training Tools: Technology provides an opportunity to enhance safety performance by understanding strengths and weakness. Two tools to accomplish this analysis include video recording and simulation.

In the health care setting, video recording of performance permits the practitioner to review his/her performance in the smallest detail. Likewise, it affords the analyst the opportunity to gather quantitative and qualitative data for training purposes that is unavailable through other mediums.

Simulation has been successfully applied in high risk organizations such as aerospace and space exploration. Simulation in healthcare, although more a technique than a technology, nonetheless relies heavily on technology for training experiences. In training experiences, health care providers can practice skills in the simulations until proficiency levels are reached that would permit safe patient care^{30,31,32}. Other types of simulation, such as augmented reality display, have also been deployed in actual health care delivery systems^{33,34}.

The future of simulation and video analysis depends on the ability of the provider community to see a linkage between these technologies and improved patient safety.

³⁰ Patrow CA. Improving patient safety through simulation technology. AHIP Cover 2004 May-June; 45(3):74-7.

³¹ Haskvitz LM, Koop EC. Students struggling in clinical? A new role for the patient simulator. J Nurs Educ 2004 Apr;43(4):181-4.

³² MacIntrye NR. Respiratory systems simulations and modeling. Respir Care 2004 Apr;9(4):401-8. discussion 408-9.

³³ Ormerod DF, Ross B, Nalwai-Cecchini A. Use of augmented reality display of patient monitoring data to enhance anesthesiologist' response to abnormal clinical events. Stud Health Techn Inform 2003;94:248-56.

³⁴ Kerner KF, Imielinska C, Rolland J, Tang H. Augmented reality for teaching endotracheal intubation: MR imaging to create anatomically correct models. AMIA Annual Symp Proc 2003:888.

EVIDENCED BASED MEDICINE (EBM)

PURPOSE

As stated in the Institute of Medicine's report,³⁵ "In today's health care system, it is widely believed that the best care for individuals is based on the training and experience of professionals. The new rules, on the other hand, could be stated: The best care results from the conscientious, explicit and judicious use of current best evidence and knowledge of patient values by well-trained, experienced clinicians."

This purpose acknowledges the use of knowledge gained from various sources in the decision making process. This broad approach integrates not only the results of randomized clinical controlled trials (which is estimated takes between 15 and 20 years to be incorporated into practice), but also results from sources such as population based data, epidemiological data, the clinical experience of the practitioners, and their knowledge of the patient's particular case. Thus, all of these sources of information can be integrated to provide the best possible care.

DEFINITION

Literature, textbooks, research studies and organizations involved in evidence based research provide a number of definitions of evidence based medicine. The common concept of these sources is to move research into clinical practice. A broad definition including these concepts would be: an approach to problem solving at the individual clinician level that requires the use of the current best evidence in making medical decisions about patients.

Specifically, evidence-based practice has been defined by the Institute of Medicine as, "The integration of the best research evidence with clinical expertise and patient values."³⁵

Best research evidence refers to clinically relevant research, often from the basic health and medical sciences, but especially from patient-centered clinical research into the accuracy and precision of diagnostic test; the power of prognostic markers; and the efficacy and safety of therapeutic, rehabilitative, and preventive regimes.

Clinical expertise is the ability to use clinical skills and past experience to rapidly identify each patient's unique health status and diagnosis, individual risks and benefits of potential interventions, and personal values and expectations.

³⁵ Institute of Medicine. Crossing the Quality Chasm. Washington (DC): National Academy Press; 2001.

Patient values refer to the unique preferences, concerns, and expectations that each patient brings to a clinical encounter and that must be integrated into clinical decisions if they are to serve the patient.

DISCUSSION

The Institute of Medicine's report, *Crossing the Quality Chasm; a New Health System for the 21st Century*, recommends ten rules for the evaluation and redesign of health care process. These rules are based on the belief that "care must be delivered by systems that are carefully and consciously designed to provide care that is safe, effective, patient-centered, timely, efficient, and equitable. Such systems must facilitate the application of scientific knowledge to practice, and provide clinicians with the tools and supports necessary to deliver evidence-based care consistently and safely."³⁵

Rule five of the ten rules states, "Evidence-based decision making. Patients should receive care based on the best available scientific knowledge. Care should not vary illogically from clinician to clinician or from place to place."³⁵

Decisions that are based solely on clinical instinct or experience in the absence of a consideration for scientific evidence pose risk to the system of care. Evidence based medicine avoids reliance on the instincts and experiences of individuals and the potential resultant conflict in decision making when opinions differ.

The promotion of evidence based medicine is not without its' critics. For example, Williams and Garner³⁶ indicate there is a concern that "too great an emphasis on evidenced-based medicine oversimplifies the complex and interpersonal nature of clinical care." Discussions of concern can be reviewed in the letters submitted to the *British Medical Journal*³⁷. Other researchers present barriers to implementation and means to overcome these challenges.^{38,39}

Additionally, some clinical specialties have sought to interpret evidence based principles and practices in the manner most appropriate to their areas. Hospitals have also highlighted their use of particular technologies for implementing evidence based medicine.

³⁶ Williams DD, Garner J. The case against "the evidence": a different perspective on evidence-based medicine. *British Journal of Psychiatry* 2002 Jan;180:8-12.

³⁷ Druss B. Evidence based medicine: does it make a difference?: Use wisely. *BMJ* 2005;330:92-94.

³⁸ Sams L, Gannon ME, Evidence-based practice and clinical work assessment. *Semin Periop Nurs* 2000 July;9(3):125-32.

³⁹ Gennaro S, Hodnett E, Kearney M. Making evidence-based practice a reality in your institution. *MCN Am J Matern Child Nurs* 2001 Sept-Oct; 26(5):236-44;quiz 245.

RESOURCES

<http://www.ebmny.org/thecontr2.html> is a partnership between the New York Academy of Medicine and the Evidence Based Medical Committee of the American College of Physicians, New York Chapter under a grant from the National Institute of Health. This website contains: “references, bibliographies, tutorials, glossaries, and on-line guides for those embarking on teaching and practicing evidence-based medicine. It offers tools to support critical analysis of the literature and MEDLINE searching, as well as other sites that help enable evidenced-based medical care.”

<http://library.umassmed.edu/EBM/> is an effort between the Lamar Soutter Library at the University of Massachusetts Medical School and the Department of Family Medicine and Community Health operating under an Innovation in Medical Education Grants Program. This site contains tutorials on EBM, describes the components of EBM, lists database resources, and provides listings of other EBM sources. In addition, the Lamar Soutter Library tab lists free resources to all users, including: systematic reviews that focus on diagnosis or therapy, summaries of EBM studies, a link to the National Guidelines Clearinghouse, meta-search tools and textbooks, links to primary source search engines and links to on-going clinical trials and clinical alerts about NIH-funded trials.

<http://www.cebm.net/> is the Centre for Evidence-Based Medicine in Oxford, UK. This website provides information on: what EBM is and is not, study designs, glossaries, download for course, a toolbox, announcement of upcoming events, and information on practicing EBM.

<http://healthpolicy.stanford.edu/stanford-ucsf-epc/> Stanford-University of California San Francisco (UCSF) Evidence-based Practice Center (EPC) – is a joint collaborative effort between Stanford and UCSF. The EPC provides an infrastructure and focal point for the conduction of high quality systematic literature reviews, supplemental syntheses, technology assessments, and generation of evidence reports.

<http://www.guideline.gov/> is the National Guideline Clearinghouse. This clearinghouse is “a public resource for evidence-based clinical practice guidelines.” The Agency for Healthcare Research and Quality (AHRQ), the American Medical Association and America’s Health Insurance Plans created this resource.

<http://www.ahrq.gov/clinic/> this AHRQ website provides links and materials on: evidence based principles, outcomes and effectiveness, technology assessments, preventive services and a link to the clinical practice guidelines.

<http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat> - HSTAT is “part of the expanded Health Services Research Information Program coordinated by NLM’s National Information Center on Health Services Research and Health Care Technology (NICHSR). NICHSR works to improve the organization and dissemination of the results of health services research, including practice guidelines and technology assessments.”

www.herts.ac.uk/lis/subjects/health/ebm.htm provides website journal references by year beginning in 1994. Listings of protocols and evidence based case reports are described. Databases with an Evidence-Based focus are linked to this website.

<http://www.cche.net/main.asp> provides User's Guides to Evidence Based Practices. "How to Use a Clinical Practice Guide" at this website provides: a sample clinical scenario, describes the steps for performing a literature research search, outlines decision questions for determining whether research recommendations are valid and provides references.

Articles

Williams JK. **Understanding evidence-based medicine: a primer.** American Journal of Obstetrics and Gynecology. 2001 Aug; 185(2):275-8.

Gordon MD. **Review of evidenced based practice for the prevention of pressure sores in burn patients.** Journal of Burn Care and Rehabilitation. 2004 Sep-Oct; 25(5): 338-410.

McKendry MJ, Van Horn J. **Today's hospital-based case manager: how one hospital integrated/adopted evidence-based medicine using InterQual criteria.** Lippincotts Case Management. 2004 Mar-Apr; 9(2): 61-71.

Mozlin R. **Evidence-based medicine.** Optometry. 2000 Aug; 71(8): 490-500.

Hougaard J. **Developing evidence-based interdisciplinary care standards and implications for improving patient safety.** Int J. Med Inform. 2004 Aug; 73(7-8):615-24.

