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WILLIAM T FUJIOKA
Chief Executive Officer

August 13, 2010

To: Supervisor Gloria Molina, Chair
Supervisor Mark Ridley-Thomas
Supervisor Zev Yaroslavsky
Supervisor Don Knabe
Supervisor Michael D. Antonovich

From: William T Fujioka
Chief Executive Officer

DEPARTMENT OF HEALTH SERVICES - INDEPENDENT REVIEW SERVICES: EVALUATION OF THE MEDICAL MALPRACTICE/QUALITY IMPROVEMENT UNIT (AGENDA OF AUGUST 17, 2010)

On December 16, 2008, your Board instructed the Chief Executive Officer (CEO) to issue a Request for Statement of Qualifications (RFSQ) for an independent review entity or contractor, reporting directly to your Board, to examine, assess, and make appropriate recommendations on the administration, operations, and functions of the Department of Health Services (DHS) and to bring the highest-ranked proposers (up to six) to your Board for review.

OVERVIEW

On February 10, 2009, our Office issued the RFSQ, and proposals were due by March 11, 2009. Further, in a memo to your Board dated July 28, 2009, we reported that the six proposals received in response to the County's RFSQ for the DHS Independent Review Entity were transmitted to your Board on June 30, 2009, including the evaluations of the proposals which had been prepared by an evaluation panel.

As the Independent Review Entity would serve at your Board's discretion, a Closed Session was held on September 22, 2009, to review the proposals and the evaluations. Two firms, Health Management Associates (HMA) and The Abaris Group (Abaris)

advanced to the contract negotiations phase and agreements were executed under the CEO's delegated authority. Each firm was to complete pilot study projects with separate scopes of work, project timelines, and to make presentations to your Board upon completion of their review.

Based on input from your offices, HMA was selected to conduct an evaluation of DHS' Office of Managed Care (OMC)/Community Health Plan (CHP), and Abaris to assess the Medical Malpractice/Quality Improvement Unit. On April 13, 2010, at your Board's meeting, HMA consultants reported on their findings and recommendations.

The Abaris' consultants are scheduled to present their report as a set item for discussion at your Board's meeting on August 17, 2010. The Abaris Group report is discussed further below:

EVALUATION OF THE MEDICAL MALPRACTICE/QUALITY IMPROVEMENT UNIT

Consistent with the Abaris Delegated Authority Agreement, the firm was asked to: 1) conduct a comprehensive assessment of the current operation of DHS' Medical Malpractice and Quality Improvement Unit for the delivery of medical services to reduce risks of County liability; 2) evaluate the effectiveness of risk measures currently in place to protect patient safety, quality of care, potential liability, and claims relevant to medical services; 3) assess and analyze how DHS can more effectively use lessons learned from past malpractice claims to improve medical quality and reduce future malpractice claims and costs; and 4) provide written analyses and recommendations regarding these areas.

Abaris' report on key findings and recommendations are provided in Attachment I and summarized below. Additionally, DHS has provided input (Attachment II), to Abaris' recommendations.

Key Abaris Findings:

1. There has been a significant reduction in the total number of medical malpractice cases in recent years, both within LA County and with healthcare providers, as a result of patient-safety efforts in the healthcare industry.

2. There is evidence that DHS is progressing towards more timely and comprehensive responses to patient safety events and reducing timeframes for the Corrective Action Plans (CAPs) submittals and mitigation steps.

3. The role of the Quality Improvement and Patient Safety (QIPS) unit has expanded dramatically within the last decade, with the necessary system-level work, the day-to-day processes (i.e., CAPs) of patient safety, and outside requests/demands not reflected in the current CAP process. This has greatly impaired QIPS' ability to create a system-wide culture of patient safety, with clear priorities that improve quality and reduce claims.

4. Attempts to improve the CAP process have been made, however, the timeframe is still too long. Overlaps in the CAP event reporting and mitigation process needs significant re-engineering and timeframes reduced to ensure timely, but accurate, action plans.

5. DHS has developed an extremely complex patient safety and initiative implementation process to sustain system needs which could potentially minimize the DHS' focus on key topics for resolution.

Key Abaris Recommendations:

1. **CAP/Summary CAP Process:** The CAP process should continue to be re-engineered towards a "system" rather than an "event" focus and a reduction of the concentration on a "blame" methodology.

2. **Patient Safety vs. Medical Malpractice Claims:** The current overlap between patient safety and the claim management processes needs to be refocused, with overlaps removed and the claim process redesigned to follow industry claim process standards.

3. **QIPS Reporting Process:** The organizational placement of the QIPS unit, consistent with the trend of other healthcare organizations, should be realigned to report directly to the DHS Director's Office with a matrix reporting relationship to the DHS Chief Medical Officer (CMO) position.

4. **Health Facility Governing Board:** The Board of Supervisors should adopt a governing body role of strategic development for patient safety including setting patient safety goals, expectations, and adopting a focus on creating a safe environment within the hospital and clinics it oversees.

5. **Dashboard:** A corporate patient safety dashboard should be published, endorsed, and monitored by all in the DHS patient care arena with Board oversight.

6. **QIPS Best Practices:** A smaller but dynamic grouping of four best practice groups should replace many of the current advisory quality process groups, meeting twice a month, using a defined charter including goals with rigorous and focused statements to create, spread and ensure adoption of patient safety best practices and a more disciplined process for conducting their work.

7. **Reduction in Variation:** DHS and its clinical care units should consistently endorse enterprise-wide initiatives and not allow the sites to operate as silos on patient safety issues. Roll outs of site-based Information Technology (IT) solutions should be minimized and eventually eliminated.

8. **EHMR:** The goal of a comprehensive electronic health medical record (EHMR) should be given a high priority, with planning completed and refined and full implementation of the EHMR within an aggressive time period (i.e. five years).

9. **Data/Trending:** DHS should acquire more analytical resources and use these resources more effectively to trend their patient safety needs, initiatives, and outcomes to allow more clarity of their direction and transparency to their audience.

CONCLUSION

We have reviewed the Abaris report and the results are responsive to the statement of work. DHS concurs with five of the nine recommendations identified by Abaris, partially concurs with two, and does not concur with one recommendation, and one recommendation is a matter of Board policy. Overall, DHS notes the advances that have been made within the department, but recognizes that there is room for improvement.

The CEO-Risk Management (CEO-RM) has been available throughout this evaluation process and will continue to work with DHS to further enhance their program. CEO-RM will support DHS leadership, provide guidance and other consultative assistance, and monitor the department's implementation efforts.

If you have any questions, please contact me or your staff may contact Sheila Shima, Deputy Chief Executive Officer, at (213) 974-1160 or sshima@ceo.lacounty.gov.

WTF:SAS:MLM
AMT:gl

Attachments

c: Executive Office, Board of Supervisors
County Counsel
Health Services

081310_HMHS_MBS_ABARIS REPORT - BOS MEMO (3)

County of Los Angeles

Independent Review: Department of Health Services Medical Malpractice Risk Management

County of Los Angeles

Prepared by The Walter Group, Walnut Creek, CA

EXECUTIVE SUMMARY

PURPOSE OF THE STUDY

The purpose of this study is to provide the Los Angeles (LA) County Board of Supervisors with an in-depth analysis of the LA County Department of Health Services' (DHS) Medical Malpractice Risk Management Program.

The study entailed a total assessment of DHS' medical malpractice risk management program; an evaluation of risk-mitigation measures currently in place regarding patient safety, quality of care, potential liability, and claims relevant to medical services; and analysis and recommendations on how DHS can learn from past malpractice claims as well as "best practices" to improve patient safety and reduce future malpractice risk and liabilities.

PROCESS USED

The Abaris Group conducted numerous interviews with key stakeholders from the DHS' management team (the DHS Director and Chief Medical Officer [CMO]); members of DHS' Quality Improvement and Patient Safety Unit (QIPS); DHS' Pharmacy Unit and the Division of Audit and Compliance; site visits to a sample of DHS' clinics and to DHS' four hospitals, including meeting with their leadership, patient safety and patient care staff; and others knowledgeable on healthcare risk management within and outside the County.

During the site visits, The Abaris Group was able to interview individuals involved in each facility's risk management and process improvement activities. Data on claims and events were requested as well as examples of QIPS staff work and initiatives and those of the patient safety officers at each major clinical site.

The Abaris Group also interviewed staff from the County Counsel's Office and the Chief Executive Office's (CEO) Office of the Inspector General, along with a team from Sedgwick Claims Management Services, DHS' third-party administrator for medical malpractice claims management.

Additionally, The Abaris Group conducted extensive research regarding healthcare industry practices and benchmarks for medical malpractice, risk management and patient safety.

STRENGTHS AND WEAKNESSES

Strengths – Inside DHS

- There has been a relatively new progressive leadership team at the CMO and Director of QIPS levels.
- The corrective action plan/summary corrective action plan (CAP/SCAP) process is comprehensive and appears increasingly timely for each clinical site delivery of their CAP initial reports.
- The CAP process has been significantly revised in recent years to achieve more accountability and transparency to the process.
- DHS has developed and maintained a robust medical staff endorsed peer-review process.
- DHS is pursuing many contemporary patient safety and quality performance measures.
- A complete understanding and acceptance of DHS' quality and patient-safety initiatives is in place at some clinical sites.
- DHS participates in a number of statewide and national quality improvement initiatives.
- There are best-practice "pockets" of quality and safety activity within DHS that could be used as models for other efforts.

Strengths – Outside DHS

- The entities working on medical malpractice claims outside of DHS appears to be using prudent judgment for the disposition of medical malpractice claims.

Weaknesses – Inside DHS

- It is not clear that trending and loop closure activities including documentation even exist in DHS or are effective on patient-safety issues.

- There are poor to non-existent medical risk management database and analytical tools within the QIPS Unit to assist with trending and event loop closure.
- There is no current overall information technology (IT) vision for a DHS' electronic medical health record (EMHR).
- The current CAP process in use is extensive, complicated and does not always contribute to rapid medical risk event identification and mitigation.
- During the study there was significant distrust that existed between DHS and its clinical sites for the CEO's Office of Inspector General (OIG), as well as the Board of Supervisors involvement on medical malpractice claims management and the CAP process.
- QIPS leadership and staff seemed overwhelmed and demoralized during this study due in part to the nature and extent of outside department scrutiny.
- The relationship between the clinical site patient safety staff and the patient safety officers to DHS initiatives is not apparent and their current roles may not further overall system initiatives.
- Significant silos and variation of patient safety interest and practices were evident at each DHS campus site.

Weaknesses – Outside DHS

- There is a strong reliance throughout the County on a "blame" philosophy regarding medical errors and adverse events which is inconsistent with the industry's direction and with the goals of an effective and transparent patient safety program.*
- There is a considerable overlap between the clinical staff medical malpractice evaluation and response process to the legal staff's process of claim adjudication.

** Having a "no-blame" philosophy does not mean not taking disciplinary action against staff that were negligent in their duties.*

PRINCIPAL FINDINGS

There has been a significant reduction in total medical malpractice cases in recent years both within LA County and with health providers in general that may partially relate to the patient-safety efforts in the healthcare industry in general and at DHS.

In spite of The Abaris Group's limited access to sites, project data, and CAPs, there is evidence that DHS is progressing towards more timely and comprehensive responses to patient safety events through reduced timeframes for CAP submittals and mitigation steps, including some evidence of verification of mitigation efforts by DHS at the clinical sites. **

The work conducted at DHS and its QIPS Unit has expanded dramatically. The necessary system-level work, as well as the day-to-day demands (i.e. CAPs) of patient safety, have grown large and the process cumbersome with many intervening outside requests and demands not reflective in the formal CAP flow chart. This has greatly impaired QIPS' ability to create a system-wide culture of safety with clear priorities that improve quality and reduce claims.

While progress has been made with re-engineering the CAP process, the CAP timeframe is still protracted and would need further reduction and focus to assure timely but accurate action plans especially for those claims that may have more significant impact (i.e. so called "never events"). Some overlaps occur and there is a bias not to finalize the CAP until the Settlement Letter has been completed. The CAP and event reporting/mitigation process will require significant re-engineering to achieve its true value and to hold gains on patient safety.

*** While conducting some on-site observation sessions at provider sites and obtaining various patient-safety data and more recent CAP documents was a challenge during this project, these challenges did not materially affect the study's final observations and conclusions.*

With a significant re-engineering of the CAP process, with input and participation of non-DHS staff will allow some non-DHS staff to become more confident with DHS' role and direction of patient-safety issues that will in turn lead to over time, a reduction in the level of oversight required by the Board of Supervisors and the CEO's Office of the Inspector General.

DHS has also developed a complex process for patient safety and initiative implementation. For example, there were approximately 20 patient safety committees (mostly peer review) and other special topic groups (non-peer review) at the department level during the study period. One committee, while popular, had 31 listed members and another nearly double that number. DHS' CMO had assigned himself to chair most of these committees. This level of complexity will be difficult to sustain and may dilute the focus on important key topics and their resolution.

Continued endorsement and participation by DHS on national and state initiatives and implementation should be reinforced. This involvement combined with the recommendations of this report will likely continue DHS' progress to an optimized patient care process and limiting medical risk.

STUDY RECOMMENDATIONS

(1) **CAP/SCAP Process**: The entire CAP process should continue to be re-engineered towards a "system" rather than an "event" focus and a reduction of the concentration on a "blame" methodology.

(2) **Patient Safety vs. Medical Malpractice Claims Management**: The current overlap between patient safety and the claim management processes needs to be refocused, with overlaps removed and the claim process redesigned to follow industry claim process standards.

(3) **QIPS Reporting Process**: The Abaris Group recommends that organizational placement of QIPS, consistent with the trend of other healthcare organizations, be redefined to report directly to the DHS Director's office with a matrix reporting relationship to DHS' CMO position.

(4) **Health Facility Governing Board**: The Board of Supervisors should adopt a governing role focusing on strategic development for patient safety including setting patient-safety goals, expectations and adopting a focus on creating a safe environment within the hospitals and clinics that it oversees.

(5) **Dashboard**: A corporate patient safety dashboard should be published, endorsed and monitored by all in the DHS patient care arena with Board of Supervisors' oversight.

(6) **QIPS Best Practices**: A smaller, but dynamic grouping of no more than four best-practice groups should replace many of the current advisory quality process groups, which would meet twice a month using a defined charter including goals with rigorous and focused aim statements, to create, spread and ensure adoption of patient safety best practices. These best-practice groups should use more disciplined processes for conducting their work.

(7) **Reduction of Variation**: The DHS and its clinical care units should consistently endorse enterprise-wide initiatives and not allow the sites to operate as silos on patient safety issues. Roll outs of site-based IT solutions should be minimized and eventually eliminated.

(8) **EHMR**: The goal of a comprehensive electronic health medical record (EHMR) should be given a high priority, with planning completed and refined and full implementation of the EHMR within an aggressive time period (i.e. five years).

(9) **Data/Trending**: The DHS should acquire more analytical resources and then use these resources more effectively to trend their patient safety needs, initiatives and outcomes to allow more clarity of their direction and transparency to their audience.

More details on the principle findings, recommendations and background are provided in the body of the report and accompanying Appendix.

GOING FORWARD

The key step identified in these recommendations is establishing the Board of Supervisors in a more strategic role of designing patient safety goals and monitoring progress of these goals. Also required is the refinement and streamlining of the CAP process. To these ends, the QIPS Unit should more sharply focus their patient safety and best-practice initiatives and assure DHS-wide adoption and accountability. Without these steps, the medical malpractice and patient-safety needs of the County will continue to grow as separate and disparate activities fueling the current gap and confidence in the process and reducing effectiveness of these activities. The strategic governing role towards a contemporary hospital patient-safety governing board (the Board of Supervisors) should occur within the next 12 to 18 months with the CAP re-engineering process taking less than 12 months, using a collaborative County internal stakeholder process.

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PATIENT SAFETY HISTORY

Patient safety has been an active topic among hospitals, healthcare and government organizations since the Institute of Medicine (IOM) released its report: *To Err is Human* in 1999. Prior to this report, there was relatively little attention paid to patient safety on many levels (county, state, and national), and the public was generally not informed about the extent of the problem of medical errors in hospitals and other parts of the health system. *To Err is Human* drew attention to the prevalence of medical errors in hospitals throughout the country, and brought to the public's attention the impact of such errors in terms of both financial cost and lives lost. The IOM report is significant because it concluded that fundamental defects in the systems that provide healthcare, not reckless individuals are responsible for most medical errors.