Klardie KA, Johnson J, McNaughton MA, Meyers W. **Integrating the principles of evidence-based practice into clinical practice.** J Am Acad Nurse Pract. 2004 Mar;16(3):98,100-2, 104-5.

Sedgewick JM. **Evidence based nephrology care.** EDTNA ERCA Journal. 2003 Jul-Sep (3):143-7.

Mangelsdorff AD, Rogers J, Finstuen K, Pryor R. **U.S. Army-Baylor University Health Care Administration Program: evidence based outcomes in the military health system.** J Health Adm Edu. 2004 Winter;21(1):81-9.

Dubouloz CJ, Egan M, Vallerand J, Von Zweek C. **Occupational therapists' perceptions of evidence-based practice.** Am J. Occup Ther. 1999 Sept-Oct;53(5):537-9.

Strohschein S, Schaffer MA, Lia-Hoagberg B. **Evidence-based guidelines for public health nursing practices.** Nurs Outlook. 1999 Mar-Apr;47(2):84-9.

THE PATIENT SAFETY COMMITTEE

PURPOSE

A commitment to patient safety requires a clearly defined and coordinated approach to integrating all functions and activities that may have an impact on patients' safety. Healthcare organizations should establish a structure to ensure commitment to patient safety. There are several ways that institutions can choose to develop such a structure including establishing a committee, such as a Patient Safety Committee (PSC) or Patient Safety Steering Committee, or they can accomplish this through existing groups or committees depending upon available resources and culture of the organization.

DISCUSSION

For many hospitals, especially large institutions, a multidisciplinary PSC may be the best choice to implement a patient safety program. Many groups, clinical and non-clinical, in a big organization may work on patient safety issues within their departments but their approaches may not be coordinated across the organization and may frequently involve duplication of efforts. By improving communication among different departments and services, a patient safety committee could foster teamwork and coordination of patient safety efforts. There are additional benefits to creating a patient safety committee that even the smaller organizations may find attractive such as:

- It provides a structure for implementation of the patient safety program objectives.
- It helps the organization develop standardized approaches to providing safe care.
- It creates greater visibility of the organization's commitment to patient safety.
- It assists leaders by providing them with a comprehensive assessment of the institution's overall compliance with patient safety initiatives.

Committee Structure

The PSC is a multidisciplinary team that takes a proactive approach to patient safety. Commonly, the PSC includes physician, nursing, pharmacy and administrative leaders including the chief executive officer. The committee has representatives from clinical and non-clinical areas, quality management, risk management, and infection control. It may be beneficial to add a patient representative to the committee as an ad hoc member. Patients provide a valuable perspective on safety based on their own experiences.

The PSC may function with a patient safety officer, or its members may bear the responsibility for the program collectively. Whether an organization appoints a patient safety officer or designates a committee to oversee its patient safety program, selecting the right people for the committee is critical to the success of the program.

(An example of a Patient Safety Committee is shown in Figure 1.)

Committee Charter

The PSC will provide leadership and oversight in improving patient safety within the institution. It will accomplish this by developing standardized patient safety policies, generating and implementing a patient safety plan, creating and disseminating patient safety-related educational material, and designing implementation and monitoring tools to comply with patient safety initiatives such as the National Patient Safety Goals (NPSGs) and patient safety standards.

Committee Functions

The PSC should meet regularly. The frequency of meeting should be consistent with the scope of services provided and the needs of the facility. The PSC of a facility could be assigned the following responsibilities

Assessment

- Conduct annual surveys intended to assess:
 - The organization's culture of patient safety including employees' willingness to report errors
 - The effectiveness of the Patient Safety Program and identify priorities for the program
 - Opportunities for improving patient safety.
- Review, analyze, and act upon aggregated findings of patient safety surveys

Adverse Event Detection, Analysis and Prevention

- Encourage reporting of adverse events including near misses and patient safety related events.
- Ensure adverse events, including near misses are analyzed (e.g. root cause analysis).
- Participate, in proactive risk analyses (Failure Mode, Effects, and Criticality Analysis) selected by the leadership.
- Evaluate and incorporate evidence based medicine and consensus guidelines as appropriate.

Staff Support

- Define mechanisms for providing psychological support to staff who have been involved in an adverse event.

Patient Safety Awareness

- Establish mechanisms to promote patient safety awareness.
- Engage leadership by implementing leadership WalkRounds.
- Promote institution's participation in National Patient Safety Week.

Education

- Develop educational material on patient safety for employees and patients.

Documentation

- Maintain documentation supporting the structure, processes and evidence of effectiveness of the Patient Safety Program

Integration

- Integrate patient safety program into the organization's strategic plan and organizational plan.

Reporting

- Provide patient safety reports to hospital leadership.

National Patient Safety Goals (NPSGs) Compliance

- Oversee development of policies and monitoring procedures to document compliance with NPSGs and patients safety standards.

Annual Evaluation

Annually, members evaluate the committee's performance to ensure it is fulfilling its role. Typically, such assessment surveys involve:

- A review of committee structure, function, and membership for appropriateness.
- An assessment of effectiveness and relevance of committee's activities, goals, and priorities.
- Determination of goals and priorities for the following year.

Confidentiality

Appropriate safeguards should be established to restrict access to sensitive and confidential information protected against disclosure and discoverability through California Evidence Code 1157. All committee reports, minutes, and recommendations are kept confidential.

RESOURCES

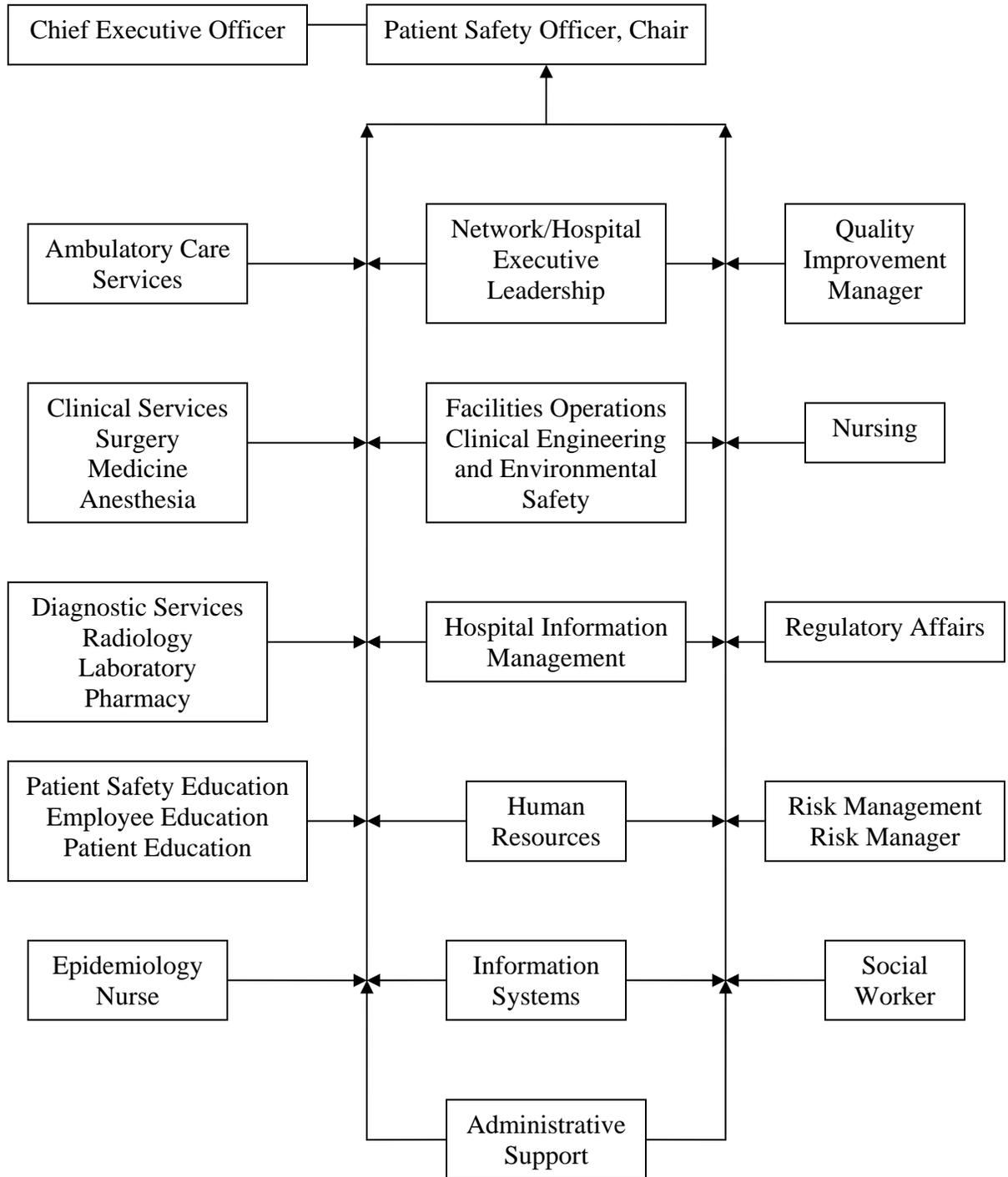
<http://www.ellishospital.org/quality2.cfm> - This page talks about a hospital's Patient Safety Committee, its meeting schedule, composition, and the awards and grants it received. It has a link to individual programs.

<http://www.opm.gov/insure/04/safety/43.asp> - This page talks about patient safety efforts, including a committee, in the Panama Canal Area which is administered by the Health Network America, which is why the address is a U.S. Government office of personnel management link.

<http://www.legis.state.pa.us/WU01/LI/BI/BT/2001/0/HB1802P3420.HTM> - The state of Pennsylvania has a lot of information on their Governor's proposal for legislation, of which one component was mandating Patient Safety committees.

<http://www.jcrinc.com/index.asp?durki=2> - Patient Safety Committees: The foundation of a safety culture.

Figure 1. An example of a Patient Safety Committee Membership



PATIENT SAFETY OFFICER

PURPOSE

The Institute of Medicine's report recommends, "All health care settings should establish comprehensive patient safety programs operated by trained personnel within a culture of safety."⁵

"Organizations fully committed to safety should designate a dedicated patient safety officer, an individual who promotes action through training of staff and implementation of proven methods. Ideally, safety would be the patient safety officer's primary assignment, not an extra task in addition to other jobs."⁴⁰

DISCUSSION

The primary role of the Patient Safety Officer (PSO) is to promote a culture of safety and coordinate the systematic implementation of an effective Patient Safety Program. The PSO contributes to the strategic planning of healthcare network through assessing, organizing, and managing the network's Patient Safety Program.

Specific Functions:

Leadership

- Direct the Patient Safety Program.
- Provide leadership for the Patient Safety Committee and ensure that the elements of the Patient Safety Plan are integrated throughout the organization.
- Serve as an internal consultant to executive council, clinical departments, other services, and performance improvement teams on patient safety initiatives.
- Serve as an advisor to medical staff on methodology for reporting medical/health care errors.
- Develop responses to Sentinel Event Alerts published by the JCAHO or other similar alerts as appropriate.

Compliance

- Develop and implement key patient safety indicators approved by the hospital leaders (e.g. National Patient Safety Goals and patient safety standards).
- Ensure ongoing monitoring of departmental patient safety compliance data

⁴⁰ <http://www.ihl.org/>

Education

- Educate staff, employees, patients/patient family, and leadership on patient safety initiatives.
- Design and implement patient safety education modules for employee orientation and continuing education.
- Maintain a consistent presence in patient safety educational activities.
- Promote patient safety awareness events.

Proactive Risk Analysis and Risk Reduction

- Integrate patient safety into performance improvement and risk reduction activities.
- Participate in proactive risk analyses (Failure Mode Effects, and Criticality Analysis) selected by the leadership.

Communication

- Provide patient safety reports at leadership meetings.
- Conduct leadership surveys intended to assess the effectiveness of the Patient Safety Program.
- Conduct organization-wide surveys for assessing employees' willingness to report errors, and for identifying opportunities to improve patient safety.

Management/Administration

- Develop policies and procedures to support an effective and comprehensive Patient Safety Program.
- Assist the Chief Executive Officer and Chief Medical Officer in implementing a robust Patient Safety Program.
- Define mechanisms for providing psychological support to staff who have been involved in a sentinel/critical clinical event.
- Maintain documentation supporting the structure, processes and evidence of effectiveness of the Patient Safety Program.
- Provide input into the budget process for expenses related to patient safety.

Skills Required

- Leadership
- Decision-making
- Accountability
- Ability to inspire others to believe in the culture of patient safety.
- Effective communication with staff, peers, and leaders to coordinate implementation of patient safety-related practices.
- Information management skills including flowcharting, data analysis and report preparation.
- Knowledge of and experience with analytic tools such as root cause analysis, Pareto charts, Failure Mode Effect Analysis, and FOCUS-PDCA improvement models.

- Familiarity with quality improvement, performance assessment, and risk management functions.
- Specialized knowledge of the accrediting and licensing regulations pertaining to patient safety.
- Management skills to complete projects in a timely manner.

Integration into Organizational Structure

- There are many models for integrating PSO position into the organization's structure. (See figures 2 through 5 for examples.)

RESOURCES

<http://www.legis.state.pa.us/WU01/LI/BI/BT/2001/0/HB1802P3420.HTM> - The state of Pennsylvania has information on their Governor's proposal for legislation, of which one component was mandating Patient Safety committees. They have a published plan, copy of the legislation, etc on their web

<http://www.ihl.org> -The Institute for Healthcare Improvement has developed a program for Patient Safety Officers. Information about this program is available on the IHI website

www.npsf.org/html/psofficer.html -National Patient Safety Foundation (NPSF)- Provides job descriptions of patient safety officers and related job titles.

Figure 2. - Integration of PSO Position into Organizational Structure

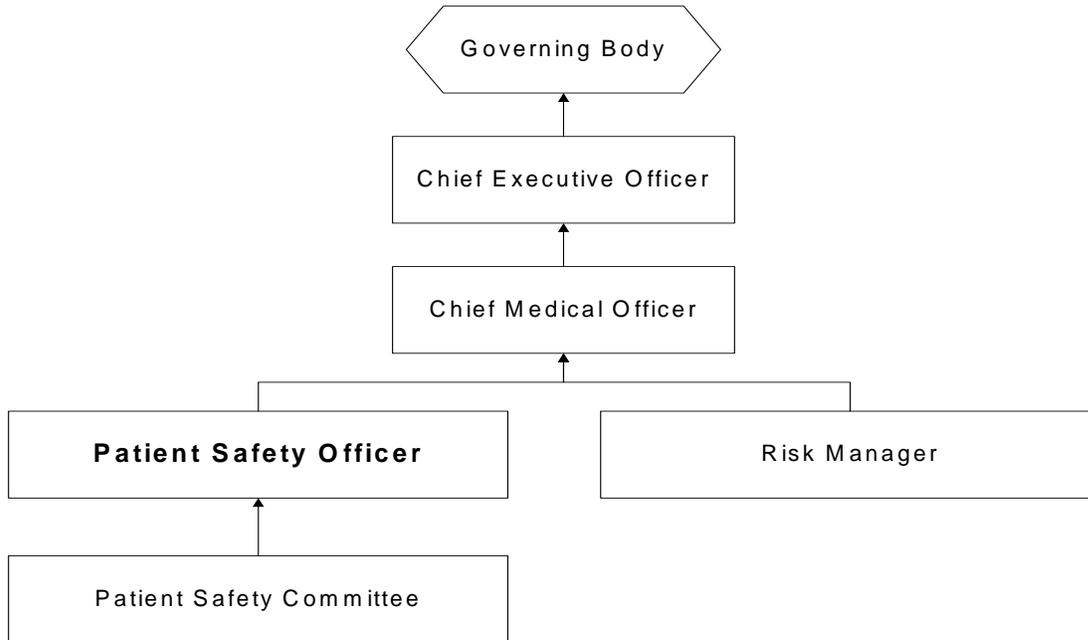


Figure 3.

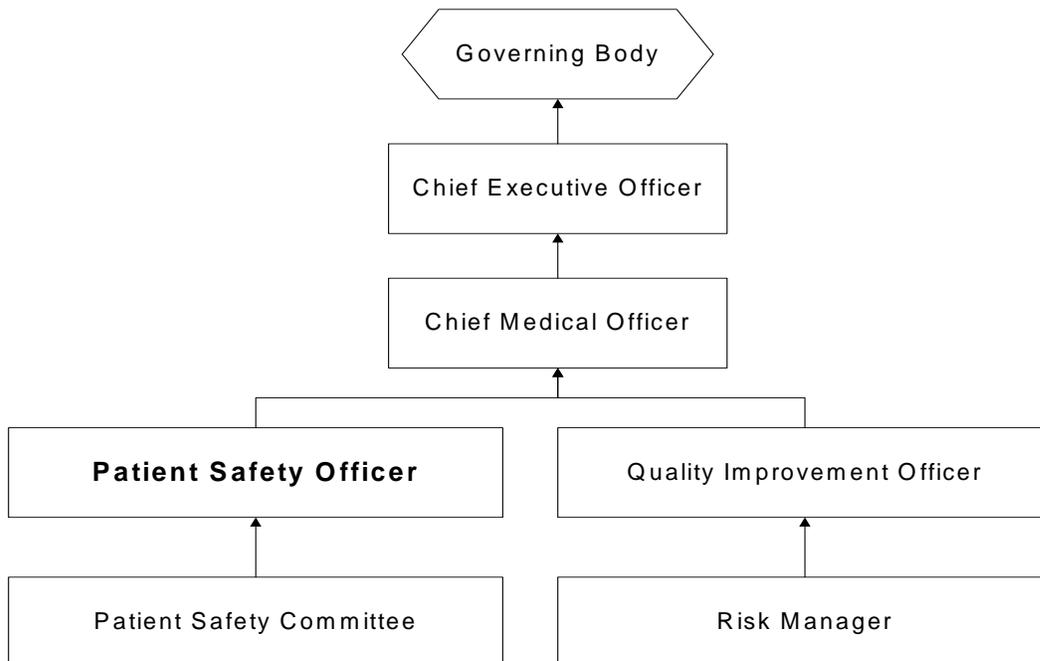


Figure 4.