Today a number of organizations exist to assist healthcare providers in reducing medical errors and improving patient safety. It has been recognized that taking steps towards reducing medical errors will not only improve the quality of care provided to patients, but reduce costs to healthcare providers due to reduced medical malpractice premiums and liabilities.***

****A recent The RAND Corporation report reinforced the fact that in recent years medical malpractice claims have fallen dramatically in California primarily due to patient safety initiatives ("Is Better Patient Safety Associated with Less Malpractice Activity", The RAND Corporation, April 2010)*

More detailed information about the history of the patient-safety movement, current trends and applicability to this study can be found in the Appendix section of this report.

STUDY EXPECTATIONS

The purpose of this study is to provide the Los Angeles (LA) County Board of Supervisors with an in-depth analysis of the LA County Department of Health Services' (DHS) Medical Malpractice Risk Management Program.

The study entailed a total assessment of DHS' medical malpractice risk management program; an evaluation of risk-mitigation measures currently in place regarding patient safety, quality of care, potential liability, and claims relevant to medical services; and an analysis and recommendations on how DHS can learn from past malpractice claims as well as "best practices" to improve patient safety and reduce future malpractice risk and liabilities. Specifically, The Abaris Group was retained to:

- Conduct a comprehensive assessment of the current operation of DHS' Quality Improvement & Patient Safety (QIPS) Unit for the delivery of clinical services to reduce risks of County liability
- Evaluate the effectiveness of risk measures currently in place that address patient safety, quality of care, potential liability, and claims relevant to medical services
- Assess and analyze how DHS can more effectively use lessons learned from past malpractice claims to improve medical quality and reduce future malpractice claims and costs
- Provide written analyses and recommendations regarding these areas

The Abaris Group defined this work to include but not solely concentrate on all patient-safety "events" (medical malpractice or non-malpractice claim based). The "event" approach was taken to assure a comprehensive review of all patient-safety medical risks whether claims-based or not (for example a review was made on "near miss'" reports that may not result in a claim). This study looked at event identification, documentation, reporting, resulting actions taken for overall medical management on risk identification (including peer review, studies of faulty practices, non adherence to the standards of practices, etc.) and mitigation steps taken even if the event never resulted in a claim.

The Abaris Group was also asked to provide recommendations on how DHS' medical malpractice risk management program could improve its organizational structure, address operational/infrastructure needs, improve policies and procedures, internal processes, the corrective action process (including CAPs), and performance management/quality-control processes.

In addition, The Abaris Group was asked to research best practices relating to the following topics: the use of information technology (IT) for collecting, tracking, and analyzing case data as well as for automating the peer-review process as required for the Joint Commission's Ongoing Professional Practice Evaluation (OPPE); risk-averse training, risk assessments, and innovative risk management; and the CAP (and its other derivative, the SCAP) process. In addition, a sample of adverse events commonly measured for patient safety was researched that included:

- reducing the incidence of hospital-acquired pressure ulcers
- unintentionally retained foreign bodies following surgery
- patient falls

PROCESS USED

The Abaris Group conducted numerous interviews with key stakeholders from the DHS' management team (the DHS Director and Chief Medical Officer), members of DHS' QIPS Unit; site visits to DHS' clinics and hospitals, including meeting with their leadership, patient safety and patient care staff; and others knowledgeable on healthcare risk management within and outside the County.

The following table lists the facilities that were visited.

Table 1 – Hospital, Clinic and MACC Site Visit Locations

Site Visits Hospitals	Clinics and MACCs
LAC+USC Medical Center	Edward R. Roybal Comprehensive Health Center
Harbor-UCLA Medical Center	Martin Luther King, Jr. Multi-Service Ambulatory Care Center (MACC)
Olive View-UCLA Medical Center	Long Beach Comprehensive Health Center
Rancho Los Amigos National Rehabilitation Center	High Desert Health System Multi-Service Ambulatory Care Center (MACC)
	Mid-Valley Comprehensive Health Center

During the site visits, The Abaris Group was able to interview individuals involved in each facility's risk management and process improvement activities. Data on claims and events were also requested as well as examples of QIPS staff work and initiatives and those of the patient-safety officers at each major clinical site. The study staff also interviewed staff from the Pharmacy Unit of DHS as well as the Division of Audit and Compliance.

Additionally, The Abaris Group interviewed staff from the County Counsel's Office and the Chief Executive Office's (CEO) Office of the Inspector General, along with a team from Sedgwick CMS, DHS' third-party administrator for medical malpractice claims management.

Finally, The Abaris Group conducted extensive research regarding healthcare industry practices and benchmarks for medical malpractice, risk management and patient safety.

OVERVIEW OF THE MEDICAL MALPRACTICE, RISK MANAGEMENT AND PATIENT SAFETY PROGRAMS

LA County DHS has had a claims management and mitigation effort in place for many years. A review of early policies suggests that this office's formal activities on medical practice began approximately during 1992. The DHS has a Chief Medical Officer (CMO), who reports to the DHS Director; a Corporate Patient Safety Officer (who reports to the DHS CMO); and other Patient Safety Officers (appointed physicians) at all of the hospital campuses. The CMO

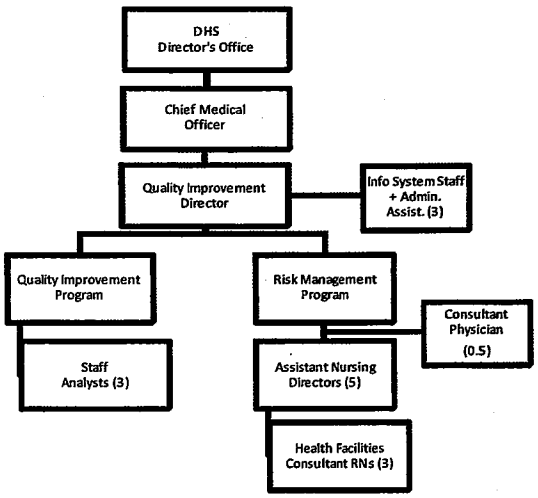
is also responsible for direct and indirect management of patient safety issues at all of the County clinic sites.

The CMO has 11 core committees and subcommittees and approximately nine specialty expert panels that meet periodically and provide advice, guidance and, in the case of policy development, input and direction on patient safety policies.

The Director of the QIPS Unit, within DHS, reports to the CMO. The Unit has 15.5 full-time staff equivalents (FTEs) including one half-time physician.

The new Risk Management Sub Unit recently approved by the Board of Supervisors to address non-clinical risk management (e.g. human resource issues); will be staffed from vacancies within the QIPS department. Figure 1 presents the current QIP organizational chart.

Figure 1 – Current QIPS Medical Risk Management Organizational Chart



DHS has policies and procedures in place for reporting and investigating patient-safety events as required for compliance with state law, county ordinances and policies, and the Joint Commission policies (formerly known as the Joint Commission on Accreditation of Healthcare Organizations or JCAHO).

Table 2 – DHS Key Patient Safety Policies

DHS Patient Safety Policies	
Policy Number	Title
Policy 311	Incidents Involving Potential Claims (v. 1/05)
Policy 311.201	Policy of Unanticipated Outcomes (v. 7/07) Codifies and memorializes County Ordinance 2.76.590, Risk Management Protocol, DHS - Quality Improvement Program
Policy 311.202	Adverse Event and Reporting to the State Department of Public Health (v. 1/08)
Policy 311.3	Licensee Reporting to Licensing Board

There are also policies and procedures in place to comply with the Board of Supervisors motion of December 10, 1996 to ensure that complete and appropriate CAPs accompany recommendations for settlements to the Board of Supervisors. This motion was further clarified by the March 1, 2010 memo to all department heads from William T Fujioka, Los Angeles County CEO, on the review and pre-approval requirement by the CEO's Office's Inspector General on all CAPs prior to Board of Supervisors' review.

DHS/QIPS UNIT OVERVIEW

The work of the DHS QIPS Unit is a combination of screening and investigating events and monitoring the development of CAPs for events and claims. They are also involved in facilitating and developing best-practice initiatives using a multisite collaborative model as well as providing assistance with physician peer review and non-peer review activities (i.e. other patient safety sub committees as well as annual QIPS-sponsored seminars for DHS facilities).

An Executive Quality Improvement Committee reports to the DHS' CMO and has up to 11 subcommittees including the Executive Peer Review Subcommittee charged with reviewing CAPs. These two committees were specifically described during the study by DHS staff as California Evidence Code Section 1157 "peer-review" protected committees. There may be other subcommittees of the 11 listed that may be considered by DHS as "protected" as well.

DHS facilities have participated since 2006 with the Patient Safety Network (PSN). This is an "event" disclosure process sponsored by the University HealthSystem Consortium. The Consortium is a nationally-recognized purchasing, benchmarking and best-practice inventory group specializing in supporting the mission of major academic and public hospitals. The PSN relies on members reporting "events," as defined by the PSN, to a national database which then provides benchmarking data and reports back to their member hospitals. Considerable work is spent by the QIPS Unit on completing and monitoring the CAP processes, including follow up on additional data and investigations that the unit or the Board of Supervisors or other authorized individuals responding to these inquires may require.

DHS' Division of Audit and Compliance, is designed to be a neutral review body, completes department-based independent periodic reviews of the CAPs for completeness for claims greater than $100,000 and using a sample review process for the remaining CAPs but the sampling process is completed generally after the CAP process. In addition, the CEO's Office of the Inspector General has been responsible for, and has recently assumed a growing role, conducting non-department-based independent reviews of CAPs which now includes the review of all CAPs requiring the Board of Supervisors' consideration (claims greater than $100,000). This office also offers consultative services on risk management and CAPs.

STRENGTHS AND WEAKNESSES

STRENGTHS – INSIDE DHS

- <u>There has been a relatively new progressive leadership team at the CMO and QIPS levels.</u> DHS and its QIPS Unit have had relatively new leadership, which has led to a significant overall improvement and an expanded vision of the mission for patient safety, risk management and medical malpractice work of the DHS. This has led to the execution of new policies and practices regarding patient safety directly through the CMO office or through the relatively recent new appointment of the Director of the QIPS Unit of Kim McKenzie, RN (appointed September 2009). However, both had inherited a significant backload of work including work within the complex structure of the DHS medical-malpractice process that is somewhat unique to the County of Los Angeles. DHS, through their leadership, has adopted more aggressive timelines and corresponding support for accelerating the physician peer-review process and the delivery and review of CAPs to address patient risk and malpractice claims.
- <u>The CAP/SCAP process is comprehensive and increasingly timely for early clinical site delivery of the initial CAPs.</u> The Abaris Group evaluated the CAP process' timeliness of clinical site reporting. While The Abaris Group was not given complete access to all recent CAPs (see notes under Commentary of the Process), those reviewed appeared comprehensive and increasingly timely (improvement was noted on CAPS that previously took greater than 45 days and sometimes 180 days or longer to complete). Even with the small sample of more current CAPs, The Abaris Group found these CAPs were largely in compliance with the 45-day requirement of the process. The CAP process logic (tying the root-cause analysis to actual mitigation steps) appears in place. There is also evidence, in the more current CAPs reviewed, of site and QIPS Unit follow up, audits, and documentation of mitigation-effort completion.
- <u>The CAPs process has been significantly revised in recent years to achieve more accountability and transparency with the process.</u> While the CAP process appears complicated, it has continued to undergo significant review and re-working over the past few years by a variety of stakeholders to achieve better disclosure and DHS accountability.
- <u>DHS has developed and maintained a robust medical staff-endorsed peer-review process</u>. The DHS and its CMO have developed and maintained

a robust physician peer-review process, not only eliminating a four-year backlog of peer review for CAPs but conducting current reviews in closer proximity to the actual events (i.e. for some cases within the month of the event). This has been very challenging to accomplish given the multifaceted and complex environment of DHS' teaching hospitals, the community clinics, affiliated medical schools, large medical staffs (approximately 3,750 physicians), and the extensive number of medical and resident students (approximately 2,100 students/residents in any given year).

- DHS is pursuing many contemporary patient safety and quality performance measures. There are a number of best-practice collaboratives (committees and task forces) that have been implemented in the past three years, many of which are making significant progress on initiatives or have completed their work. Most notably is the work on the Intensive Care Unit and Anesthesia Best Practice Collaboratives, which identified targeted goals and have completed work on most of those goals. These collaboratives or committees rely on published literature and data analysis (evidence-based processes). They also use newsletters, special memorandums and annual conferences to spread the initiatives' expectations and progress. All of these groups appear to be making patient-safety progress at the medical staff, nursing staff, pharmacy and other staff levels.
- A complete understanding and acceptance of the DHS' quality and patient-safety initiatives is in place at some of the clinical sites. For most clinical sites, there is some knowledge of the majority of initiatives from the executive team through patient-care givers on topic specific initiatives (i.e., skin integrity initiatives).
- DHS participates in a number of statewide and national quality improvement initiatives. This voluntary participation includes several statewide collaboratives ("Just Culture", "Patient Safety First") and national collectives (The Kaiser Foundation's/National Association of Public Hospitals' "Patient Safety Initiative at America's Public Hospitals" initiative) that are, or will, focus on patient safety, risk reduction, overall accountability and improved patient outcomes.
- There are best-practice "pockets" of quality and safety activity within DHS efforts that could be used as models for other similar efforts. For example, the Anesthesia Work Group on patient safety and the Department of Pharmacy's work on medication errors appear to have added much value to the patient-safety efforts due to their disciplined approach using root-cause analysis, pre- and post-measures, and evidence-based interventions.

STRENGTHS – OUTSIDE DHS

- The entities working on medical malpractice claims outside of DHS appear to be using prudent judgment for the disposition of medical malpractice claims. Both County Counsel and DHS' Third Party Administrator appear to be using appropriate logic and forecasting skills to estimate claim risk, establish reserves and settle cases. This may seem contrary to some clinicians that oppose settling claims but their expertise is generally limited to the clinical merits of the case and not necessarily the legal or other risks (i.e., reputational-resource consumption) of an individual case.

WEAKNESSES – INSIDE DHS

- There are poor to non-existent medical risk management databases and analytical tools within the QIPS Unit to assist with trending and event loop closure. The QIPS Unit does not appear to have internal databases (or if they exist they do not appear to be used) to assist with trending and outcome verification of the CAPs process. This was evidenced by the repeated and limited delivery of trended data on adverse events, demonstration and documentation of CAP tracking systems with outcomes, and for

analytic tools used for medical risk management. The goal of any patient-safety program should be to use past experience, adjusted rates of events and other incidents and trends, such as peer group benchmark data, to identify significant enterprise risks and systemic issues, judge relative performance over time, assess the utility of various interventions, and address the key drivers of medical malpractice claims and other events in order to design clinical systems to ensure a safer and less expensive risk environment. The one large exception to this observation is the use of the PSN which has robust data trending capabilities for "events." However, the PSN-requested reports delivered to The Abaris Group were not comprehensive or tied directly to the work being conducted by the QIPS Unit in a consistent manner.

- It is not clear that trending and loop closure documentation activities even exist in DHS or are effective on patient-safety issues. Logs on case closure that were submitted during this study at the request of The Abaris Group did not have the level of detail or result reporting that would be expected and needed in many patient-safety initiatives of the magnitude of DHS due to its size, complexity of issues, and number of care sites. Having total event closure and risk management monitoring tools and documentation that describe and verify closure is imperative.
- There is no overall information technology (IT) vision for DHS' electronic medical health record (EMHR). The Abaris Group was unable to locate a global plan for a medical IT system. While there is some DHS work on this subject underway, it is important that the final IT plan goals be to reduce real-time risk (i.e. real-time patient care flags for procedures or medication conflicts), provide automated quality improvement, assist with coordination of care between all clinical sites and optimize research on patient-safety trends. There is work progressing on an EMHR for the DHS and its clinical sites, but this work is complicated by many past stand-alone site specific IT solutions at various phases of implementation that are widely disparate and do not have the ability to communicate with an enterprise system including between the care sites. The overall cost of such a DHS-based enterprise system is also daunting as is the availability of funding sources for the global IT solution. This situation is somewhat offset given the availability of significant funds for future IT expansion under the 2009 Health Information Technology for Economic and Clinical Health Act (HITECH) Act, which are tied to proposed federal standards for hospitals, critical-access hospitals, and eligible providers who are successful in becoming "Meaningful Users" (MU) of certified EMHR technology.
- The current CAP process is extensive, complicated and does not always contribute to rapid medical risk event identification and mitigation. While the CAP process has improved accountability, it is also time consuming with the entire CAP process taking up to several years for final approval and disposition. Some of this time may be necessary due to pending litigation, but the perceived original goal of rapid medical risk identification and mitigation is not being achieved because of an over abundance of checks, balances and micromanagement. Much of the oversight has been necessary to achieve confidence in the CAP process but has resulted in excesses which have limited DHS staff's ability to finalize CAPs and potential to work comprehensively on proactive medical risk management initiatives.
- Significant distrust exists between DHS, its clinical sites, the CEO's OIG, as well as the Board of Supervisors on medical malpractice claim management and the CAP process. The lack of trust surrounding this process has contributed to breakdowns in communication. There is a perceived lack of transparency between the DHS claim and risk-response process, witnessed throughout this study. This is focused by non-DHS staff on the topics of full disclosure of root causes and also on the adequacy of the corrective actions. Frequently, DHS' position has been that

much of the documentation requested by outside DHS entities, including the Board of Supervisors, is "peer protected." For example, the CEO's Office of the Inspector General, who has oversight for CAPs at the request of the Board of Supervisors, was not allowed by the DHS during the study period, to review certain key documents due to the peer protection concern by DHS.