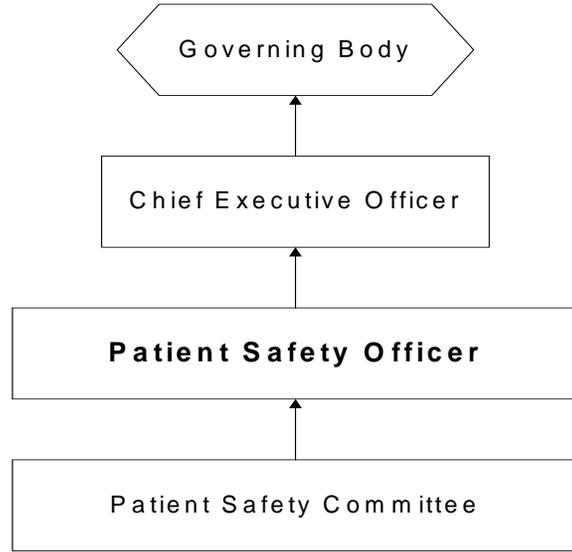
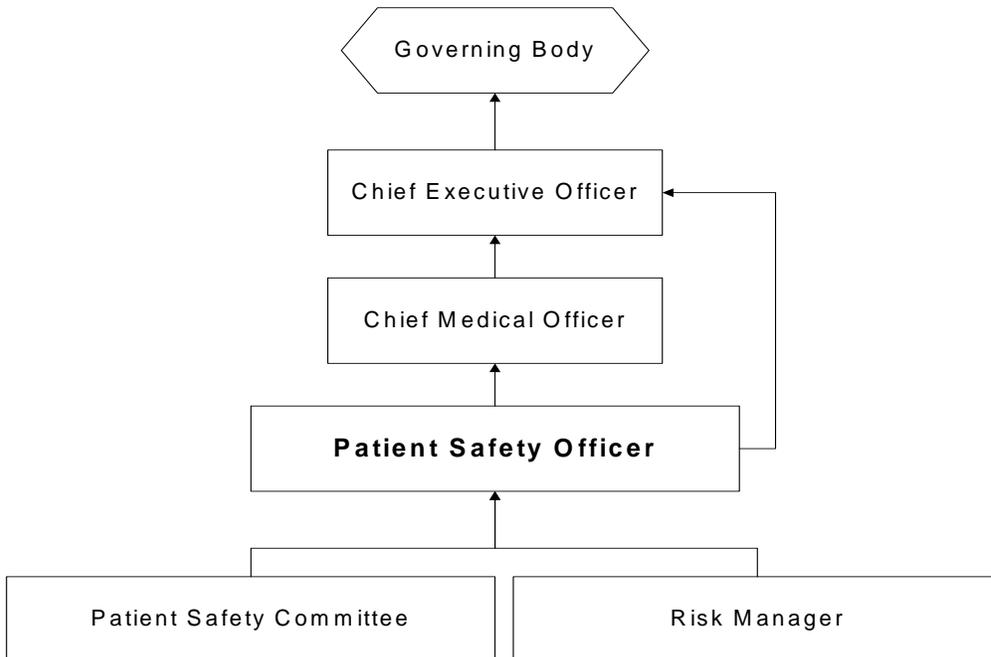


Figure 5.



EDUCATION AND TRAINING

PURPOSE

To create a culture of patient safety, it is crucial that staff and faculty embrace the institution's Patient Safety Program. This can be accomplished most successfully if they are educated and properly trained in patient safety initiatives. The training must be focused, evidence based, ongoing, and supplemented with regularly held safety awareness activities.⁴¹

DISCUSSION

New staff orientation

Orientation is the process of educating newly hired staff in health care institutions to organization-wide, departmental, and job-specific policies, procedures, and competencies before they provide patient care services.⁴²

"Newly hired staff" includes, but is not limited to, regular staff employees, contracted staff, agency (temporary) staff, float staff, part-time staff, volunteer staff, students, housekeeping, and maintenance staff. Human Resources department should incorporate patient safety into its orientation policies.

Sample topics to be included in patient safety orientation are:

- Description of the facility's Patient Safety Program.
- Procedures for reporting patient safety near misses, adverse events, and critical events.
- Institutional policy on hand hygiene.
- If applicable, JCAHO National Patient Safety Goals and/or patient safety standards.

Ongoing training

Staff, as appropriate, should participate in the following:

- In-service training to increase knowledge of patient safety requirements.
- In-service training to encourage reporting of adverse events and near misses.
- Monthly educational modules addressing patient safety issues that are updated yearly.

⁴¹ Joint Commission: Hospital Accreditation Standards, 2005, p EC-1.

⁴² Joint Commission: The Source, Volume 3, Number 3, March 2005, pp. 3-4(2).

Sample modules to be included in monthly education:

TOPIC NO.	MONTH	TOPIC
1	January	Introduction to Patient Safety - JCAHO National Patient Safety Goals
2	February	Reportable Events/Sentinel Events
3	March	Restraints
4	April	Medication Administration
5	May	Blood Transfusion
6	June	Patient Education
7	July	Avoiding Wrong Site/Side/Person Surgery
8	August	Infection Control/Hand Hygiene
9	September	Clinical Alarms
10	October	Security Issues
11	November	Environmental Hazards
12	December	Injury Prevention (Falls)

Graduate medical education (GME) training programs

According to the Association of American Medical Colleges (AAMC), graduate medical education (GME) can make significant improvements in patient safety by incorporating it into the GME curriculum. Knowledge on patient safety must be integrated and embedded in day-to-day practice to create a sustained change in the behavior of house staff, faculty, and organizations. Ideally, patient safety education should begin in medical schools and should be required in all health care professional schools. Educational curricula needs to incorporate information about human factors, building patient safety culture, pro-active approaches to reducing risk, event reporting and event analysis. The curriculum must be based on adult learning principles and team training.⁴³

In addition to monthly education on patient safety designed for all employees, residency training might include specific patient safety activities such as:

- Procedure-specific credentialing of residents under faculty supervision.
- Participation in clinical service’s mortality and morbidity conferences to learn how to analyze errors encountered in the provision of patient care and prevent future occurrences.⁴⁴

⁴³ Philibert I. Patient Safety and Graduate Medical Education. Accreditation Council for Graduate Medical Education February 2003.

⁴⁴ Philibert I. Patient Safety and Graduate Medical Education. Accreditation Council for Graduate Medical Education August 2004.

- Involvement in multidisciplinary root cause analyses of sentinel events, errors and near misses as opportunities for patient safety improvements.
- Participation in institutional quality improvement, blood utilization and patient safety committees.
- Mastery of specific curriculum on the ethics of patient disclosure of adverse outcomes.
- Awareness of institutional web sites where residents could report actual or potential errors and near misses anonymously.
- Training to encourage patient and family participation in medical decision-making, i.e. the “Speak Up” campaign.

Training and orienting staff effectively

Effective training programs for employees can take many forms. Organizations may wish to use web based or paper based training programs, and utilize the following aides:

- Case studies and problem-based exercises
- Simulation techniques
- Classroom instruction
- Self-instructional training packets with pre- and post-tests
- Multi-media presentations
- Computer-aided training
- Videotapes
- Outside education programs

Team Training

People work together in diverse groups throughout healthcare whether it’s an interdisciplinary team assembled for management of specific clinical condition or the operation of a clinical care unit such as the emergency room or surgical services. However, members of the team are typically trained in separate disciplines and educational programs. They may not appreciate each other’s strengths or recognize weakness except in crises, and they may not have been trained together to use new or well-established technologies.

Facilities should establish team training programs for personnel that are expected to work in teams especially for management of high risk procedures, care processes or clinical care units. Simulation is an effective training technique that should be considered in the development of team training programs.³

Documenting Orientation and Training

It is important to document all job-specific orientation and training activities in employee's file. Some of the ways organizations can document training include:

- Checklists that house the competencies required of the position.
- Documenting continuing education courses completed.
- Using computer-based training can help automate the documentation process. When an individual completes a computer-based training program, the computer can be programmed to send an e-mail to the appropriate individual who is responsible for maintaining documentation of the training program in the individual's file.

Assessing the effectiveness of an orientation and training program

It is important to determine whether the organization's training and orientation programs are effective. Pre- and post-tests, aggregate scores for all individuals taking the course, surveys of participants, and direct observation are among some of the methods institutions can utilize to measure the effectiveness of their programs.

RESOURCES

www.med.umich.edu/patientsafetytoolkit/overview.htm - University of Michigan Health System Patient Safety Tool kit provides a chapter on "Safety Plan Chapter."

<http://www.opm.gov/insure/04/safety/43.asp> - This page talks about the patient safety efforts, including their committee, in the Panama Canal Area which is administered by the Health Network America, which is why the address is a U.S. Government office of personnel management link.

<http://www.patientsafety.gov/psc/pscurric.html> - This is a Patient Safety Curriculum Tool kit put together by the V.A. National Center for Patient Safety.

PATIENT INVOLVEMENT

PURPOSE

“Patient safety programs should invite the participation of patients and their families and be responsive to their inquiries.” – One of the seven recommendations from the Institute of Medicine’s report.⁵

DEFINITION

Over the past 10 years, patient involvement in their medical care evolved to the extent that a new term, “patient-centered care” was coined. The Institute of Medicine’s report, *Crossing the Quality Chasm – A New Health System for the 21st Century*, provides several dimensions of “patient-centered care.” Those dimensions include:

- Respect for patients’ values, preferences, and expressed needs
- Coordination and integration of care across boundaries of the system
- Provide the information, communication, and education that people need and want
- Guarantee physical comfort, emotional support, and the involvement of family and friends

DISCUSSION

“Care that is truly patient-centered considers patients’ cultural traditions, their personal preferences and values, their family situations, and their lifestyles. It makes the patient and their loved ones an integral part of the care team who collaborate with health care professionals in making clinical decisions. Patient-centered care puts responsibility for important aspects of self-care and monitoring in patients’ hands — along with the tools and support they need to carry out that responsibility. Patient-centered care ensures that transitions between providers, departments, and health care settings are respectful, coordinated, and efficient. When care is patient centered, unneeded and unwanted services can be reduced.”⁴⁵

Literature demonstrates that even modest amounts of patient and family-centered care is associated with improved clinical outcomes, patient loyalty, increased patient safety, and is linked to higher employee satisfaction. Patients who are given sufficient amounts of the right information and support will show greater confidence in their ability to manage their care and as a result use fewer health care resources.⁴²

⁴⁵ www.ihl.org/IHI/Topics/PatientCenteredCare/PatientCenteredCareGeneral

There is a variety of ways to encourage participation of patients in their care. Some suggestions include:

- Educate patients and their families on their right and responsibility to be actively involved in healthcare decisions and implementing their medical treatment plan. This can be accomplished through use of direct mailers to health plan consumers, inclusion of information on admission agreements, facility posters in common areas or included as part of the patient intake process.
- Focus groups to survey patients on their perception of patient safety and to identify barriers to involvement of patients in their care. Questions can include:
 - What is patient safety?
 - What are medical mistakes?
 - Why do you think medical mistakes happen?
 - Does this healthcare organization deliver safe medical care?
 - How can patients prevent further medical mistakes?
- Use of easy-to-read brochures that list specific patient suggestions on how to be more active in their care. An example is the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) “Speak Up” brochure. It is support material for the Speak Up program that urges patients to get involved with their care. Kaiser Permanente has a similar brochure from for patients, “Patient Safety – What You Can Do.” *(To request a copy, please contact the Patient Safety Department, Kaiser Permanente, at (510) 987-2820, as this material is copyright protected.)*
- Distribution of educational materials on specific patient safety issues. Kaiser Permanente has produced a tip sheet; “Understanding Your Medication” for three consumer audiences, adults, seniors and children. Understanding Your Medication gives medication tips for the home and suggests questions to ask in the pharmacy and in the doctor’s office. *(To request a copy, please contact the Patient Safety Department, Kaiser Permanente, at (510) 987-2820, as this material is copyright protected.)*

Develop a Patient Safety Advisory Council for patients and their families. This will open the door for consumers to have an ongoing voice in medical center-wide patient safety activities. Councils can support and complement existing patient safety initiatives. This may create an atmosphere that encourages patients and their family members to take an active role in safe healthcare. The council can also be used as a consulting group for medical center patient safety projects, including hospital design and literature for patients. As the council develops, their role may broaden to include designing safe delivery systems that are responsive and cost-effective, as well as serving on other medical center committees.

RESOURCES

<http://www.familycenteredcare.org> - The Institute for Family-Centered Care, a non-profit organization, provides essential leadership to advance the understanding and practice of family-centered care. The website contains information for consumer advisers, a catalogue of brochures, videos, publications and guides. It also has links to other family-centered resources.

<http://www.npsf.org/html/patients.html> - The National Patient Safety Foundation is a resource for individuals and organizations committed to improving the safety of patients. The website offers information patients as well as hospitals, healthcare professionals, health care leaders, companies and researchers. There is information on their Patient and Family Advisory Council and links to Focus on Patient Safety - NPSF's quarterly publication.

<http://www.jcaho.org/general+public/gp+speak+up/speak+up+initiative.htm> - The Joint Commission on Accreditation of Healthcare Organizations offers information for patients on their “Speak Up” campaign as well as on wrong site surgery, infection control and medication mistakes.

<http://www.patientsafety.org> - Consumers Advancing Patient Safety is a good resource for consumers who want to know what is happening in patient centered care on a national level.

Articles

Berntsen KJ. **The Patient’s Guide to Preventing Medical Errors**, (2004). Westport, Connecticut, Praeger

Spath P. **Partnering with Patients to Reduce Medical Errors** (2004). Chicago: Health Forum, Inc, Aha Press

Webster PD, Johnson B. **Developing and Sustaining a Patient and Family Advisory Council**, Institute for Family-Centered Care. (2000) Maryland: Institute for Family-Centered Care.

Fact sheets for patients:

Agency for healthcare Research and Quality: <http://www.ahrq.gov>

Association of periOperative Nurses: <http://patientsafetyfirst.org>

Council on Family Health: <http://www.cfhinfo.org>

Institute for Safe Medication Practices: <http://www.ismp.org>

National Council on Patient Information and Education: <http://www.talkaboutrx.org>

ENVIRONMENT OF CARE

PURPOSE

There are many environmental elements that impact patient safety, including security, construction, use and treatment of hazardous materials, facility layout and design.

A successful patient safety program is predicated on consideration of the environment of care and its' impact on patient safety.

DEFINITION

The "environment of care" is made up of three basic components: building(s), equipment, and people.⁴¹ Effective management of the environment of care includes using processes and activities to do the following⁴⁶:

- Reduce and control environmental hazards and risks.
- Prevent accidents and injuries.
- Maintain safe conditions for patients, staff, and others coming to the hospital's facilities.
- Maintain an environment that is sensitive to patient needs for comfort, social interaction, and positive distraction.
- Maintain an environment that minimizes unnecessary environmental stresses for patients, staff, and others coming to the hospital's facilities.

DISCUSSION

There should be a method for coordinating the effective management of environment of care and the patient safety program activities. The model for the coordination of environment of care and patient safety will vary depending upon the organization.

This discussion will provide the two most common methods for incorporating management of the environmental of care with the patient safety program.

Model One: This model keeps environment of care and patient safety separate in terms of the committee and support structures.

⁴⁶ JCAHO accreditation manual 2003

It is essential however that environment of care status, measures and action plans be incorporated into the patient safety committee. It is also important that environmental issues be a part of the patient safety improvement priorities, in order to demonstrate the successful integration of environmental safety into a patient safety program.

Model Two: This model supports two separate structures that are integrated at an oversight level. For example, the environment of care may be coordinated under an environment of care committee or under the direction of an individual (e.g. environmental safety expert). Patient safety has a different committee and sub committee structure (e.g. medication safety, communication and education, and clinical safety measurement/monitoring). In this model, the “two arms”; EOC and patient safety may then be combined into an integrated safety committee, which incorporates all elements of safety for patients, employees and visitors.

Each of these models needs to be evaluated to determine the best fit for an organization prior to adopting either approach.

RESOURCES

<http://gundluth.org/web/misc/scope.nsf> - Safety Collaborative for the Outpatient Environment (SCOPE). This tool kit was developed to help medical providers evaluate their offices' practices in identified structural and process measures that relate to patient safety.

<http://www.osha.gov> - U.S. Department of Labor Occupational Safety & Health Administration. OSHA's mission is to assure the safety and health of America's workers by setting and enforcing standards; providing training, outreach, and education; establishing partnerships; and encouraging continual improvement in workplace safety and health.

<http://www.jcaho.org> - The Joint Commission has numerous standards that help to outline elements for incorporating environmental safety into a patient safety program. For the text copy of the standards, see the 2004 Hospital Accreditation Standards, Joint Commission, copy write 2004 by the Joint Commission on Accreditation of Healthcare Organizations, Joint Commission Resources, Inc (JCR).

RESEARCH EXAMPLES

The Institute of Medicine was asked by the Agency for Healthcare Research and Quality of the US Department of Health and Human Services to study the working conditions of nurses and their relationship to patient safety. This project identified:

- key aspects of the work environment for nurses that likely have an impact on patient safety; and

- potential improvements in health care working conditions that would likely increase patient safety.

The report's findings and recommendations address the related issues of management practices, workforce capability, work design, and organizational safety culture. Actions needed from the federal and state governments, as well as from coalitions of parties involved in shaping the work environments of nurses also are specified.

The report presents evidence from health services, behavioral and organizational research, and human factors and engineering to address pressing public policy questions, including nurse staffing levels, nurse work hours, and mandatory overtime.

Keeping Patients Safe: Transforming the Work Environment of Nurses, Institute of Medicine *Report*, November 4, 2003

Current AHRQ research on Working Conditions and Patient Safety – www.ahrq.gov/news/workfact.htm includes the following research topics

Impact of Nurses' Workload and Working Conditions
Effects of Fatigue and Stress
Working Conditions in Nursing Homes
Reducing Adverse Events
Organizational Climate and Culture
Learning from Other Industries

EXTERNAL INFLUENCES

PURPOSE

In the development of a patient safety program, each facility should take into consideration the external influences that may impact decision-making and the setting of program priorities and initiatives.

DEFINITION

External influences, for the sake of this document, refer to any association, group or agency whose activities or oversight may influence an entity's patient safety program. This includes both regulatory and advisory groups.

DISCUSSION

External influences that impact patient safety program considerations are numerous and varied as demonstrated in Figure 4.

External influences an entity may consider includes:

Regulatory Agencies

- Licensure - Department of Health Services (DHS) – California Code of Regulation Title 22
- Certification – Centers for Medicaid and Medicare (CMS) – Code of Federal Regulations (CFR) Part 42
- Professional Licensing Boards – such as Board of Pharmacy, Board of Registered Nursing, Medical Board, etc.