- QIPS leadership and staff seemed overwhelmed and demoralized during this study due to the nature and extent of outside department scrutiny. A significant result of the complicated CAPs process and the resulting multiple oversights is that the DHS staff feel frustrated, overwhelmed and are perceived by others to act defensive to outside DHS entities requesting specifics on malpractice case investigation details. This impacts DHS' work and the energy the staff dedicate to that work. This further compounds the level of transparency desired by some outside DHS bodies.
- The relationship between the clinical site patient safety staff and the patient safety-officers to the DHS initiatives is not apparent and their current roles may not further overall system initiatives. Even though there was some level of site knowledge of system initiatives, the total and universal level of knowledge of system initiatives by key site stakeholders was not consistently described during the clinical site visits with the patient-safety staff and officers. Instead there was evidence of site specific priorities and methods for patient-safety mitigation that are different from the objectives identified by the QIPS Unit staff which were originally developed by the DHS and the QIPS Unit after significant research, documentation and collaborative input from the sites.
- Significant silos and variation of patient safety interest and practices were evident at each DHS campus site. The sites have much variability with implementing the patient-safety initiatives adopted by the DHS some of which have been identified as system-wide priorities. Many of these implied imperatives were collaboratively developed by the sites. This collaborative process has lead to some site-perceived permission to opt out or slow implementation of key initiatives (i.e. with the automated patient consent process, with some sites have negotiating up to a year for implementation.) In the past, DHS has used this highly-collaborative process between itself and the sites to bring about change in processes where outsiders might interpret that change and outcomes to be an imperative. However, some of this variation of implementing the DHS initiatives can be attributed to the DHS process used and its correspondence directing implementation. For example, a review of a sample of DHS CMO memos on apparent global safety initiatives demonstrated some with very clear mandates, but some worded with terms like "it is recommended," (i.e., vaginal probe cleansing memo) or "I am requesting..." (i.e., Procedure for Compliance with CAPs memo). Another example that shows variation in patient-safety initiatives is the wide range of color coding used for special emergency "alerts" within each hospital (i.e., fire, psychiatric emergencies, floor codes, etc.). Each campus has their own codes; which likely would cause confusion for those medical staff members and nurses circulating among campuses. There are greater than 100 permutations of these codes and color descriptions between all campuses, some of which were the same codes/color descriptions but most were different. The DHS used a similar collaborative process to attempt to streamline the color coding, but this process was recently abandoned due to "campus' concerns that change (i.e., consistency with the color codes) could result in patient-safety issues themselves". This is in spite of the fact that the California Association of Hospital Systems (CAHS) and the local Hospital Association of Southern California (HACS) both have strongly endorsed a statewide standardization for all its member hospital alert codes.

While there is a collaborative approach for many key initiatives which requires global endorsement and implementation of DHS' initiatives, some lack the clarity of purpose and mandate, making systemic patient safety initiative results variable and possibly ineffective.

WEAKNESSES – OUTSIDE DHS

- <u>There is a strong reliance throughout the County on a "blame" philosophy on medical errors and adverse events which is inconsistent with the industry's direction and with the goals of an effective and transparent patient safety program.</u> Targeting "individual" behaviors and not faulty "processes" has been the mainstay throughout the country for corrective actions on patient-safety issues for many years but this trend is changing. This historical blame mentality leads to a concentration on events and people rather than system trends/issues and the blame mentality has been shown to limit root-cause analysis. Studies have shown that a blame approach will limit overall reporting, the thoroughness of reporting and thus continue to undermine patient-safety goals. *Note: A change in approach for individual versus process review would not relieve the County of certain statutory reporting obligations of provider involvement in key malpractice cases.*
- <u>There is a considerable overlap between the clinical medical malpractice evaluation process and the legal process used for claim adjudication.</u> This overlap is complicated by an unusual pairing of clinical staff with the legal and risk management staff "communicating" on case adjudication with no clear lines of demarcation. Many comments were heard from clinical staff that "the County is just settling cases too early" and yet there is no real concern about their inclusion in the process but rather whether their input is "valued."

COMMENTS ON THE STUDY PROCESS

Strengths

During this study, The Abaris Group asked for and was allowed to conduct interviews with a wide range of DHS and non-DHS staff that have a relationship to patient safety and DHS medical malpractice issues. The firm was eventually allowed to obtain access to a range of patient safety initiative documents, action plans and the DHS sources and justification for use of their best practices used for their mitigation efforts.

Weaknesses

Also during the study, there were significant challenges to achieving full access to all relevant CAP documentation and other DHS data and initiative documents. The site visits were controlled and this protracted the study's timetable and somewhat limited access to the latest available date and thus the total conclusions of that data that were reached regarding improvement on CAP response times, on the effectiveness of investigations, and on the clinical sites plan of action on CAPs.* Some of this was driven by DHS and some may have been due to outside department input. For example, The Abaris Group was only allowed access to "closed" CAPs, which severely limited the review to older CAPs and thus the verification of process and closure of more recent initiatives (generally CAPs less than two years old) was limited. Data and observations at clinical sites during the site visits were also carefully controlled in spite of the authorized scope of the study and the accompanying confidentiality and non-disclosure terms of the firm's contract. No direct patient-care observation sessions were permitted in spite of a study imperative that The Abaris Group be allowed this access within the scope of the statement of work.

** While conducting some onsite observation sessions at provider sites and obtaining various patient safety data and more recent CAP documents were challenges during this project, they did not materially affect the study's final observations and conclusions.*

OVERALL IMPRESSION

- There has been a significant reduction in total medical malpractice cases in recent years both within LA County and with health providers in general that may partially relate to the patient-safety efforts of healthcare in general and at DHS.
- In spite of The Abaris Group's limited access to sites, project data, and CAPs, there is evidence that the DHS is progressing towards more timely and comprehensive responses to patient safety events through reduced timeframes for CAP submittals and mitigation steps, including some evidence of verification of mitigation efforts by the DHS at the clinical sites.
- The work conducted at the DHS and its QIPS Unit has expanded dramatically. The necessary system-level work, as well as the day-to-day demands (i.e. CAPs) of patient safety, has grown large and the process cumbersome with many intervening outside requests and demands not reflective in the CAP flow chart. This has greatly impaired QIPS' ability to create a consistent system-wide culture of safety with clear priorities that improve quality and reduce claims.
- While progress has been made with re-engineering the CAP process, the CAP timeframe is still protracted and would need further reduction and focus to assure timely but accurate action plans. The CAP and event reporting/mitigation process will require significant re-engineering to achieve its true value and to hold gains on patient safety.
- With a significant re-engineering of the CAP process, non-DHS staff will become more confident with the DHS' role and direction of patient safety issues that will in turn lead to, over time, a reduction in the level of oversight now required by the Board of Supervisors and its CEO's Office of the Inspector General.
- The DHS has also developed a complex process for patient safety and initiative implementation. For example, there are now approximately 20 patient safety committees (mostly peer review) and other special topic groups (non-peer review) at the department level. One committee, while popular, has 31 listed members and another nearly double that number. The DHS' CMO has assigned himself to chair most of these committees. This level of complexity will be difficult to sustain and may dilute the focus on important key topics and their resolution.
- Continued support for and participation by the DHS on national and state initiatives and implementation should be endorsed. This involvement combined with the recommendations of this report will likely continue DHS' progress to an optimized patient care process and limiting medical risk.

RECOMMENDATIONS

1) **CAP/SCAP Process**: While much work has occurred on revising the CAP/SCAP processes in recent years, this process should continue to be re-engineered towards a "system" focus (rather than an "event" focus) that reduces the concentration of individual blame, eliminates overlaps and improves timelines for CAP approval and issue rectification. This revision needs to result in an increase in the speed of identifying and responding to claims and events (including "near misses") and also expand the system's trend analysis. The proposed re-engineering process should generate improved mutual trust between all County stakeholders and transparency of mission as well as outcomes. Further, the revised CAP process should be collaboratively developed by key staff from the Board of Supervisors office, the CEO's office, County Counsel, Sedgwick CMS, the DHS, and its associated clinical sites. At a minimum, briefings on all current work and innovations that are occurring with DHS on patient safety issues should be held and ultimately the development of a shared vision, an understanding of full and transparent

accountability with maximized accuracy, and specific timelines need to be included. One immediate step would be to accelerate the initial filing of a CAP report to 21 days for select "sentinel" events as defined by the Joint Commission. Another step would be, after confidence in the process is achieved, to change the Office of Inspector General's review of CAPs to a random selection or to only a few targeted CAPs (e.g. sentinel events). The relationship with the OIG and DHS' Office of Audit and Compliance with resulting potential for overlap should be adjudicated. Figure 2 shows the current CAP process, while Figure 3 presents a proposed CAP process.

Figure 2 – Current CAP Process

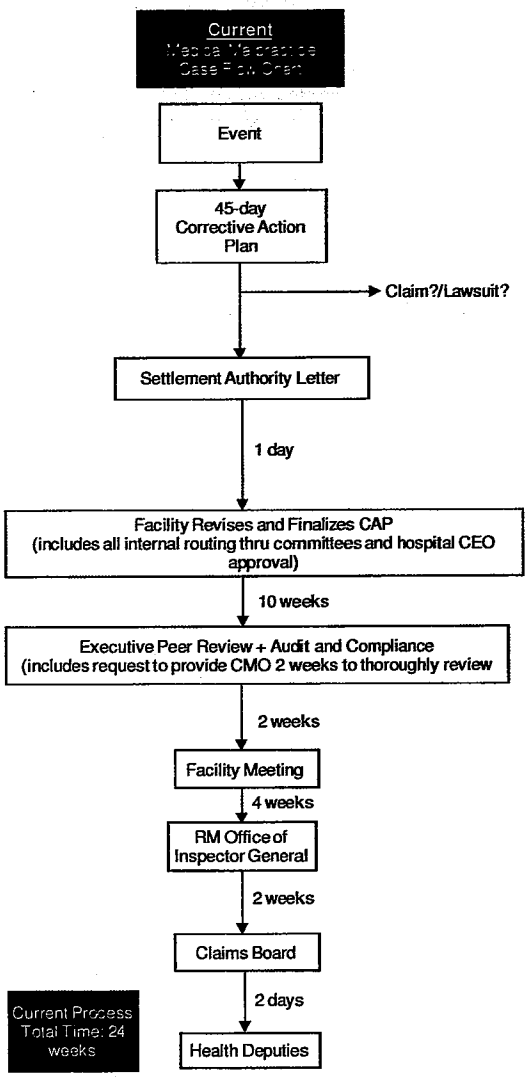
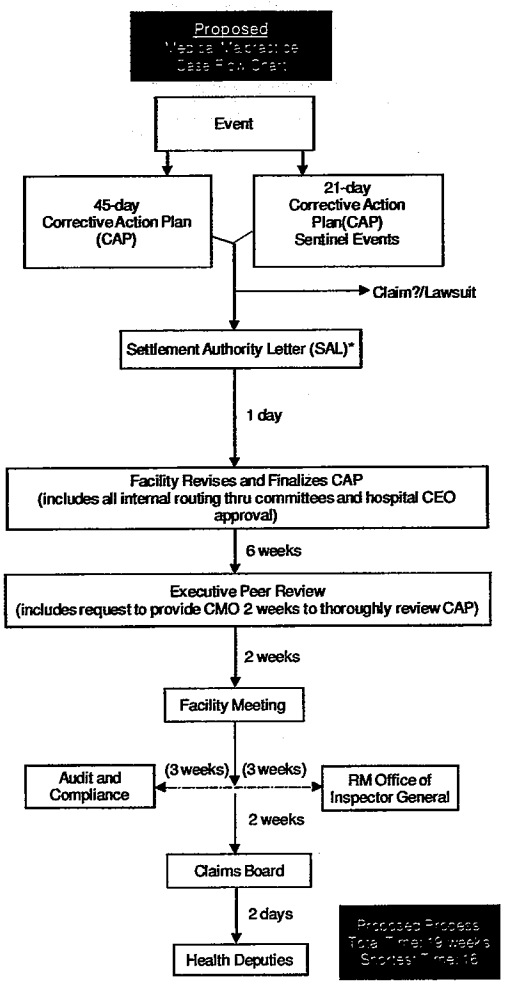


Figure 3 – Proposed CAP Process



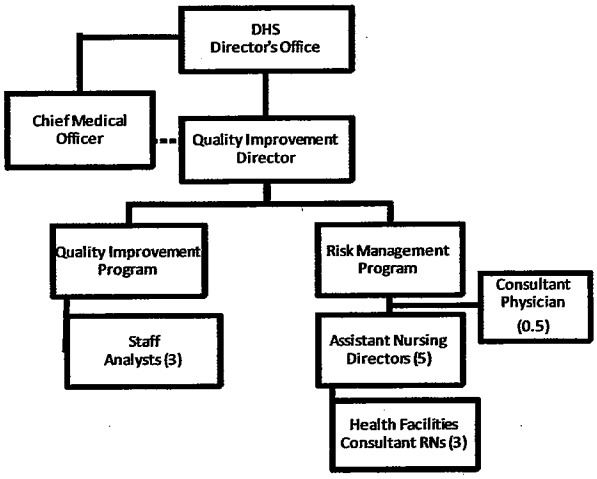
The use of the term "sentinel event" under proposed CAP initial report delivery date does not imply endorsement by The Joint Commission, but rather this term is used as a convenient threshold for expediting reporting on significant cases.

Note: These charts do not include the time for the Settlement Authority Letter (SAL), which can take up to two years. This does not preclude the County from completing a preliminary CAP prior to the SAL.

2) **Patient Safety versus Medical Malpractice Claims Management**: The current overlap between the patient safety and the claims management processes needs to be refocused, with overlaps removed and the claims process redesigned to follow industry standards. Even with this recommendation, important current clinical staff input would still be provided but the claim process would be less subject to the protracted and unproductive "negotiation" period that now exists between the clinical and legal staff and should also result in accelerating the claim process.

3) **QIPS Reporting Process**: The QIPS Unit is staffed sufficiently to conduct its work as long as there is a reduction of the unnecessary and redundant work (as previously mentioned). QIPS is currently conducting initiatives consistent with their scope of work. However, QIPS is also tied to the CMO and to the peer-review process, which may prevent some of the desired transparency that is needed and that should be expected of such a unit. It is recommended that the QIPS Unit, consistent with national patient safety trends, report directly to the DHS Director's Office with a matrix reporting relationship to the DHS' CMO position. This would allow a higher level of accountability for the QIPS Unit, more clarity to their core role of patient safety and assure that key system initiatives are carried out DHS-wide. This step would also minimize QIPS' current investment in the peer-review process, with peer review limited to separate medical staff functions. Under this model, the QIPS Unit would have higher organizational visibility, be more globally patient safety oriented, and interface with the peer review process only as necessary. Figure 4 presents a proposed organizational chart for QIPS.

Figure 4 – Proposed QIPS Medical Risk Management Organization Chart



4) **Health Facility Governing Board**: Historically, the Los Angeles County Board of Supervisors has focused on managing medical-risk management and malpractice events and has not undertaken a potential strategic role on patient safety as the governing body for the DHS' clinical facilities. While this would require certain structural changes to the Board's role on this topic and is made more complex due to the public nature of this role, an enhanced Board of Supervisors' role is available to the Board. As part of this enhancement, it is recommended that the Board of Supervisors adopt a strategic role for patient safety that includes setting patient safety goals, expectations, and adopting a focus that is more effectively and proactively based on creating a safe environment within the hospitals and clinics that it oversees. For example, the Board's time might be better spent ensuring that fundamental safe practices are uniformly adopted across its healthcare system with clear outcomes (i.e. decreasing complications arising from treatment) and demand accountability for achieving those outcomes. With this in mind, either the full Board of Supervisors or a carefully selected delegated subgroup of the Board should consider adopting a more global

"governing" oversight process on patient safety. This would include orientation to nationally-recognized patient safety and best-practice oversight processes, quality outcome standards development, and monitoring and participation in the CAP re-engineering process listed earlier in this section. (For more details of the current expected roles of healthcare governing boards, contemporary trends in claims management and patient safety, see the Appendix.)

5) **Dashboard**: No current DHS-wide quality dashboard was evident during this study. A corporate patient safety dashboard should be published, endorsed and monitored by all stakeholders in the patient care arena of DHS with Board of Supervisor oversight. The dashboard should be designed according to an annually prepared patient safety strategic plan. Please see the sample patient safety dashboard in the Appendix.
6) **QIPS Best Practices**: The QIPS best-practice groups have all made some progress towards their intended goals, but it appears that many have not met recently and others meet only periodically throughout the year suggesting they have met their goals, or have lost their purpose or focus. It is recommended that a smaller, but dynamic, group of four best-practice groups meet twice a month relying on a formal charter that would include goals based on rigorous and focused aim statements to create, spread ensure adoption of best practices and a more disciplined process for conducting their work. These more disciplined groups should include identification of baseline and ongoing data points and the use of rapid cycle testing (an Institute of Health Improvement [IHI] best-practice tool for improving quality and spreading change of evidence-based best practices). The best-practice groups would initially follow the current high-risk topic areas but eventually mature to other topics as success with the original topics is achieved. This recommendation should be replicated for the many DHS peer review committees and initiatives as well. These committees should be tied to an overall Board of Supervisors' patient safety strategic plan that is supported by each facility's strategic patient safety plan and the number of projects should be limited to allow for a focused project completion within a specific timeline.
7) **Reduction of Variation**: Even with the DHS' progress on patient safety efforts, there is tremendous variation between care sites on patient-safety initiatives, endorsement and ownership. DHS and its care units should be seen as endorsing enterprise-wide initiatives and not allow sites to operate as silos on patient safety issues. Roll outs of site-based IT solutions should be minimized and eventually eliminated.
8) **EHMR**: There is an electronic health medical record (EHMR) effort underway within the DHS and its emphasis should be a highly prioritized, completed, refined and fully implemented DHS-wide within an aggressive time period (i.e. five years). Federal stimulus funding and other creative funding sources (e.g. vendor "beta" testing, vendor lending and leasing) should be fully explored. The DHS needs to develop a comprehensive plan for how it will comply with federal Meaningful Use regulations if it intends to access federal reimbursement.
9) **Data/Trending**: The DHS should acquire more analytical resources and then use these resources effectively to trend their patient safety needs, initiatives and outcomes. This would enable more clarity of their direction, outcomes and transparency to their audience, including the Board of Supervisors, their governing board.

GOING FORWARD

The key step identified in these recommendations is establishing a strategic role for the Board of Supervisors on designing and monitoring patient-safety goals. Also required is the refinement and streamlining of the CAP process. To these ends, the QIPS Unit should more sharply focus its patient safety and best-practice initiatives and assure DHS-wide adoption and accountability. Without these steps the medical malpractice and patient safety needs of the County will continue to grow as separate and disparate activities furthering the current gap and reducing effectiveness of these activities. The strategic governing board work could occur within the next 12 to 18 months with the CAP re-engineering process taking less than 12 months, using a collaborative County stakeholder process.

County of Los Angeles

Independent Review: Department of Health Services Medical Malpractice Risk Management – Appendix

County of Los Angeles

APPENDIX – TABLE OF CONTENTS

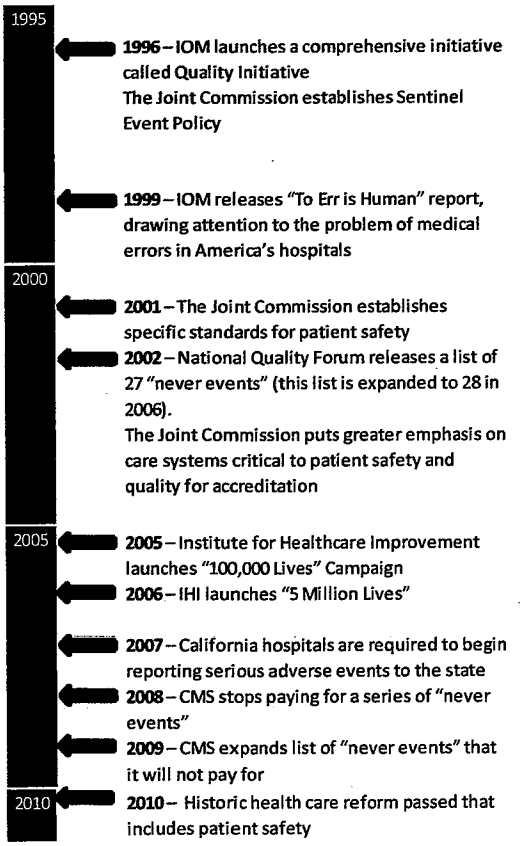
LIST OF TABLES AND FIGURES

PATIENT SAFETY HISTORY OVERVIEW

Until fairly recently, there was relatively little attention paid to patient safety and the necessary efforts to reduce medical errors. However, for the last 15 years patient safety has been recognized as a major healthcare industry priority, with all major players in the industry from hospitals and healthcare organizations, state and local governments, the Joint Commission (JC) [formerly known as the Joint Commission on Accreditation of Healthcare Organizations (or JCAHO)], and the Institute of Medicine (IOM) dedicating time and resources towards improving the quality and safety of care delivered in America's healthcare system.

The following timeline outlines some of the most notable events in the patient safety movement.

Table 1 – Patient Safety Timeline



The following sections describe significant events in the history of patient safety.

EARLY EFFORTS IN PATIENT SAFETY

One of the earliest efforts aimed at improving patient safety was the Institute of Medicine's (IOM) Quality Initiative, a comprehensive effort focusing on many aspects of patient safety, launched in 1996. That same year, the JC established its Sentinel Event Policy. The Sentinel Event Policy requires accredited organizations to create a procedure for identifying, reporting, and managing sentinel events, although each organization is allowed to come up with its own definition for "sentinel event."

IOM – *TO ERR IS HUMAN*

In November 1999, the IOM released its report titled *To Err is Human: Building a Safer Health System*. This report is often credited with inspiring the patient safety movement, as it brought the issue of preventable medical errors to the public's attention. The report stated that between 44,000 and 98,000 people die each year because of preventable medical errors, and preventable medical errors cost an estimated $17 billion to $29 billion annually. The IOM concluded that most medical errors are not caused by reckless or irresponsible individuals or groups, but rather imperfect systems or processes that allow individuals to make mistakes or lack the necessary safeguards to prevent mistakes from being made. The healthcare system needs to be redesigned in such a way to make it harder for healthcare providers to do something wrong. The IOM offered guidance as to what needed to be done by the federal government, state governments, hospitals and health systems, patient-safety organizations, and patients to help reduce the incidence of medical errors. As a result of this report, both Congress and the President pushed for an increased focus on patient safety.

Since the IOM report, a number of organizations have placed a greater emphasis on patient safety

initiatives. For example, in 2001, the JC established specific standards for patient safety, called National Patient Safety Goals.[1]

NATIONAL QUALITY FORUM "NEVER EVENTS"

In 2002, the National Quality Forum (NQF) released its list of Serious Adverse Events, commonly called "never events," a series of events that should never happen. Currently, there is a movement to take the word "never" out of the definition, which will allow more events to be added to this list and therefore may lead to greater reporting of events.[2]

This list serves as a guideline for many state medical error reporting systems. The events are broken into six general topics: surgical events, product or device events, patient protection events, care management events, environmental events, and criminal events.

A complete list of NQF's "never events," compared with the list of California's reportable serious adverse events and the "never events" that Centers for Medicare and Medicaid Services no longer pay for, can be found on page eight of this document.

IHI PATIENT SAFETY CAMPAIGNS

The Institute for Healthcare Improvement (IHI) launched a campaign in 2005 titled "100,000 Lives Campaign," which sought to eliminate at least 100,000 instances of medical errors in hospitals. IHI offered guidance and recommendations for improvements that participating hospitals could make to reduce errors. In fact, the IHI exceeded this goal, preventing an estimated 122,000 medical errors. In 2006, IHI expanded the scope of this campaign, including more hospitals and more ambitious goals, for their "5 Million Lives Campaign."

STATE ADVERSE EVENT REPORTING SYSTEMS

In 2007, California Department of Health Services began requiring hospitals to report on a series of serious adverse events similar to NQF's list.[3] California does not require hospitals to report on one item from NQF's list: artificial insemination with the wrong donor sperm or wrong egg. Instead, California adds another category of reportable events, and makes hospitals report on any adverse event or series of adverse events that is the cause of death or serious disability of a patient, a member of the facility's personnel, or a visitor.

Hospitals must report an urgent event within 24 hours of becoming aware of the event, and a non-urgent event within 5 days.

Many other states have their own reporting requirements, which differ from one another in terms of who is required to report, what events are considered reportable, and to what extent reported events will be kept confidential. California's reporting system is not kept confidential; in fact the state displays each hospital's reported events on a public website along with all complaints made against the facility and any state enforcement actions (such as fines for failing to report an error) against the facility. California's reporting system is also unique in that hospitals are required to notify the patient of the event *before* reporting to the state.[4]

CENTERS FOR MEDICARE AND MEDICAID SERVICES

[1] The current National Patient Safety Goals can be found at the Joint Commission's website: http://www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals/ (site access verified as of 3/4/2010)

[2] McKinney, M. "A new definition: NFQ wants to take 'never' out of 'never events.'" *Modern Healthcare*. February 1, 2010.

[3] California Health and Safety Code Sections 1279.1-1279.3, 1280.4

[4] http://www.socalpatientsafety.org/materials/docs/01-22-2009/02-Mark%20A.%20Kadzielski.pdf (site access verified as of 1/27/2010)

Beginning in fiscal year 2008, CMS stopped paying for several of NQF's "never events." The idea being that if hospitals will not be reimbursed for costs associated with these outcomes, they will focus more attention on eliminating the occurrence of these events and thus improve patient safety. Those events initially targeted included retained foreign bodies in a patient after surgery, death or serious disability resulting from an intravascular air embolism, blood incompatibility, hospital-acquired stage III or IV pressure ulcers[5], injuries related to falls and traumatic events (electric shocks and burns).

The following year, CMS expanded the list of events for which it would not reimburse to include several of NQF's surgical "never events." Specifically, CMS will not pay for the wrong surgery or invasive procedure, surgery on the wrong body part, or surgery on the wrong patient.

[5] There are four stages of pressure ulcers defined by the National Pressure Ulcer Advisory Panel. Stage III and IV are the most severe, characterized by full thickness tissue loss. http://www.npuap.org/pr2.htm (site access verified as of 3/4/2010)

COMPARISON OF REPORTABLE ADVERSE EVENTS AND "NEVER EVENTS"

The National Quality Forum (NQF) is a nonprofit organization that aims to improve the quality of healthcare for all Americans through fulfillment of its three-part mission: setting national priorities and goals for performance improvement; endorsing national consensus standards for measuring and publicly reporting on performance; and promoting the attainment of national goals through education and outreach programs.

NQF created a list of Serious Adverse Events, or "never events," which should never happen in a patient care setting (28 in total). The table below lists each of these events, and compares that list with the list of adverse events that California requires its hospitals to report (29). The table also shows which of these events are on the Centers for Medicare and Medicaid Services' (CMS) list of "never events" which it will not pay for.

Table 2 – Comparison of NQF "Never Events," California "Adverse Events," and CMS "Never Events"

Comparison of NQF "Never Events," California "Adverse Events," and CMS "Never Events"				
		NQF	CA	CMS
1	Surgery performed on the wrong body part	√	√	√
2	Surgery performed on the wrong patient	√	√	√
3	Wrong surgical procedure performed on a patient	√	√	√
4	Unintended retention of a foreign object in a patient after surgery or other procedure	√	√	√
5	Intraoperative or immediately postoperative death in an American Society of Anesthesiologists Class I patient	√	√	
6	Artificial insemination with the wrong sperm or donor egg	√		
7	Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the health care facility	√	√	
8	Patient death or serious disability associated with the use or function of a device in patient care, in which the device is used for functions other than as intended	√	√	
9	Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a health care facility	√	√	√
10	Infant discharged to the wrong person	√	√	
11	Patient death or serious disability associated with patient elopement (disappearance)	√	√	
12	Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a health care facility	√	√	
13	Patient death or serious disability associated with a medication error	√	√	
14	Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products	√	√	√
15	Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a health care facility	√	√	
16	Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a health care facility	√	√	
17	Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates	√	√	
18	Stage 3 or 4 pressure ulcers acquired after admission to a health care facility	√	√	√
19	Patient death or serious disability due to spinal manipulative therapy	√	√	
20	Patient death or serious disability associated with an electric shock or electrical cardioversion while being cared for in a health care facility	√	√	√
21	Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances	√	√	

Table 2 - Comparison of NQF "Never Events," California "Adverse Events," and CMS "Never Events", continued

Comparison of NQF "Never Events," California "Adverse Events," and CMS "Never Events"				
		NQF	CA	CMS
22	Patient death or serious disability associated with a burn incurred from any source while being cared for in a health care facility	√	√	√
23	Patient death or serious disability associated with a fall while being cared for in a health care facility	√	√	√
24	Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health care facility	√	√	
25	Any instance of care ordered by or provided by someone impersonating a physician,	√	√	
26	Abduction of a patient of any age	√	√	
27	Sexual assault on a patient within or on the grounds of the health care facility	√	√	
28	Death or significant injury of a patient or staff member resulting from a physical assault (ie, battery) that occurs within or on the grounds of the health care facility	√	√	
29	Adverse event or series of adverse events that is the cause of death or serious disability of a patient, a member of the facility's personnel, or a visitor		√	

Source: http://www.psnet.ahrq.gov/primer.aspx?primerID=3 (site access verified as of 2/24/2010); California Health and Safety Code Section 1279.1; Centers for Medicare and Medicaid Services (CMS).

LA COUNTY DHS CURRENT PATIENT SAFETY INITIATIVES

The following are some current patient safety initiatives and organizations which LA County DHS is or likely will participate with.

PATIENT SAFETY INITIATIVE AT AMERICA'S PUBLIC HOSPITALS

The National Association of Public Hospitals and Health Systems (NAPH) and the National Patient Safety Foundation (NPSF) joined together to create the Patient Safety Initiative at America's Public Hospitals. Through this project, participating organizations will have access to a number of tools, resources, and educational opportunities to help implement patient safety projects. This project was funded by a grant from the Kaiser Permanente Community Benefit Fund. The Los Angeles County DHS hospitals are among those participating in the program.

More information about the Patient Safety Initiative at America's Public Hospitals can be found here: http://www.naph.org/Main-Menu-Category/Our-Work/Quality-Overview/Strategic-Alliances/NPSF-Initiative.aspx (site access verified as of 2/24/2010)

PATIENT SAFETY FIRST

Earlier this year, Anthem Blue Cross of California provided funding for a patient safety collaborative in California called Patient Safety First. Anthem Blue Cross is working with the Hospital Association of Northern and Central California, the Hospital Association of San Diego and Imperial Counties, the Hospital Association of Southern California, and the National Health Foundation on this three-year project. The collaborative will work to establish benchmark data regarding patient safety, as well as providing participants with opportunities to share best practices and ideas for improving patient safety. Specific focuses of the project include reducing hospital-acquired infections in ICUs and decreasing sepsis.

More information can be found here: http://www.anthem.com/ca/shared/f0/s0/t0/pw_b141675.pdf (site access verified as of 2/24/2010)

CALIFORNIA HOSPITAL PATIENT SAFETY ORGANIZATION

The California Hospital Patient Safety Organization's (CHPSO) was formed by the California Hospital Association. Its mission is to help eliminate preventable harm to patients and to improve the quality of care in hospitals throughout the state. CHPSO works with each of the California regional hospital associations as well as various patient safety collaboratives across the state to achieve its goal. CHPSO offers resources on its website with information for helping hospitals reduce adverse events.