Organizations associated with safety standards

- National Quality Forum (NQF)
- Leapfrog
- Institute For Safe Medication Practices (ISMP)
- Institute For Healthcare Improvement (IHI)
- National Patient Safety Foundation (NPSF)
- Accreditation organizations – such as JCAHO and American Osteopathic Association (AOA)

In addition to the organizations and agencies that contribute to patient safety, highly visible medical accidents, reported through the media, of the relationship of safety in healthcare, may impact the evaluation or redesign of a patient safety program.

RESOURCES

Regulatory

www.medbd.ca.gov – California Medical Board

www.pharmacy.ca.gov – California Board of Pharmacy

<http://www.rn.ca.gov> - California Board of Registered Nursing (BRN)

<http://www.dhs.ca.gov/lnc> - California Department of Health Services, Licensing and Certification Division

<http://ccr.oal.ca.gov> - California Code of Regulations

www.leginfo.ca.gov California Legislative information (Assembly and Senate) – The following website provides access to a schedule of legislative committee hearings, a list of committees of the legislature and their members, the text of each bill introduced including each amended, enrolled and chaptered form of each bill, the California codes (laws) and the California constitution.

<http://www.cms.hhs.gov> - Centers for Medicare & Medicaid Services (CMS)

Regulations for various facilities can be found at the following appendices

http://www.cms.hhs.gov/manuals/107_som/som107_appendixtoc.asp - These appendices provides access to health care facility specific federal regulations and accompanying surveyor guidance.

<http://www.access.gpo.gov/nara/cfr/cfr-table-search.html#page1> - This provides access to all federal codes.

<http://www.fda.gov> - The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

<http://oig.hhs.gov> - Health and Human Services (HHS) Office of Inspector General (OIG) – The mission of the OIG, as mandated by Public Law 95-452 is to protect the integrity of Department of Health and Human Services (HHS) programs, as well as the health and welfare of the beneficiaries of those programs. The OIG has a responsibility to report

both to the Secretary and to the Congress program and management problems and recommendations to correct them. The OIG's duties are carried out through a nationwide of audits, investigations, inspections and other mission-related functions performed by OIG components.

www.gao.gov - Government Accountability Office (GAO) –The GAO is an agency that works for Congress and the American people. Congress asks GAO to study the programs and expenditures of the federal government. GAO, commonly called the investigative arm of Congress or the congressional watchdog, is independent and nonpartisan. It studies how the federal government spends taxpayer dollars. GAO advises Congress and the heads of executive agencies (such as Environmental Protection Agency, Department of Defense, and Health and Human services) about ways to make government more effective and responsive.

Organizations associated with safety standards

<http://www.qualityforum.org> National Quality Forum is a private, not-for-profit membership organization created to develop and implement a national strategy for healthcare quality measurement and reporting.

<http://www.leapfroggroup.org> The Leapfrog Group is an initiative driven by organizations that buy health care who are working to initiate breakthrough improvements in the safety, quality and affordability of healthcare for Americans. It is a voluntary program aimed at mobilizing employer purchasing power to alert America's health industry that big leaps in health care safety, quality and customer value will be recognized and rewarded.

<http://www.ismp.org> - Institute for Safe Medication Practices (ISMP) is a nonprofit healthcare agency comprised of pharmacists, nurses, and physicians. Founded in 1994, this organization is dedicated to learning about medication errors, understanding their system-based causes, and disseminating practical recommendations that can help healthcare providers, consumers, and the pharmaceutical industry prevent errors.

<http://www.ihl.org/ihl> The Institute for Healthcare Improvement (IHI) is a not-for-profit organization driving the improvement of health by advancing the quality and value of health care. Founded in 1991 and based in Cambridge, Massachusetts, IHI offers comprehensive products and services.

<http://www.npsf.org> - The National Patient Safety Foundation is a not-for-profit organization dedicated to improving the safety of patients through efforts to: identify and create a core body of knowledge; identify pathways to apply the knowledge; develop and enhance the culture of receptivity to patient safety; raise public awareness and foster communications about patient safety; and improve the status of the foundation and its ability to meet its goals.

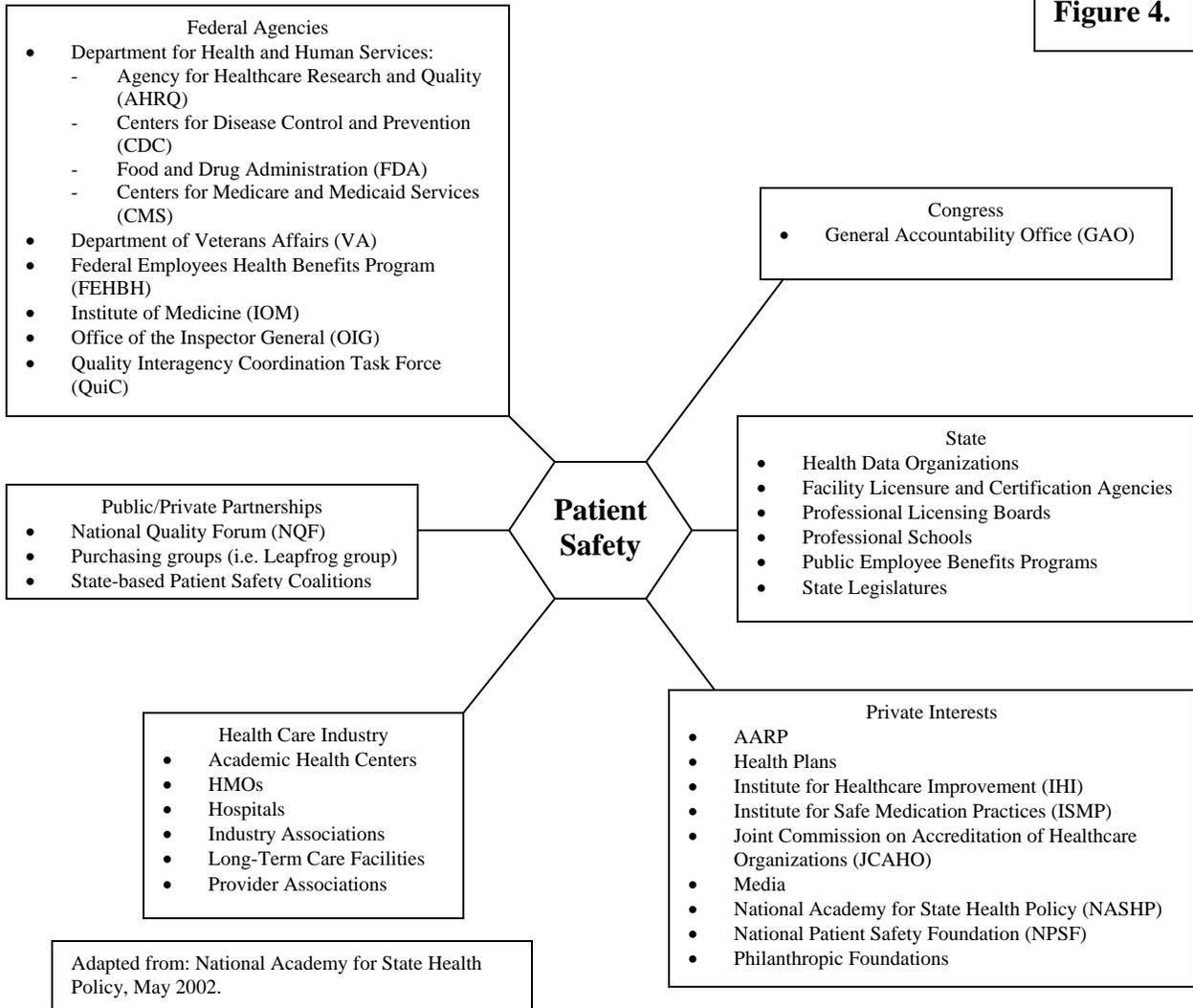
<http://www.iom.edu> - The Institute of Medicine (IOM) is a nonprofit organization created to give science-based advice on matters of biomedical science, medicine, and health. The IOM's mission is to serve as adviser to the nation to improve health. The Institute provides unbiased, evidence-based, and authoritative information and advice concerning health and science policy to policy-makers, professionals, leaders in every sector of society, and the public at large.

<http://www.ahrq.gov> - Agency for Healthcare Research and Quality (AHRQ) is a part of the U.S. Department of Health and Human Services, is the lead agency charged with supporting research designed to improve the quality of healthcare, reduce its cost, improve patient safety, decrease medical errors, and broaden access to essential services. AHRQ sponsors and conducts research that provides evidence-based information on healthcare outcomes; quality; and cost, use, and access. The information helps healthcare decision makers—patients and clinicians, health system leaders, and policymakers—make more informed decisions and improve the quality of healthcare services.

<http://www.cdc.gov> - The Centers for Disease Control and Prevention (CDC) is one of the 13 major operating components of the Department of Health and Human Services (HHS), which is the principal agency in the United States government for protecting the health and safety of all Americans and for providing essential human services, especially for those people who are least able to help themselves. CDC's mission is to promote health and quality of life by preventing and controlling disease, injury, and disability.

<http://www.jcaho.org> - Joint Commission on Accreditation of Healthcare Organizations. Mission: To continuously improve the safety and quality of care provided to the public through the provision of health care accreditation and related services that support performance improvement in health care organizations.