CHPSO's website can be found here: http://www.chpso.org/ (site access verified as of 2/24/2010)

CALIFORNIA PATIENT SAFETY ACTION COALITION

The California Patient Safety Action Coalition (CAPSAC) is made up of representatives from more than sixty hospitals and health systems (including Los Angeles County DHS), professional organizations, patient safety organizations, medical malpractice insurers, and others throughout the state of California. Its goal is to help healthcare organizations move to a "fair and just culture" when it comes to reporting medical errors and adverse events. CAPSAC and its volunteer member organizations believe that this approach allows providers to learn from their mistakes and improve the overall safety of the healthcare delivery system, particularly when compared with a punitive approach that discourages transparency and often results in covering up of adverse events.

The website for CAPSAC can be found here: http://www.capsac.org/ (site access verified as of 2/24/2010)

CALIFORNIA ASSOCIATION OF PUBLIC HOSPITALS – SAFETY NET INSTITUTE

The California Association of Public Hospitals and Health Systems' (CAPH) Safety Net Institute (SNI) works with California's public health systems to facilitate the delivery of high quality, cost-effective, and culturally appropriate services to the state's most vulnerable populations. The SNI develops and funds improvement programs to help spread innovative best practices throughout California's public hospitals and clinics.

LA County Harbor-UCLA Medical Center was a 2009 Quality Leaders Award honorable mention at the 2009 CAPH Annual Conference. The hospital was recognized for work done with its Concurrent ORYX Review Program (CORP). CORP allows for a real-time review of patient documentation that helps the staff provide the best recommended care and document the care.

SNI's website can be found here: http://www.safetynetinstitute.org/content/ (site access verified as of 2/24/2010)

JUST CULTURE

Many hospitals and healthcare organizations are joining the Just Culture movement, an approach to error prevention that originated in the airline industry. Just Culture encourages an environment where individuals learn from their mistakes in order to avoid similar mistakes in the future. The premise of Just Culture enables individuals to report on errors and near-misses and learn from these experiences, without worrying that they will be punished for reporting events that resulted from unintended "human error" or system failures.

A just culture is not the same as a "blame-free" culture; individuals are still held accountable and punished in instances where they behaved recklessly or with negligence. In addition, a just culture also recognizes that adverse events can be caused by "at-risk behavior," in which a provider does not follow the recognized safe process or procedure, but believes that these actions will not actually cause harm. In instances where a provider has demonstrated at-risk behavior, he or she should be coached as to why the behavior was risky and how to behave appropriately in the future.

"Having a safety culture doesn't mean there is no role for punishment. Punishment is indicated for willful misconduct, reckless behavior, and unjustified, deliberate violations of rules...but not for human error."[6]

A number of organizations have developed algorithms to help determine whether an adverse outcome was the result of human error, at-risk behavior, or reckless behavior. More and more hospitals and health care organizations are embracing a just culture attitude, as they recognize that such an attitude is necessary for an environment focused on safety.

Los Angeles County DHS was one of the earliest health systems to adopt a "just culture," according to a press release on the Just Culture Community website.[7]

More information about Just Culture can be found at the following website: http://www.justculture.org/ (site access verified as of 2/24/2010)

[6] Leape, Lucien. "Faulty systems, not faulty people." *The Boston Globe.* January 12, 1999.

[7] http://www.justculture.org/downloads/CAPSACpress release:pdf (site access verified as of2/24/2010)

UNIVERSITY HEALTHSYSTEM CONSORTIUM

The University HealthSystem Consortium (UHC) is an alliance of 107 academic medical centers and 232 of their affiliated hospitals representing approximately 90 percent of the nation's non-profit academic medical centers. The mission of UHC is to advance knowledge, foster collaboration, and promote change to help members succeed in their respective markets. UHC offers an array of performance improvement products and services, including the Patient Safety Network (PSN), which is an online tool that allows hospitals to report, track and trend adverse medical events in real time. The data collected by the PSN can be used for quality improvement projects, and can be compared with the aggregate data set from all members of the UHC.

DHS hospitals all use the PSN, and DHS recently designated the UHC as the Patient Safety Organization (PSO) for LA County's hospitals and the Multi-Service Ambulatory Care Centers (MACC).[8] DHS requires its hospitals to report all patient safety events and near misses, either clinical or non-clinical, to the PSN.

More information about the UCH's PSN can be found here https://www.uhc.edu/11851.htm (site access verified as of 2/24/2010)

[8] http://file.lacounty.gov/bc/q1_2010/cms1_141980.pdf (site access verified as of 2/24/2010)

DATA OVERVIEW OF LA COUNTY DHS HOSPITALS

LA County DHS manages four hospitals, including an in-patient rehabilitation hospital:

- Harbor-UCLA Medical Center
- LAC+USC Medical Center
- Olive View-UCLA Medical Center
- Rancho Los Amigos National Rehabilitation Center

The largest of these hospitals, LAC+USC Medical Center, has 600 licensed general acute care beds and had 37,132 discharges in 2008. The smallest is Olive View-UCLA Medical Center, with 297 licensed beds and 13,301 discharges in 2008.

Table 3 – LA County DHS Hospitals Selected Variables, 2008

LA County DHS Hospitals Selected Variables, 2008	Harbor-UCLA	LAC+USC	Olive View	Rancho Los Amigos
Licensed Beds	531	600	297	395
Hospital Discharges	21,518	37,132	13,301	3,169
Average Length of Stay	5.2	5.2	4.5	18.8
ED Beds	40	90	15	n/a
Total ED Visits	82,393	140,054	42,421	n/a
% of ED Visits Admitted	19.9%	18.8%	21.5%	n/a
Total Live Births	1,101	1,377	1,002	-
Total Operating Rooms	11	31	10	7
Total Surgical Operations	9,779	12,937	6,660	1,697

Source: OSHPD Annual Utilization Report of Hospitals, 2008

LA COUNTY DHS PATIENT SAFETY MEDICAL EVENTS AND CLAIMS DATA

LA County DHS' hospitals report serious adverse events to the state as required by law. Table 3 presents the types of events reported by each of these hospitals in 2008, as well as a comparison with the average events at all general acute-care hospitals in California, with greater than 290 licensed beds. Only 2008 data are included because the law did not go into effect until midway through 2007. Anything before July 2007 represents voluntary reporting and may not give an accurate view. At the time of this report, 2009 data were not publically available in their entirety.

Table 4 – Serious Adverse Event Reporting, 2008

Serious Adverse Event Reporting, 2008	Harbor-UCLA	LAC+USC	Rancho Los Amigos	Olive View	Statewide[1] Average per Hospital
Total Entity Reported Incidents	**21**	**30**	**2**	**8**	**10.8**
Accidents	-	-	-	-	0.1
Adverse event or series of events	1	1	-	1	0.1
Death - general	1	-	-	-	0.3
Death during or up to 24 hours after surgery	-	-	-	-	0.1
Death/disability due to a fall	-	-	-	-	0.2
Death/disability due to labor/delivery/post delivery	1	-	-	-	0.0
Infection control	-	-	1	1	0.2
Medication error	1	-	-	-	0.2
Nursing services	-	-	-	-	0.1
Pharmaceutical Services	-	-	-	-	0.1
Physical environment	-	-	-	-	0.2
Physician services	-	-	-	-	0.1
Quality of care/treatment	4	6	-	2	2.4
Resident/patient/client abuse	-	-	-	-	0.3
Resident/patient/client rights	-	-	-	1	0.2
Retention of a foreign object in a patient	1	4	-	-	0.9
Stage 3 or 4 ulcer acquired after admission	12	18	1	2	4.5
Suicide or attempted suicide	-	1	-	1	0.1
Surgery performed on the wrong body part	-	-	-	-	0.1
Other	-	-	-	-	0.7

[1]Includes all general acute care hospitals with greater than 290 licensed beds (85 total). Source: California Health Facilities Consumer Information System - Health Facilities Information; http://hfcis.cdph.ca.gov/default.aspx (site access verified as of 1/27/2010); Abaris calculations.

Table 4 shows the rate of adverse events per 1,000 discharges.

Table 5 – Serious Adverse Event Reporting per 1,000 Discharges, 2008

Serious Adverse Event Reporting per 1,000 Discharges, 2008	
Harbor-UCLA	0.98
Rancho Los Amigos	0.63
LAC+USC	0.81
Olive View	0.60
Statewide[1]	0.60

[1]Includes all general acute care hospitals with greater than 290 licensed beds. Source: Serious Adverse Event data: California Health Facilities Consumer Information System - Health Facilities Information; http://hfcis.cdph.ca.gov/default.aspx (site access verified as of 1/27/2010); and discharge data from OSHPD Annual Utilization Pivot Profiles for Hospitals, 2008; Abaris calculations.

Harbor-UCLA had the highest rate of reported adverse events in 2008, with 0.98 events per 1,000 discharges. More than half of these events were hospital-acquired pressure ulcers. LAC+USC Medical Center reported 0.81 events per 1,000 discharges, and again the majority of these were hospital-acquired pressure ulcers. Rancho Los Amigos and Olive View Medical Center showed 0.63 and 0.60 events in 2008, respectively. On average, California general acute care hospitals with greater than 290 licensed beds reported 0.60 events per 1,000 discharges in 2008. It should be noted that the data from all hospitals is subject to reporting compliance which may vary by hospital.

MEDICAL MALPRACTICE CLAIMS

The following figures show information on medical malpractice claims against LA County DHS and its hospitals, including total new claims files, claims settled, and settlements paid. The data are from the LA County Risk Management Information System (RMIS) and DHS' claims data.

It is important to note that while the following data are presented by calendar year, the data may vary because of variables such as the timing of the

calendar claim (e.g. date filed within a year), the process of settlement, and the settlement dates.

The number of new files (a file includes any event that may eventually lead to a claim) has declined steadily each year since 2002. In 2002, there were a total of 354 new files, while in 2009 there were 107 new files.

Figure 1 – DHS Medical Malpractice New Files

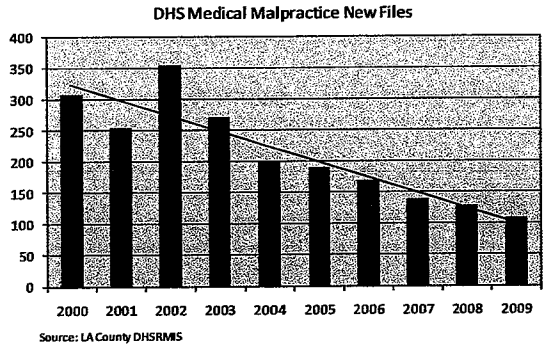
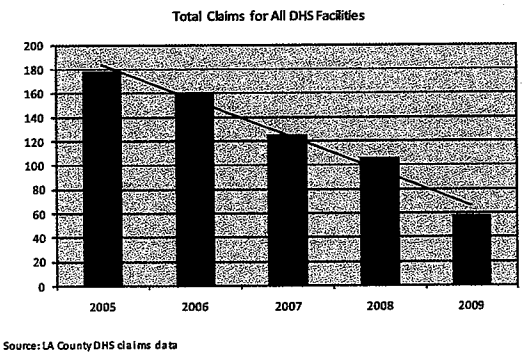


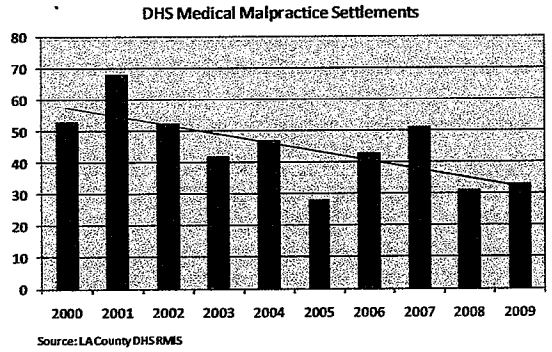
Figure 2 – Total Claims for All DHS Facilities

Total claims for DHS' facilities have also experienced a decline. The change from 2005 to 2009 was a drop of 67.4 percent (or an absolute change of 120 claims).



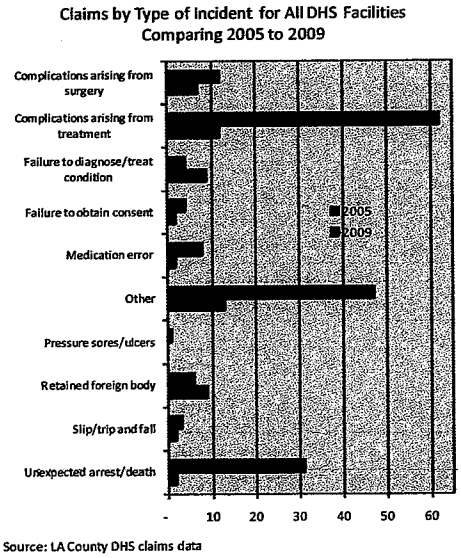
Total settlements have fluctuated over the past ten years. However, the trend shows a general decline. Averages of 44.8 claims were settled each year from 2000 to 2009.

Figure 3 – Total Settlements for All DHS Facilities



In 2005 the type of incidence with the most claims was complications arising from treatment (62 claims), while in 2009 the most claims fell into the other[9] category (13), followed closely by complications arising from treatment (12).

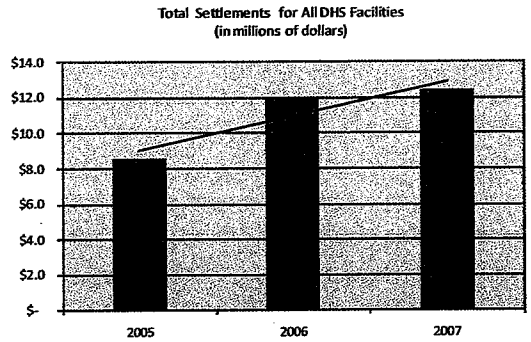
Figure 4 – Claims by Type of Incident for All DHS Facilities, Comparing 2005 to 2009



[9] A sample of the categories in "Other" are: abandonment, delay in accepting transfer, elopement, equipment/machinery, physical abuse, as well as others occurring too few in number to be compared.

While the number of new files, claims and settled claims have been declining, the dollar amount of the settled claims has risen each year from 2005 to 2007 (there are still outstanding claims for 2008 and 2009, thus it was not possible to include these years in the comparison).

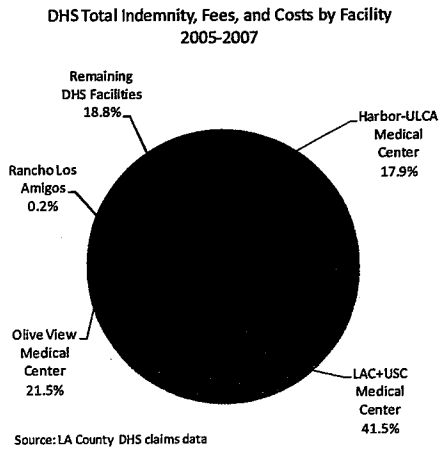
Figure 5 – Total Settlements for All DHS Facilities



Source: LA County DHS

The dollar value of settled claims from LAC+USC Medical Center accounted for 41.5 percent of all such DHS payments from 2005 to 2007. Another 21.5 percent of total payments were for Olive View claims, and 17.9 percent were for Harbor-UCLA. Payments for claims originating at Rancho Los Amigos made up 0.2 percent of total payments for the same time period.

Figure 6 – DHS Total Indemnity, Fees and Costs by Facility, 2005-2007



Source: LA County DHS claims data

CALIFORNIA MEDICAL MALPRACTICE LAW

The following sections describe medical malpractice laws applicable to those health providers in California.

CA STATUTE OF LIMITATIONS

In California, a medical malpractice lawsuit must be filed within three years of the incident, or one year after the plaintiff discovers (or reasonably should have discovered) the injury, whichever is first.

Exceptions of the three-year deadline include events where there is proof of fraud, intentional concealment of the event, or the presence of an unintended retained foreign body in a patient that was not discovered until later (CA Code of Civil Procedure Section 340.5). A lawsuit may not be filed unless the defendant is given at least 90 days notice of the intention to file a lawsuit (CA Code of Civil Procedure Section 364(a)). If a plaintiff serves the notice of intention within 90 days of the deadline imposed by the statute of limitations, then the deadline for filing a lawsuit will be extended by 90 days from the date of the notice (CA Code of Civil Procedure Section 364(d)).