Figure 4.



FUTURE OF PATIENT SAFETY

PURPOSE

While considering the future of patient safety, it is important to consider the multiple elements that support a patient safety program. This includes, but is not limited to, technology, human factors, leadership, clinical advances, and environmental safety. Patient safety is a comprehensive program and staying abreast of future developments can be challenging.

DISCUSSION

The discussion below outlines several considerations for keeping a patient safety program current and anticipating future developments in patient safety. There are numerous resources available to help inform an organization about the future direction and developments in patient safety. As advancements in patient safety are constantly evolving, it is critical for organizations to identify and use key resources to help them stay informed about the latest patient safety developments and recommendations.

The most up to date patient safety information is available on the internet. Included in the resource section below are several key internet resources that will make staying current with patient safety innovations a more manageable process. A complete list of patient safety resources is too extensive to include in its entirety, so listed below are some of the most useful resources available today.

RESOURCES

<http://psnet.ahrq.gov> - is a national web-based resource featuring the latest news and essential resources on patient safety. The site offers weekly updates of patient safety literature, news, tools, and meetings (“What’s New”), and a vast set of carefully annotated links to important research and other information on patient safety (“The Collection”). Supported by a robust patient safety taxonomy and web architecture, AHRQ PSNet provides powerful searching and browsing capability, as well as the ability for diverse users to customize the site around their interests (My PSNet). It also is tightly coupled with AHRQ WebM&M, the popular monthly journal that features user-submitted cases of medical errors, expert commentaries, and perspectives on patient safety.

<http://www.ahrq.gov> - Agency for Healthcare Research and Quality (AHRQ). This site offers health care information, research findings, and data to help consumers, health providers, health insurers, researchers, and policymakers make informed decisions about health care issues.

webmm.ahrq.gov - AHRQ WebM&M (Morbidity and Mortality Rounds on the Web) is the online journal and forum on patient safety and health care quality. This site features expert analysis of medical errors reported anonymously by our readers, interactive learning modules on patient safety, Perspectives on Safety, and forums for online discussion.

<http://www.npsf.org> - National Patient Safety Foundation: Mission: To improve the safety of patients through efforts to: Identify and create a core body of knowledge; Identify pathways to apply the knowledge; Develop and enhance the culture of receptivity to patient safety; Raise public awareness and foster communications about patient safety; and Improve the status of the Foundation and its ability to meet its goals. This site has a host of resources available, including partnerships you can pay to be involved in, online safety courses for physicians and nurses, patient advocacy information, a client list-serve, and other tools to help providers and consumers stay current with evolving patient safety information.

<http://www.qualityforum.org> - The National Quality Forum is a private, not-for-profit membership organization created to develop and implement a national strategy for healthcare quality measurement and reporting. The mission of the NQF is to improve American healthcare through endorsement of consensus-based national standards for measurement and public reporting of healthcare performance data that provide meaningful information about whether care is safe, timely, beneficial, patient-centered, equitable and efficient.

<https://leapfrog.medstat.com> - The Leapfrog Group is an initiative driven by organizations that buy health care who are working to initiate breakthrough improvements in the safety, quality and affordability of healthcare for Americans. It is a voluntary program aimed at mobilizing employer purchasing power to alert America's health industry that big leaps in health care safety, quality and customer value will be recognized and rewarded.

<http://www.jcaho.org> - Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is a quality oversight body for health care organizations and managed care in the United States. This site includes the latest information regarding the National Patient Safety Goals, Sentinel Event Alerts, the Quality Check Report, and other patient safety information.

Articles

Michael Romano. (2005, February). **Honest assessment**. Modern Healthcare, 35(9), 8-9. As a snapshot of the US healthcare system, two reports from the Federal Agency for Healthcare Research and Quality provided a mixed view of overall quality and patient safety. The two contrasting portraits were contained in the National Healthcare Quality Report and the National Healthcare Disparities Report, which help track progress in a wide range of clinical areas. While the report suggests that much progress has been made in recent years in raising awareness about patient safety and national reporting standards, it concludes that data remain incomplete for a comprehensive national assessment in the wake of the IOM's 1999 report.

Linda Wilson (2004, July). **Maybe not a safety indicator**. Modern Healthcare: supplement, 6, 8, 10. This article outlines research done by Solucient to determine if those hospitals that were a part of Solucient's Top 100 Hospitals awards were significantly safer than other hospitals when all key measures of patient safety were considered. The article also helps to highlight many of the complexities facing patient safety improvements and the future development of patient safety initiatives.

Patient safety: The cultural connection (2005). Industrial Engineer, 37(1). A health care information technology company conducted a study of women hospital executives. The study showed that women CEOs believe that changing their organizational culture (51 percent) and training/educating their staff (43 percent) are the most important changes a hospital can make to improve patient safety, rather than implementing appropriate technology (9 percent).

Examples of Patient Safety Program Plans

(Please note: This information may be out of date, and may not be in concurrence with our views. It is included in this manual to provide examples of patient safety program plans.)

<http://www.ihl.org/IHI/Topics/PatientSafety/SafetyGeneral/Tools/Patient+Safety+Plan.htm> - St. Joseph Hospital (Bloomington, Illinois, USA), part of the Order of St. Francis Health System, has developed a Patient Safety Plan that may be a helpful reference to other organizations developing their own plans and programs for patient safety.

<http://www.ihl.org/IHI/Topics/PatientSafety/SafetyGeneral/Tools/Patient+Safety+Program.htm> - This document describes the Patient Safety Program used at Wentworth-Douglass Hospital (Dover, New Hampshire, USA), including definitions of terms and processes for collecting information and reviewing events.

RESOURCES

Patient Safety Organizations

Patient Safety Net – <http://psnet.ahrq.gov> - A continuously updated, annotated, and carefully selected collection of patient safety news, literature, tools, and resources.

Patient Safety Journal - <http://webmm.ahrq.gov> - Morbidity and Mortality Rounds on the Web: This web-based patient safety resource and journal features expert analysis of medical errors cases each month in the areas of medicine, surgery/anesthesia, obstetrics-gynecology, pediatrics and other. Interactive learning modules, forums for online discussion and resources links are also included.

National Patient Safety Foundation - www.npsf.org Mission: to improve the safety of patients through efforts to: identify and create a core body of knowledge, identify pathways to apply the knowledge, develop and enhance the culture of receptivity to patient safety, raise public awareness and foster communications about patient safety, and improve the status of the Foundation and its ability to meet its goals.

Institute for Healthcare Improvement (IHI) - www.ihl.org -Description: This site focuses on quality improvement including culture change concepts, design, and education. See also [Quality of Care](#)

Institute of Medicine (IOM) - www.iom.edu - Description: This site includes all current and past reports and studies related to quality of care and patient safety. To read the five patient safety IOM reports, visit the [National Academies Press](#)

Veteran’s Administration (VA) National Center for Patient Safety:
www.patientsafety.gov (National Center for Patient Safety) Patient safety:
<http://psrs.arc.nasa.gov> (VA Patient Safety Reporting System - PSRS)
Description: This site has extensive resources in patient safety. Highlights include information on culture of safety, root cause analysis, a glossary of terms, a discussion room, and a library. Also check out the virtual learning center located at www.va.gov/vlc. The Patient Safety Reporting System (PSRS) is a voluntary, confidential, non-punitive program available to all VA employees for the reporting of events and concerns related to patient safety.

eHealth Initiative - www.ehealthinitiative.org - The eHealth Initiative and the Foundation for eHealth Initiative are independent, non-profit affiliated organizations whose missions are the same: to drive improvement in the quality, safety, and efficiency of healthcare through information and information technology.

Leapfrog Group - www.leapfroggroup.org - Description: Contains information on the Leapfrog Group's approach, as well as information and fact sheets on three initiatives, including computer physician order entry, evidence-based hospital referral, and ICU physician staffing. Also includes tool kit for purchasers, and links to other patient safety and healthcare Web sites.

Emergency Care Research Institute (ECRI) - www.ecri.org - Patient safety: www.mdsr.ecri.org (Medical Device Safety Reports) Description: ECRI provides a range of tools and resources related to patient safety and healthcare quality, particularly focusing on devices and technology. Medical Device Safety Reports is a repository for incidents related to device errors.

National Guideline Clearinghouse - www.guideline.gov The NGC team catalogues a guideline as patient safety-related when it provides recommendations on how care should be given. Traditionally, guideline recommendations assist in decision-making on what care should be given, when, to whom, where, and why. With the increasing emphasis on the need to reduce medical errors and improve patient safety, guideline developers may purposefully include statements about how that care should be given, such as checking patient identification before dispensing medication, and by whom it should be given. To find these safety-related evidence-based guidelines, use the [detailed search feature](#) (scroll approximately two-thirds down, select "safety" in the IOM Domain field box, scroll to the bottom of page, and select Search).

Joint Commission on Accreditation of Healthcare Organizations
Patient Safety site: www.jcrinc.com/generic.asp?durki=6860 Quality Check site: www.jcaho.org/quality+check/ Description: This site provides good general information regarding standards, standards development, sentinel events, and legislative issues. It contains: Sentinel Event Alert, a glossary, statistics, resources on reporting and responding to sentinel events, as well as links to other sites. The Quality Check site includes information on hospitals and other healthcare institutions.