When the claim is against a public entity, a claim must first be filed no later than six months after the initial incident (CA Government Code Section 911.2(a)). A lawsuit may not be filed against a public entity unless a claim has been filed within the six-month deadline (CA Government Code Section 945.4).

MEDICAL INJURY COMPENSATION REFORM ACT (MICRA)

In 1975, California legislature passed the Medical Injury Compensation Reform Act (MICRA) in response to escalating medical malpractice costs that were driving many healthcare practitioners out of business. As a result of the crippling malpractice costs, there were shortages of healthcare providers, which limited access for patients. This was particularly true for high-risk specialties, such as OB-GYN, community clinics, and rural providers that could not afford to pay increased premiums.

In the ten years prior to MICRA, the number of insurance claims in California had increased by 200 percent, and the dollar amounts that were awarded increased 1,000 percent. As a result, many medical malpractice insurers found it too risky and unstable to continue to write policies in the state. In 1975, one major malpractice insurer announced that it would cease coverage for approximately 2,000 physicians in Southern California, while another insurer increased premiums by 380 percent for 4,000 physicians in Northern California.

Specifically, MICRA does the following:

- Allows for binding arbitration to settle disputes
- Ensures compensation for economic damages
- Limits attorney contingency fees on a sliding scale
- Places a $250,000 limit on non-economic damages only
- Provides a statute of limitations on claims
- Provides for periodic payment for future damages
- Requires 90-day advance notice of a claim

Under MICRA, patients are still able to seek an unlimited amount of economic damages following an incident of medical malpractice, including damages for past and future medical costs, lost wages, lifetime earning potential and any other conceivable economic damage; and punitive damages; however speculative non-economic damages (pain and suffering) are limited to $250,000.

Additionally, MICRA limits attorneys' fees so that patients receive a greater portion of the amount awarded in a malpractice lawsuit. Because of MICRA,

more than $190 million in high-damage awards went

to the patient, rather than lawyers, from 1999 to 2006.

"Today MICRA saves the healthcare system billions of dollars each year and increases patients' access to healthcare by keeping doctors, nurses, and other healthcare providers in practice and hospitals and clinics open."[10]

In May 2003, the Wall Street Journal praised MICRA, saying it "has held down liability costs for doctors and hospitals while speeding settlements and fairly compensating patients who have been genuinely harmed."

A 2004 Rand study found that MICRA reduced defendants' liabilities by 30 percent. Although MICRA has not significantly reduced the number of lawsuits filed in California (in fact the per capita filings today are higher than they were pre-MICRA), the average payment on large-loss claims has decreased dramatically (after adjusting for inflation). In 2004, California had the third lowest average per-claim malpractice payment, of about $132,696 (http://www.hcla.org/studies/2005MICRA&AccessToHC.pdf (site access verified as of 2/23/10)).

Since MICRA, California's medical malpractice premiums have remained relatively flat, particularly when compared with other states that have not enacted any sort of malpractice reform.

[10] Californians Allied for Patient Protection. http://www.micra.org/about-micra/about-micra.html (site access verified as of 2/24/10)

RISK MANAGEMENT INFORMATION TECHNOLOGY

The healthcare industry is generally considered to be lagging behind other industries in terms of adoption and utilization of information technology (IT), despite the fact that IT has the potential to greatly enhance patient safety. According to the IOM report *Crossing the Quality Chasm: A New Health System for the 21st Century*, the use of information technology in the delivery of healthcare, specifically in automating transactions and processes, is essential for reducing medical errors in the future.

IT can be particularly beneficial for risk managers, who make many decisions and plan patient safety projects based on the data available to them.

ELECTRONIC MEDICAL HEALTH RECORDS (EMHRS)

Anecdotal evidence suggests that EMHRs may help reduce a physician or hospital's medical malpractice liability, by improving quality of care and patient safety. The use of EMHRs may help reduce diagnostic errors, improve follow-up for abnormal test results, encourage better adherence to guidelines and recognized standards of care, create more complete and legible documentation, and facilitate better patient-physician communication. Additionally, the enhanced documentation provided by EMHRs can help a provider defend himself against claims in which the standard of care was followed.

A study published in the November 24, 2008 issue of *Archives of Internal Medicine* attempted to determine whether EMHRs could help reduce medical malpractice claims. For physicians examined in the study, the rate of paid malpractice claims was 6.1 percent for those who use EMHRs, compared with 10.8 percent of those without EMHRs. However, this difference was not statistically significant after adjusting for other factors. The study's authors feel that these results suggest that EMHRs might help reduce malpractice claims, however further research must be done as their results were inconclusive.

While there is no definite evidence that EMHRs do reduce malpractice claims, a number of malpractice insurers are recognizing their potential to do so, and offering premium discounts to those physician practices and hospitals that adopt EMHRs.

COMPUTERIZED PHYSICIAN ORDER ENTRY (CPOE)

Computerized Physician Order Entry (CPOE) systems allow physicians to electronically order medications for patients. These systems can alert the physicians of possible prescribing errors, including potential adverse drug interactions and patient allergies. A study published in the *Journal of the American Medical Association* in 1998 found that the rate of serious medication errors decreased by more than 50 percent when physicians used computerized systems for prescribing medication.

STUDY SPECIAL TOPICS

During this study a review and commentary on four specific special topics on patient safety for this project was conducted as follows.

JOINT COMMISSION'S ONGOING PROFESSIONAL PRACTICE EVALUATION (OPPE)

The Joint Commission's Ongoing Professional Practice Evaluation (OPPE) requirement mandates that hospitals perform more frequent performance reviews for all practitioners. Hospitals typically wait to perform such evaluations until a practitioner's biennial reappointment. OPPE requires all staff to be evaluated. Although the Joint Commission does not specify how often these evaluations should be done, once every twelve months would not be too frequent to meet the "ongoing" requirement. Many hospitals are choosing to perform their OPPE every six to nine months. The type of data collected is to be defined by the individual medical staff departments, as they are the best qualified to determine what sort of data would reflect good performance versus problem performance within the department. Hospitals may perform OPPE using periodic chart review; direct observation; monitoring of diagnostic and treatment techniques; and discussion with other individuals involved in the care of each patient, including consulting physicians, assistants at surgery, nursing, and administrative personnel. The OPPE shall be used to determine if a provider's privileges should be revoked or suspended, or if further investigation is needed.

Current Status of LA County Study Health Facilities and OPPE

The LA County DHS facilities that participated in the site visits (four hospitals and five clinic sites) have elected to conduct their reviews every six months with each hospital is at a different level of execution of OPPE. Harbor UCLA and Olive View Medical Center have recently fully implemented a process, while LAC+USC and Ranchos Los Amigos have designed a process and are just beginning to implement. However, none are using a formal electronic OPPE tracking system, which is a developing industry standard. Instead the facilities are using either homegrown Excel or Access (Rancho) databases to assist them in their OPPE process. While there was a negotiated DHS CMO deadline of 100 percent compliance by July 2010, there has been considerable variability of each site's expectation and ability to meet this deadline.

Another potential weakness is responding to the amount of manual work required to provide ongoing monitoring for the facilities' current OPPE process with their available resources. It was reported that only two to three staff members are responsible for monitoring up to 2,000 medical staff and allied health professionals. While the facilities each have similar processes, it does not appear that there is a system-wide process that has been endorsed or adopted for OPPE. In addition, it was reported that if a medical staff member provides services at two facilities, for example Rancho Los Amigos and LAC+USC, the process is still conducted done separately at each facility.

PRESSURE ULCERS, RETAINED FOREIGN BODIES AND PATIENT FALLS

The Abaris Group was asked to assess and evaluate the current strategies associated with reducing hospital acquired pressure ulcers, retention of foreign bodies, and reducing patient falls at DHS' facilities. In addition, best practices were identified for each of the three topics.

Pressure Ulcers

Each facility has developed a process for pressure ulcers and each uses the "four-eyes" process, which is a best practice from the Institute for Healthcare Improvement, and all pressure ulcers are entered into the Patient Safety Network (PSN) database.

However, there is no standardization across the system to treatment mitigation such as for the use of wound-care teams (i.e. team makeup, delivery of care, etc.), equipment used. Some sites lack the right type of equipment altogether for wound care (such as wound specific supplies). Harbor UCLA appears to have the best organized process among the hospitals. Also, the nursing documentation form used by Rancho Los Amigos and Olive View Medical Center show good outcomes based on sample testing but it is still only being tested on select nursing units at both hospitals and has not been rolled out to all patient care units. Each hospital has a different sign denoting the status of pressure ulcers and a different name for their process. This could be an issue for physicians and staff that go to more than one facility. In addition, DHS has a goal of reducing pressure ulcers (also known as decubitus ulcers or bed sores) by 50 percent at each facility by the end of 2010.

Harbor UCLA has a wound care team that sees all patients with a score of 16 (Braden wound score) or lower. The Braden Scale is used to determine pressure sore risk and the higher the score the lower the risk. Thus, seeing patients with a score of 16 or less captures those patients who are considered "at risk" all the way to those who are at "very high risk." There are three teams that comprise the wound-care team and each team consists of a resident and nurse who round daily, which is considered a best practice. If a patient needs more, the hospital has special wound care beds that are available. In addition to the rounding team, Harbor UCLA also provides education about pressure ulcers during new employee orientation and also has a wound-care awareness month. A few issues identified surrounding pressure ulcers were inconsistent documentation among nursing, the medical staff and the team, the team program is only available Monday through Friday, there is a need for patient "turning teams", and the facility has very few mechanical lifts.

Like Harbor UCLA, LAC+USC also have a wound care program that consists of a certified wound nurse, burn nurse and a nurse in training. In January 2010, the hospital implemented a new program called "Roses" where a yellow rose signifies a patient is at high risk for a decubitus ulcer and a red rose signifies that the patient has already developed an ulcer. There is a protocol for nurses to document the status of their patients every four hours and the hospital also has special wound care beds if needed. A couple of issues identified included consistent documentation among residents since they rotate through monthly and the ordering of a specialty bed is a cumbersome and time consuming process that needs to be simplified.

Olive View has a wound nurse who provides education on the various stages of pressure ulcers, recommends a treatment program depending on the stage, assists other providers with proper documentation, and makes recommendations during Grand Rounds. If a patient has a pressure ulcer the bed side or room sign is an apple with bite out of it. In addition to the care the wound nurse provides, they also provide ostomy care. Like Harbor and LAC+USC, consistent documentation among the healthcare team is a challenge. However, Olive View's enhanced and tested documentation has resulted in a significant improvement in consistent documentation.

Unlike the other hospitals, Rancho Los Amigos does not have an official wound care nurse; wound issues get reported to a clinical nurse specialist. While they might not have an official wound care nurse, they do have a goal in place to have less than or equal to one pressure ulcer per 1,000 patient days and as of January 2010 they had 2 pressure ulcers. Rancho is trialing a new form on one of their units that allows the physician and nurse to document the wound care on the same form, which is considered a best practice. Another procedure that was implemented in December 2009 is called Safety Cross where the number of pressure ulcers and type are written on the cross. The visual cue is placed either at the head

or foot of the bed. Some of the nursing units also use other visual cues: a green sticker means low risk, yellow is medium, red with a check is high risk and red with black indicates that the patient has a pressure ulcer, but it is not consistent throughout the facility. Like Olive View, Rancho also uses the "four eyes" skin check procedure. One issue noted at Rancho is that the clinical specialist nurse typically does not go to other units unless asked for. Another issue is that nursing must document about pressure ulcers in three separate places, and redundant charting results in wasted time, which may lead to documentation policy noncompliance, miscommunication among the care team on wound status, and potentially delayed or misdiagnosis of care.

PRESSURE ULCERS BEST PRACTICE – THE METHODIST HOSPITAL

The Methodist Hospital (Houston) has taken steps towards improving patient safety and avoiding harmful "never events" by focusing on: preventing surgery on the wrong part of the body, preventing surgery on the wrong patient, preventing death/disability due to transfusion of blood or blood products of the wrong type, preventing severe hospital-acquired pressure ulcers, and preventing medication errors. The Methodist Hospital employs "secret shoppers" to observe the nursing and medical staff, checking that they follow the required procedures.

In acute care units, patients' skin is checked daily for any signs of redness. In intensive care units (ICU), patients are checked every four hours for signs of redness or any breakdown of skin. Every two hours, members of the nursing staff will reposition patients to help relieve pressure. Because excess moisture increases the risk of skin breakdown, nursing staff promptly clean up any incontinence. Patients who are identified as being at high risk for pressure ulcers will be given special mattresses, beds, or heel protectors. Wound care nurses are available to offer expert advice on how to prevent or treat pressure ulcers. The Methodist Hospital monitors its rate of pressure ulcers in the ICU weekly, and monthly in acute care units, to help identify problems and make adjustments as needed.

PRESSURE ULCERS BEST PRACTICE – OSF ST. FRANCIS MEDICAL CENTER

OSF St. Francis Medical Center (Peoria, Illinois) implemented a series of best-practice protocols to reduce the occurrence of hospital-acquired pressure ulcers, which were happening at a rate of about 9.4 percent. Specifically, OSF St. Francis has a skin breakdown prevention protocol, which was developed using recognized best practices from the Agency for Healthcare and Research Quality (AHRQ) and the Wound, Ostomy, and Continence Nurses Society. As part of this protocol, OSF St. Francis puts dry-flow pads under incontinent patients and uses pre-moistened disposable barrier wipes to keep the patients clean and protected.

A pressure ulcer risk assessment is performed using the Braden Scale on all patients when they are admitted, and the assessment is repeated every 24 hours. Patients with a score of 18 or lower are considered "at risk," and these patients are identified by an SOS (Save Our Skin) sign on their door. Caregivers are careful to check for and document pressure ulcers upon admission, as any pressure ulcer not documented within 24 hours of admission is considered "hospital acquired." Caregivers pay particular attention to any bony parts of the body, and remove thrombo embolic deterrent (TED) hose and socks to check the patient's heels. Preoperative patients who are assessed to be at risk for pressure ulcers are also identified by an SOS sticker on their chart, so that caregivers know to take necessary precautions against pressure ulcers in the OR and recovery room.

Additionally, OSF St. Francis purchased pressure redistribution mattresses for all patients; for patients who already have stage 3 or 4 pressure ulcers, nurses will order low-air-loss mattresses. Every two

hours, the hospital plays a portion of the Olympic theme song throughout the hospital, which serves as a reminder for caregivers to reposition at-risk patients. Additionally, a special "lift team" rounds the ICUs every two hours to help reposition patients.

The SOS team meets monthly to review progress made towards reducing pressure ulcers. This team examines performance unit-by-unit level, specifically looking at each unit's compliance with four procedures: initiating the prevention protocol; providing patient/family education; turning/tilting patients every two hours; and placing SOS signs on at-risk patients' doors.

Finally, the occurrence of hospital-acquired pressure ulcers are reported monthly to the Medical Center Quality Safety Board, the Medical Executive Committee, the Professional Staff Quality Improvement Committee, and the OSF Healthcare Corporate Office, along with other "never events" identified by the hospital.

Retained Foreign Bodies (RFB)

DHS has standardized the processes for sponge counts, gowning and gloving, and surgical scrubbing with all hospitals have good counting processes in place. However, LAC+USC will be going to radio frequency sponges, which is a best practice. Microscopic chips are placed in the sponges and a wand is used to scan whenever a count is off to locate the missing sponges. LAC+USC appears to be ahead of the other hospitals with respect to education, monitoring, etc. This is probably due to some of their past patient safety issues. Their lessons learned and processes developed would be an excellent source for the other hospitals to implement, especially the education to medical staff. All four facilities also automatically do an abdominal x-ray when there is an incorrect count and all issues go to quality improvement for loop closure.

At the time of their site visit, Harbor UCLA said that they have had two medical malpractice cases regarding retained foreign bodies. In order to deal with these cases, a patient safety consultant was brought in and areas were identified for improved processes. The hospital updated their retained foreign body policy, which now requires documentation on the surgical record, read back with the surgeon, and employs a process that marks all surgical patients prior to leaving the floor. Harbor has developed a plan to continue to improve surgical processes around retained foreign body with one being a dedicated multidisciplinary team on sponge counts.

As previously mentioned, LAC+USC has better documentation, monitoring, and updated policies on retained foreign bodies. The new RFS process is expected to begin in April 2010 with equipment in each OR suite. Currently physicians document sponges that were intentionally left in using an electronic documentation system called ORSYS. LAC+USC also does quarterly education for medical staff and since the hospital's last medical malpractice case involving retained foreign bodies (RFBs), they have not had one case pertaining to intentionally left RFBs.

Olive View Medical Center uses a pre-procedure process that employs two staff audibly counting, another count as the cavity is being closed and one more count as the skin is being closed. This process is considered a best practice.

Rancho Los Amigos has a detailed counting process that is initiated by a technician and continues from there. If any items are added, the count is repeated. All counts are posted on a whiteboard in the OR so all can see. Counts are also done if there is any change of staff and like the other facilities, there is a count when the cavity is being closed and again at the end of the procedure. No one is allowed to leave the OR if an item is missing and an x-ray is taken and read before the patient leaves the OR suite. Reportedly, Rancho has no cases involving RFBs.

RFB BEST PRACTICE – CEDARS-SINAI MEDICAL CENTER

A task force was established at Cedars-Sinai Medical Center (Los Angeles) to eliminate the occurrence of unintentional retained foreign bodies in patients following surgery. The primary focus of this task force was to determine what risk factors can lead to foreign bodies being retained after surgery and come up with methods for preventing retained foreign bodies. The following procedure was created using recognized best practices for eliminating retained foreign bodies:

- Prior to closure, the surgeon must do a final "sweep" – a "visual and manual interrogation of the cavity which has been operated on."
- An x-ray should be taken if any of the following criteria are met: sponges, needles, or instruments are not able to be counted for any reason; there was a major deviation from the planned surgery (i.e. unexpected blood loss, code blue, or unplanned increase in surgical teams); the surgery involved open chest or abdomen in a patient with a body mass index of greater than 40; or an unintended and emergent switch from laparoscopy to an open procedure.
- The wound may not be closed and the surgeon may not leave until the results of the x-ray have been received from the radiologist.

If the patient's condition becomes life-threatening, then these steps can be skipped in order to more quickly get necessary care to the patient. In this case, caregivers must properly document what was done and why the procedure was not followed.

All allied health professionals and members of the medical staff must demonstrate that they have completed an educational and training course regarding the elimination of retained foreign bodies.

RFB BEST PRACTICE – ST. MARY'S MEDICAL CENTER

After two serious adverse events in 2007 involving the retention of a foreign object in a patient after surgery, St. Mary's Medical Center in Hobart, Indiana, turned to technology to prevent these events from happening in the future. Previously St. Mary's used a simple counting system to make sure that foreign bodies were not left inside patients. When the count was not correct, x-rays were used to locate missing items. Unfortunately, x-rays won't always reveal a retained sponge, so this system still allowed the opportunity for error. St. Mary's now uses sponges with attached radio frequency (RF) tags. Prior to closure, an RF detection wand is used to locate any sponges that may have been misplaced. The patient will not leave surgery until every missing sponge is found.

Patient Falls

All the facilities have a fall prevention program in place and each has strong attributes, however, there is no system-wide standardization for fall prevention. Each facility calls their program a different name and there is separate designed signage at each site. Again, this may be an issue when staff practices at more than one facility and also does not value a best practice that may be more effective. Equipment is not standardized among the facilities. For example, LAC+USC's beds are all alarmed, while other facilities have limited or no alarmed beds available. Hourly rounding on falls is done at all facilities, which is a best practice from IHI. However, it was not clear if this is monitored or if it is done consistently on all units. Harbor UCLA has had very few falls and uses some innovative best practices to achieve this. All hospitals, except for Rancho, use arm bands to denote a fall risk, which is standard for patient safety.

Harbor UCLA states that their number of falls is very low. They cohort high-risk falls together in the same room and/or same nursing unit which has resulted a

significant reduction in the number of falls. Another best practice they use is the involvement of the family in the turning schedule. The family member must be trained and sign off on the training; they can also refuse to participate.

LAC+USC recently updated their fall policy. They conducted focus group studies and found that most falls happen when a patient is getting out of bed without assistance to use the bathroom. They also found that more than 50 percent of all patients are found to be at risk due to the high volume of intoxicated and altered level of consciousness patients. While their risk assessment tool is home grown, it was developed by a multidisciplinary clinical team and appears to work very well for them. Their visual cue is a sign showing a falling person and all beds have alarms with the alarm automatically going to the nursing station (a best practice). If the patient elects, they can sign to have the alarm turned off. LAC+USC conducts hourly patient rounding since opening the new hospital in 2008. This best practice was developed by the staff, which has been shown to increase staff compliancy. Nursing assistants are expected to round every 30 minutes (a best practice), but this may be a challenge because of a lack of nursing assistants. When this occurs the hospital uses registry sitters. However, it was not clear if there are times when patients are not monitored as the policy states.

Olive View developed its "Falling Star" program two to three years ago, which uses signs and identification bands. While Olive View is not happy with the number of falls that happen at their facility, they claim they are below national average in terms of benchmark data. Their goal is to reach no more than 2.3 patient falls using the University HealthSystem Consortium (UHC) benchmark. Olive View has reduced the number of falls by 20 percent, but believes it cannot be further reduced because of the significant number of intoxicated patients they treat who are at a high risk. The hospital does capture and trend the fall data by nursing unit. A couple of issues that were identified include the psychiatric staff tending to over report falls (often counting when a patient is found sitting on the floor as a fall) and there is no annual competency on fall prevention.

Rancho Los Amigos uses a database to document and ascertain a patient's risk assessment and they also use a fall sticker on most units. One unit uses stickers and a name plate that is on the foot of the bed that identifies that the patient is at risk. Continuous monitoring is provided by the caregiver for high-risk patients. In fact, caregivers wear a specialized name badge which is passed from caregiver to caregiver. A family member may also wear the badge. The hospital has some beds with alarms. They also have some wheelchairs with alarms (a best practice). A couple of issues that were identified include that Rancho does not use actual arm bands as the other facilities do and they only update their patient's risk every seven days, which is mainly due to their current long-term patient population. In addition, Rancho may have to have two processes – one for the rehabilitation patient and one for the acute-care patient which it is developing the capability for.

PATIENT FALL BEST PRACTICE – OWENSBORO HOSPITAL

Since implementing hourly rounding, Owensboro Hospital (Owensboro, Kentucky) has reduced annual patient falls by 363, or 81 percent, from 448 to 85. As a result of the reduction in falls, the hospital's reimbursement increased by approximately $1,169,586, based on a CMS estimate of an average reduction in reimbursement of $3,222 per fall.

Hourly rounding helps reduce falls by assisting patients with any needs that they may have, so that they do not fall while trying to do too much for themselves. In order to be effective, there are seven things that must be done during hourly rounding. These include:

- Assess the patient's level of pain
- Offer scheduled medication at the appropriate time
- Offer assistance using the toilet
- Assess the patient's comfort level and position
- Make sure that the patient can reach the call light, telephone, TV remote control, bed light, beside table, and tissues
- Offer to help with any additional patient needs
- Let the patient know that the nursing staff will be rounding again in one or two hours

In addition to helping prevent falls, hourly rounding can be effective at helping to reduce pressure ulcers. A September 2006 study in the *American Journal of Nursing* titled "Effects of Nursing Rounds on Patients' Use of Call Lights, Satisfaction, and Safety" found that hourly rounding could reduce the incidence of hospital-acquired pressure ulcers by 14 percent.

PATIENT FALL BEST PRACTICE – PARTNERS HEALTHCARE

Using grants from the Robert Wood Johnson Foundation, hospitals in Partners HealthCare (Boston) were able to study how to tailor specific interventions to the needs of individual patients for reducing falls. One of the first tasks for the Falls Prevention Team was to create a standardized risk assessment for falls. This tool was then embedded into each facility's computer system, and nurses are trained regularly to make sure that they are using this tool effectively.

Some of the tactics employed at Partners hospitals to help prevent falls include special patient bracelets or bedside signs for at-risk patients, bed lifts to make it easier for patient to get up out of bed, and hourly comfort rounds. During these comfort rounds, the nursing staff visits each patient, and assists them with any needs they might have (such as going to the bathroom, repositioning, and offering food or drink). Because of these interventions, Partners has been able to lower the rate of falls at its hospitals.

BEST PRACTICE PATIENT SAFETY PROGRAMS

A major component of a best practice patient safety program is an effective risk management program. An ideal risk management program must have the necessary authority to enact changes within the hospital, with regard to clinical practices, policies, and procedures. To command this authority, the risk management representatives should be fairly high-up in the organization's hierarchy, possibly reporting directly to the CEO. The risk management program also must be able to effectively communicate with the rest of the hospital (including all patient care providers as well as senior leadership) about what is being done to improve patient safety. Specifically, the program should regularly share information about successes and failures as they relate to improvement projects.

One of the most important features common to hospitals that have successful and effective patient safety programs is that those organizations have leaders who are dedicated to patient safety and quality improvement. Specifically, a study published in the March 2006 issue of the *Journal of Patient Safety* found that hospitals whose Board of Trustee quality committees were most active and engaged were also the hospitals that had the best performance.[11] The IHI recommends that boards of trustees should dedicate at least 25 percent of their time to patient safety and quality improvement.

"The key is for leaders to create a culture of engagement and accountability, measure frontline compliance with evidence-based guidelines, and monitor care outcomes."[12]

To demonstrate their involvement in the patient safety program, it is a good idea for a hospital's leadership to conduct regular safety rounds. Senior leadership should visit various clinical areas, including patient care units, operating rooms, the radiology department, and the pharmacy department. They should engage staff in dialogue about patient safety and what is being done to prevent errors from happening. This serves two purposes: it allows the hospital leaders to observe any patient safety issues and hear about issues firsthand, and it demonstrates to the staff the commitment of the leaders to patient safety efforts.

Because it would be unrealistic for a hospital to focus on every measure of patient safety at once and expect to achieve real improvement, it is a good idea for hospital leaders to select a handful of topics (such as four or five items from the National Quality Forum's (NQF) list of "Never Events") and concentrate on improvements and initiatives to reduce errors in those areas. Once sustainable changes are accomplished, a new collection of patient safety topics can be examined. A good starting point would be to focus on those areas that represent the greatest threat to the facility.

Another important element of a successful patient safety program is implementing a "just culture," encouraging individuals to be open about errors so that they can learn from them and improve

[11] Kroch E, et al. "Hospital Boards and Quality Dashboards." *J Patient Saf* Volume 2, Number 1; March 2006.

[12] http://www.strategiestoperform.com/volume3_issue10/volume3_issue10_e_acquired.html (site access verified as of 2/24/2010)

processes so that those errors can be avoided in the future. As stated in the IOM report *To Err is Human*, errors are most frequently caused by "faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent them." Only a small portion of all medical errors are caused by a reckless or irresponsible provider. Hospitals can gain more from trying to identify the underlying cause of an error, and not simply look to assign blame. However, a hospital must be sure to not only collect data on adverse events, but actually do something meaningful with that data.

Best practice patient safety programs generally have an obsession with failure, in the sense that they are constantly thinking about ways their systems could fail, and recognizing that "near misses" also represent system failures. In particular, near misses are identified as learning opportunities and chances to improve on faulty processes. This is particularly valuable because near misses occur somewhere between 3 and 300 times as often as actual events that cause patient harm, providing hospitals with many more learning opportunities. These events should be reviewed and analyzed in the same manner as actual adverse events. According to the Agency for Healthcare Research and Quality (AHRQ), in a high-reliability organization "rather than viewing near-misses as proof that the system has effective safeguards, they are viewed as symptomatic of areas in need of more attention."[13]

Another common practice found in successful patient safety programs is holding safety briefings at the start of each shift. These five-minute meetings are attended by representatives of every discipline involved in providing patient care. Safety briefings provide the opportunity to discuss any potential safety issues on the unit, so that providers are on guard for these potential issues. Safety briefings can also be held prior to the start of procedures, so that potential problems can be discussed at that time. Some hospitals also hold safety debriefings at the end of each shift, to share any experiences of safety lapses or near misses that could have resulted in patient harm.

Hospitals should develop evidence-based procedures for all processes in which patients could be harmed. These formal procedures should include checklists for providers to complete as they perform each task, so that they do not need to rely on memory alone. This checklist technique, which was borrowed from the airline industry, has been shown to allow for fewer mistakes.

Finally, hospitals must encourage good communication between providers and patients, both before care and after an adverse event occurs. This helps ensure that the patient has realistic expectations about the anticipated outcome of his or her treatment from the start. Additionally, a physician reduces his or her risk of being sued by establishing a good rapport with a patient, as patients are less likely to sue if the provider has earned their trust. Also, because numerous studies have shown that often the key driver leading a patient to file a malpractice suit is having unanswered questions, effectively communicating any negative or unexpected outcomes with a patient reduces the risk of a claim being filed.

"Although a perceived barrier to disclosure is the fear of increased litigation; poor communication is actually a greater risk for litigation."[14]

See the Medical "Apology" Laws section for additional information and resources.

[13] "Becoming a High Reliability Organization: Operational Advice for Hospital Leaders." Agency for Healthcare Research and Quality. http://www.ahrq.gov/QUAL/hroadvice/hroadviceexecsum.htm (access verified as of 2/24/2010)

[14] Weiss P and Miranda F. "Transparency, Apology, and Disclosure of Adverse Events." *Obstetrics and Gynecology Clinics of North America*, 2008.

ENGAGING LEADERSHIP BOARDS IN PATIENT SAFETY

After the IHI's "100,000 Lives" campaign exceeded its target of reducing the number patients affected by medical errors by 100,000, the IHI set a more ambitious goal with the "5 Million Lives" campaign, which ran from December 2006 to December 2008. The campaign emphasized the role of the boards of directors in creating a safer environment and thus reducing medical errors. IHI recognized that "it is critically important for boards to set clear expectations and goals for reducing harm to patients and to monitor progress against those goals."

Specifically, one goal of the "5 Million Lives" campaign was to "get boards on board by defining and spreading the best-known leveraged processes for hospital boards of directors, so they can become far more effective in accelerating organizational progress toward safe care." Two measureable indicators of this goal identified by IHI are:

- Hospital boards should devote a minimum of one-quarter of their time to quality and safety issues
- To get a better understanding of the impact of medical errors, boards should meet with at least one patient (or family member) who suffered serious harm at their hospital in the last year

IHI stresses the importance of keeping the board informed about any problems, and focusing discussions on those patients who experienced undesirable outcomes. According to Jim Conway, Senior Vice President of IHI,

"It's a real temptation to sit down with your board and present good statistics. You want to tell them everything's wonderful...The board of trustees thinks there are no problems, because no one wants to tell them the difficult truth."[15]

Whether in a for-profit or not-for-profit healthcare setting, the primary responsibility of a board should be to ensure the safety of patients treated in its hospital.

Six Things All Boards Should Do

The following list comes from the IHI "Getting Started Kit: Governance Leadership "Boards on Board" How-to Guide."[16]

1. **Setting Aims:** Set a specific aim to reduce harm this year. Make an explicit, public commitment to measurable quality improvement (e.g., reduction in unnecessary mortality and harm), establishing a clear aim for the facility or system.
2. **Getting Data and Hearing Stories:** Select and review progress toward safer care as the first agenda item at every board meeting, grounded in transparency, and putting a "human face" on harm data.
3. **Establishing and Monitoring System-Level Measures:** Identify a small group of organization-wide "roll-up" measures of patient safety (e.g., facility-wide harm, risk-adjusted mortality); update the measures continually and make them transparent to the entire organization and all of its customers.
4. **Changing the Environment, Policies, and Culture:** Commit to establish and maintain an environment that is respectful, fair, and just for all who experience the pain and loss as a result of avoidable harm and adverse outcomes: the patients, their families, and the staff at the sharp end of error.

[15] "IHI Calls on Boards to Lead on Quality and Safety," http://www.greatboards.org/newsletter/reprints/GB-Summer07-conway.pdf (site access verified as of 2/23/10)

[16] http://www.ihi.org/NR/rdonlyres/95EADB8F-3AD6-4E09-8734-FB7149CFDF14/0/BoardHowToGuide.doc (site access verified as of 2/23/10)

5. **Learning... Starting with the Board:** Develop your capability as a board. Learn about how "best in the world" boards work with executive and physician leaders to reduce harm. Set an expectation for similar levels of education and training for all staff.
6. **Establishing Executive Accountability:** Oversee the effective execution of a plan to achieve your aims to reduce harm, including executive team accountability for clear quality improvement targets.