International Alliance for Patient Safety World Health Organization (WHO) www.who.int/patientsafety/international_alliance/en - Their goal is the attainment by all peoples of the highest possible level of health.

National Quality Forum (NQF) - www.qualityforum.org - This site offers information regarding NQF's on-going projects and reports in patient safety, also links to reports that have already been completed. With membership, it is possible to gain access to more extensive resources. Includes information that is patient safety-focused and quality-focused.

Partnership for Patient Safety (P4PS) - www.p4ps.org -Description: This site promotes the organization’s patient-centered approach for improving healthcare. It provides information about the Partnership symposia (past and present), call for abstracts, products for sale (including the video “First, Do No Harm”), and news and reports.

Patient Safety Institute (PSI) -www.ptsafety.org -Description: This site provides information on this organization, which strives to work with hospitals, providers and patients to reduce medical error through the use of technology and the building of relationships.

Australian Patient Safety Foundation - www.apsf.net.au - The Australian Patient Safety Foundation Inc. (APSF) is a non-profit independent organisation dedicated to the advancement of patient safety. The APSF provides leadership in the reduction of harm to patients in all health care environments.

Australian Council for Safety and Quality in Health Care - www.safetyandquality.org - The Australian Council for Safety and Quality in Health Care was established in January 2000 by Australian Health Ministers to lead national efforts to improve the safety and quality of health care provision in Australia.

Victorian State Government: Improving Patient Safety in Victorian Hospitals - www.health.vic.gov.au/clinrisk/ - This site has been developed to provide health services with information including, implementation of Statewide clinical risk management initiatives, as well as other useful links.

Bridge Medical - www.bridgemedical.com - Patient safety: www.mederrors.com

Description: The general site provides information on patient safety software systems, and general culture of safety reports (i.e. Beyond Blame). Mederrors.com provides more extensive information, including a CE course titled Anatomy of an Error, features on patient safety topics, a history of tracking errors, consumer tips, a hospital checklist, legislation, grants, a library of patient safety article summaries, and FAQs.

Consumers Advancing Patient Safety - www.patientsafety.org - (CAPS) is a consumer-led nonprofit organization, incorporated in Illinois in December 2002, formed to be a collective voice for individuals, families and healers who wish to prevent harm in healthcare encounters through partnership and collaboration. CAPS envisions creating a healthcare system that is safe, compassionate and just.

Governmental Agencies**Centers for Disease Control (CDC) - www.cdc.gov**Patient safety <http://www.cdc.gov/ncidod/dhqp/index.html>

(Division of Healthcare Quality Promotion - DHQP) Description: This site provides some links to some of the main patient safety reports, as well as information related to infection control, including specific clinical guidelines

Department of Defense (DoD) - www.defenselink.mil

Patient safety www.afip.org/PSC (Patient Safety Workgroup) Description: Contains information on the center for patient safety in the Department of Defense, which is geared toward identifying systemic errors in the military system. Patient Safety newsletters included.

Food and Drug Administration (FDA)

FDA Patient Safety News -

www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/index.cfm

MedWatch: Safety Information and Adverse Event Reporting Program -

www.fda.gov/medwatch

Center for Drug Evaluation and Research -

www.fda.gov/cder/drug/mederrors/default.htm**Agency for Healthcare Research & Quality (AHRQ) - www.ahrq.gov**

This is a public health agency under the department of Health and Human Services (HHS). Patient safety: www.ahrq.gov/qual/errorsix.htm

Description: This site covers AHRQ's involvement with patient safety through links to press releases, important documents, speeches, statements and hearings. Links are also provided to fact sheets and information about the Quality Interagency Coordination Task Force.

Centers for Medicare and Medicaid Services Hospital Quality**Initiative (HQI) - www.cms.hhs.gov/quality/hospital** - CMS has several

efforts in progress to provide hospital quality information to consumers and others and improve the care provided by the nation's hospitals. These initiatives build upon previous CMS and QIO strategies to identify illnesses and/or clinical conditions that affect Medicare beneficiaries in order to: promote the best medical practices associated with the targeted clinical disorders; prevent or reduce further instances of these selected clinical disorders; and prevent related complications. This page includes links to reports and other documents that describe these efforts.

Quality Interagency Coordination Task Force (QuIC) - www.quic.gov

- Description: The site for this task force, which was developed under HHS and AHRQ, includes the Report to the President, patient fact sheet, press releases, research agenda, and general information about the work groups that are currently underway.

National Institutes of Health (NIH) - www.nih.gov -Description: Although there is no part of this site devoted to patient safety, it is possible to pull up relevant reports and statements through a search.

Medicare.com - www.medicare.gov - Description: Billed as "The Official U.S. Government Site for People with Medicare" this site offers a variety of resources information including billing, questions, downloadable publications, and a participating physician directory. It includes comparison information on dialysis facilities, nursing homes and home health programs.

Medication Safety

The Institute for Safe Medication Practices - www.ismp.org - To understand the causes of medication errors and provide time critical error-reduction strategies to the healthcare community, policy makers, and the public.

American Association of Health Plans The Tools and Techniques of Improved Medication Use - www.aahp.org/content/navigationmenu/medcollab/medcollab.htm - On this website, you will find nearly fifty scientific studies that focus on improved medication use and patient compliance, through varied intervention strategies – implementing disease management approaches, educating patients and providers, and monitoring and providing feedback about target populations. The *Tools and Techniques of Improved Medication Use* initiative seeks to translate research findings into practice by presenting detailed descriptions of intervention strategies, resources and results that can be replicated in multiple settings. Studies are categorized by medical condition and intervention strategy.

ASHP Pharmacist's Guide to Your Medications - www.safemedication.com - ASHP's mission is to support pharmacists in helping people use medications safely and effectively.

California HealthCare Foundation Addressing Medication Errors in Hospitals: A Practical Tool Kit - www.chcf.org/topics/view.cfm?itemID=12682 - Protocare Sciences prepared this tool kit for hospitals to use when considering how best to proceed in choosing and applying a variety of technological solutions, including computerized physician order entry, to prevent medication errors in the hospital setting.

US Pharmacopoeia (USP) - www.usp.org - Description: This site offers information on USP's standards and activities. In addition, USP operates two medication error reporting, tracking, and analysis programs: the Medication Errors Reporting (MER) Program (operated in collaboration with the Institute for Safe Medication Practices) and the MedMARx Program (at <http://www.usp.org/products/medMarx/>). MedMARx is an Internet-accessible database for hospitals to report and track medication errors anonymously.

Center for Proper Medication Use - <http://cpmu.org> - The mission of the Center is to improve the health and welfare of society by developing solutions to problems associated with medication use and compliance while optimizing the potential benefits of medication treatments. In addition, the Center has been a source of information for the public, media, and healthcare professionals on the subject of proper medication use.

Consumer Health Information Corporation: Taking Control of Your Medicines and Your Health - www.consumer-health.com/services/cons_takecontrol.htm - [Taking Control of Your Medicines](#)

National Coordination Council for Medication Error Reporting and Prevention - www.nccmerp.org – NCC MERP intends to mount a nationwide campaign for medication error reporting and prevention that will promote recommendations broadly to colleges, schools, and state associations of medicine, pharmacy, and nursing; national professional associations; managed care organizations; and third-party payers.

Professional Associations

American Hospital Association (AHA) - www.aha.org - Patient safety: www.aha.org/aha/key_issues/patient_safety/ Description: This site offers information on AHA's initiatives, and focuses on medication safety and safety culture. Resources include links to successful practices, reporting information, the Strategies for Leadership series in PDF format, and links to major reports.

American Medical Association (AMA) - www.ama-assn.org - Description: For information on patient safety, this site will direct you to the National Patient Safety Foundation's Web site (www.npsf.org). In addition, it is possible to pull up AMA-related reports and articles through a search.

American Academy of Pediatrics: Quality Improvement and Management - <http://www.aap.org/about.html> - The mission of the American Academy of Pediatrics is to attain optimal physical, mental, and social health and well-being for all infants, children, adolescents, and young adults.

American College of Physicians: Focus on Patient Safety - www.acponline.org/ptsafety/index.html - The American College of Physicians (ACP) is the nation's largest medical specialty society. Its mission is to enhance the quality and effectiveness of health care by fostering excellence and professionalism in the practice of medicine.

American Nurses Association: Safety and Quality - www.ana.org/quality - This site contains information on a number of topics which address the safety and quality of nursing care patients receive and the quality of nurses' work lives.

American Society for Healthcare Risk Management - www.ashrm.org/ashrm/index.jsp - ASHRM initiatives focus on developing and implementing safe and effective patient care practices, the preservation of financial resources and the maintenance of safe working environments.

American Academy of Family Physicians Quality Initiative - www.aafp.org - The mission of the AAFP is to improve the health of patients, families, and communities by serving the needs of members with professionalism and creativity.

American Academy of Orthopaedic Surgeons (AAOS) - <http://orthoinfo.aaos.org/>
Description: The patient section of this site contains information on orthopaedic conditions and treatments, injury prevention, and wellness and exercise along with fact sheets on patient safety surgery issues.

Association of Perioperative Nurses Patient Safety First – www.patientsafetyfirst.org
- AORN is the Association of periOperative Registered Nurses. The Patient Safety First program is part of AORN's broader patient safety initiative. It develops new guidelines related to patient safety issues (such as medication safety and correct site surgery) and helps health care professionals ensure that best practices are followed.