A number of things are being done to encourage boards to be more involved. For example, New Jersey was the first state to pass a law that requires hospital board of trustee members to go through formal training. In Tennessee, there is a voluntary certification program for members of hospital boards. Additionally, Blue Cross Blue Shield of Massachusetts has considered rewarding boards that are active in patient safety, by boosting payments for good performance to those hospitals whose board members have completed at least six hours of training.

In 2005, a team of researchers from CareScience (a healthcare performance analysis firm), the University Of Iowa College Of Public Health, the Wharton School, and CMS conducted a survey regarding characteristics of hospital leadership. Their research revealed that hospitals in which the board spends at least 25 percent of its time on patient safety and quality issues are more likely to provide better quality service. Additionally, hospitals in which executive compensation is based partially on quality improvement also demonstrate higher quality scores.

Research at the Governance Institute and the Solucient Center for Healthcare Improvement revealed similar results. They found a high correlation between proactive boards and high scores on both Solucient's hospital-wide performance measurement as well as each hospital's quality-specific score.

Researchers have found that boards can be most effective at helping to improve patient safety and quality of care when they hold the CEO accountable for the hospital's quality and safety goals; are involved in developing the medical staff credentialing and privileging criteria and process; review patient satisfaction scores at least annually; are responsible for setting the overall agenda for quality; and involve the medical staff in setting the agenda for the board's discussion regarding quality (Lockee, Kroom, Zablocki, Bader, 2006).

QUALITY IMPROVEMENT DASHBOARDS

One of the most important things that a hospital can do to keep its board of trustees involved in the patient safety movement is to provide the board with a patient safety or quality dashboard. The ideal dashboard would be frequently updated with new data (at least monthly), easy to understand, and contain roughly 10 to 12 measures. The quality improvement dashboard should be separate from the hospital's balanced scorecard, which may include only a small handful of quality measures. These measures should generally apply to the whole hospital, not just one department. The measures included on the dashboard should be re-evaluated at regular intervals, to ensure that the most appropriate quality indicators are being tracked.

When setting targets or goals for the indicators on the dashboard, it is important to not simply aim to be as good as the regional, state, or national average; instead the hospital should strive to be performing as well as the best-perfroming hospitals. A hospital must be careful not to set the targets too low, as doing so may indicate that the quality of care provided is satisfactory when in fact there may remain much room for improvement.

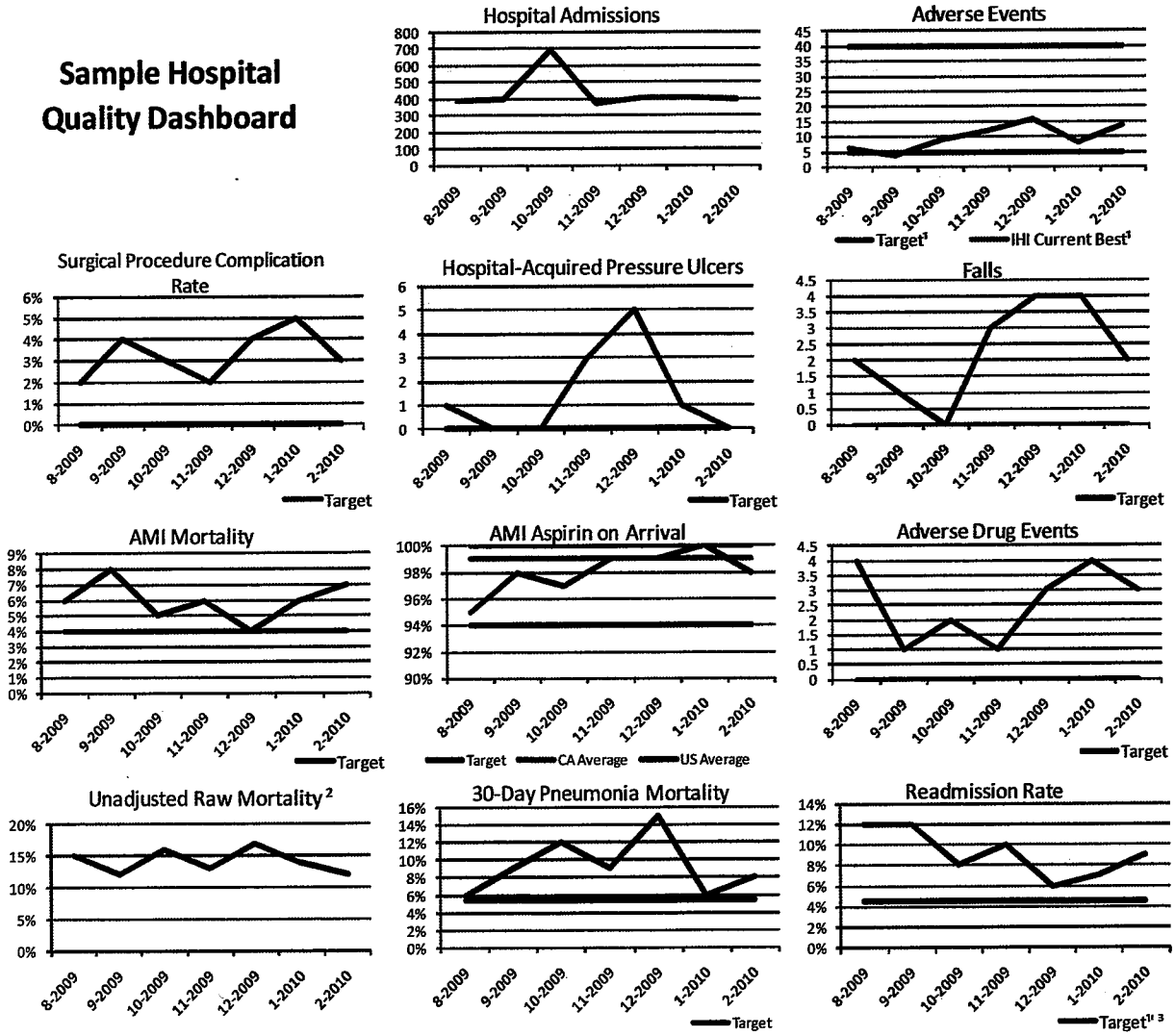
Typical items included in a quality dashboard include the following:

- 30-day pneumonia mortality
- Acute myocardial infarction (AMI) mortality rate
- Adverse drug events

- Complication rate for surgical procedures
- Patient falls
- Hospital-acquired pressure ulcers
- Rate of adverse events (inpatient)
- Rate of aspirin given on arrival for AMI patients
- Readmission rates
- Total adverse events
- Unadusted raw mortality rate

Figure 7 displays what a sample quality improvement dashboard might look like.

Figure 7 – Sample Hospital Quality Dashboard



[1] IHI "Whole System Measures White Paper"

[2] There is no target specification for this measure since unadjusted raw mortality is an organization-specific measure that does not adjust for patient and community variables.

[3] *Average top 10 percent: 4.49 percent; average top 25 percent: 5.96 percent; average: 9.11 percent; from IHI "Whole System Measures White Paper," basedon 2006 Premier Perspective Database*

MEDICAL "APOLOGY" LAWS

Thirty-five states plus the District of Columbia have passed "medical apology laws" in an effort to encourage dialogue between patients and physicians following adverse medical events. These laws usually allow physicians and providers to offer apologies following such events, without that apology being used as evidence against the provider during a malpractice lawsuit. Apology laws aim to reduce claims and lawsuits, as numerous studies have found that patients are less likely to sue if doctors express genuine empathy for a patient or family following an incident, and attempt to keep the patient well informed about the outcomes of that incident. The apology law movement is relatively new.

These laws differ from one another in terms of whose communication is protected, what sort of information is protected, to whom the protected communication may be made, what expressions are protected (i.e. sympathy versus fault), and in what contexts communication is protected. California's law is fairly typical, in that a physician's expressions of sympathy using "statements, writings, or benevolent gestures" are inadmissible in court, while any expressions indicating fault may still be admissible in court. California physicians are protected expressing sympathy to a patient, spouse, parent, grandparent, stepmother, stepfather, child, grandchild, brother, sister, half brother, half sister, adopted children of parent, or spouse's parents of an injured party.

Table 6 shows those states that have "apology laws."

Table 6 – States with "Apology" Laws

States with "Apology" Laws	
Arizona	2005
Colorado	2003
Connecticut	2005
Delaware	2006
District of Columbia	2008
Florida	2001
Georgia	2005
Hawaii	2006
Idaho	2008
Illinois	2005
Indiana	2008
Iowa	2006
Louisiana	2005
Maine	2005
Maryland	2004
Massachusetts	1986
Missouri	2005
Montana	2005
Nebraska	2007
New Hampshire	2005
North Carolina	2004
North Dakota	2007
Ohio	2004
Oklahoma	2004
Oregon	2003
South Carolina	2006
South Dakota	2005
Tennessee	2003
Texas	1999
Utah	2006
Vermont	2006
Virginia	2005
Washington	2002
West Virginia	2005
Wyoming	2004

Source: Sorry Works!
http://www.sorryworks.net/lawdoc/phtml
(site access verified as of 2/4/2010)

EFFECTIVE COMMUNICATION AND DISCLOSURE OF MEDICAL ERRORS

Numerous studies have found that physicians who communicate with patients about unexpected outcomes or errors are less likely to be sued than those who try to cover up an error or do not effectively explain what happened. This communication has been found to be most effective when it takes place as soon as possible after an event.

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DEPARTMENT OF HEALTH SERVICES (DHS) - INDEPENDENT REVIEW
EVALUATION OF THE MEDICAL MALPRACTICE/QUALITY IMPROVEMENT UNIT
CONDUCTED BY THE ABARIS GROUP

DHS' RESPONSE TO THE INDEPENDENT REVIEW

	KEY ABARIS RECOMMENDATIONS	DHS COMMENTS
1.	**Corrective Action Plan/Summary Corrective Action Plan (CAP/SCAP) Process:** The CAP process should continue to be re-engineered towards a "system" rather than an "event" focus and a reduction of the concentration on a "blame" methodology.	**DHS concurs with this recommendation.** The CAP process has been significantly re-engineered over time to include a more systems approach to corrective actions. DHS supports a "Just Culture", which recognizes that individual practitioners should not be held accountable for system failings over which they have no control. A just culture also recognizes many individual errors represent predictable interactions between human operators and the systems in which they work. However, in contrast to a culture that supports "no blame" as its governing principle, a just culture does not tolerate conscious disregard of clear risks to patients or gross misconduct (e.g., falsifying a record, performing professional duties while intoxicated). DHS began training managers for "Just Culture" in 2005. Every two years DHS conducts just culture surveys of the staff at our facilities. A policy has been prepared and is in draft. The Director, QIPS and the Corporate Patient Safety Officer continue to work with Human Resources and the Unions regarding implementation of a just culture.
2.	**Patient Safety vs Medical Malpractice Claims:** The current overlap between patient safety and the claim management processes needs to be refocused, with overlaps removed and the claim process redesigned to follow industry claim process standards.	**DHS partially concurs with this recommendation.** Historically, the focus of the CAP was on the legal aspect of the case, which is consistent with the industry claim process standards. The corrective actions provided in the CAP included personnel and facility system fixes that related to the reason the case was settled. Quality issues were identified separately, managed separately and not consistently shared system-wide. The CAP process has significantly evolved over the years. As the quality and patient safety structures evolved, DHS used events/cases to identify system weaknesses and quality/patient safety issues. While these issues may not have been limited to the legal reasons for settling a case, DHS believed there were significant learning and improvement opportunities both at the facility and on a system-wide level. Accordingly, more quality and patient safety issues have been incorporated in the CAPs and a system-wide approach was enhanced. The current "overlap" is due to DHS' effort to achieve a comprehensive approach in the overall CAP by combining both the medical malpractice claims management process as well as the patient safety and quality aspects. For the medical malpractice claims process, while the industry standard approach has been widely accepted by many organizations, DHS considers the "overlap" of the CAP process with quality and patient safety as integral to a comprehensive corrective action approach.

DEPARTMENT OF HEALTH SERVICES (DHS) - INDEPENDENT REVIEW
EVALUATION OF THE MEDICAL MALPRACTICE/QUALITY IMPROVEMENT UNIT
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3.	**QIPS Reporting Process:** The organizational placement of the Quality Improvement and Public Safety Unit (QIPS), consistent with the trend of other healthcare organizations should be realigned to report directly to the DHS Director's Office with a matrix reporting relationship to the DHS Chief Medical Officer (CMO) position.	**DHS does not concur with this recommendation.** QIPS reports to the CMO as this position has clinical oversight responsibility for DHS, and the QIPS-Director works primarily within the realm of clinical practice. Both the DHS Director and the DHS CMO are at the executive level. We understand the intent of the proposed structure was to ensure that quality is recognized by the system as a priority; however, in the current structure, we believe that quality is seen as a priority, and in order to ensure consistency, the current structure should be retained.
4.	**Health Facility Governing Board:** The Board of Supervisors should adopt a governing body role of strategic development for patient safety including setting patient safety goals, expectations and adopting a focus on creating a safe environment within the hospital and clinics it oversees.	**Board policy.** In an effort to enhance the current process, DHS will present annually to the Board of Supervisors its quality and patient safety activities and proposed goals. Additionally, the Board will be invited to the Governing Body meetings which occur on a quarterly basis. At these meetings the facilities report on their quality and patient safety initiatives, goals and progress toward meeting their goals. The Governing Body meetings review and discuss programs which integrate the review activities of all hospital services for the purpose of enhancing the quality of patient care and identifying and preventing malpractice. Additionally, Medical Staff committee reports are presented and discussed as well as other medical staff issues.
5.	**Dashboard:** A corporate patient safety dashboard should be published, endorsed and monitored by all in the DHS patient care arena with Board oversight.	**DHS partially concurs with this recommendation.** Although DHS has a comprehensive report card in place, we are working to develop a more concise tool that can be published and monitored. In addition, DHS is working on the development of a Quality and Patient Safety website for public access. It is planned that links directly to DHS data will be provided for ease of use.
6.	**QIPS Best Practices:** A smaller but dynamic grouping of four best practice groups should replace many of the current advisory quality process groups, meeting twice a month using a defined charter including goals with rigorous and focused statements to create, spread and ensure adoption of patient safety best practices and a more disciplined process for conducting their work.	**DHS concurs with this recommendation.** Many committees are being restructured or have been eliminated. There are currently five Best Practice groups (Intensive Care Unit, Emergency Room, Anesthesia, Infection Control and Medication Safety) which will remain in place. These committees have clinical representatives from each facility that are involved in direct patient care. The groups meet at least quarterly, in person, and monthly as needed by conference call. Each committee has a charter and goals. Due to regulatory mandates, evolving clinical practice, clinical events, DHS needs, etc., the goals of the committees may change.

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7.	**Reduction in Variation:** DHS and its clinical care units should consistently endorse enterprise-wide initiatives and not allow the sites to operate as silos on patient safety issues. Roll outs of site-based Information Technology (IT) solutions should be minimized and eventually eliminated.	**DHS concurs with this recommendation.** DHS continues to work with the facilities to function as a system, while recognizing that some variation may be appropriate due to specific facility operational issues and patient population needs. IT site based solutions will be reduced as department-wide IT solutions are rolled-out, including Wellsoft for the Emergency Rooms, Atlas Guardian Infection Control Software, iMed Consent and the Electronic Health Medical Record (EHMR).
8.	**EHMR:** The goal of a comprehensive electronic health medical record should be given a high priority, with planning completed and refined and full implementation of the EHMR within an aggressive time period (i.e. five years).	**DHS concurs with this recommendation.** DHS continues to actively work towards the purchase and implementation of an EHMR system, with target dates of: November 30, 2010 - complete EHR strategy, December 31, 2010 - complete recalibration of vendor assessment, and February 28, 2011 - complete procurement strategy for EHR. The time line for the out years will be determined at which time the procurement decision is completed.
9.	**Data/Trending:** DHS should acquire more analytical resources and then use these resources more effectively to trend their patient safety needs, initiatives and outcomes to allow more clarity of their direction and transparency to their audience.	**DHS concurs with this recommendation.** DHS continues to work towards the purchase and implementation of an EHMR, which will allow more data collection. This data will be analyzed, tracked and trended by qualified staff that can use it to implement appropriate patient safety and quality projects to improve patient care. The University Healthsystem Consortium and the Patient Safety Network are excellent sources for data trending and analysis, however, these systems cannot be used for case specific medical malpractice data collection, tracking or analysis. Other analytical tools to track and trend medical malpractice data would be useful in setting patient safety and quality goals. Although more sophisticated systems would facilitate and expedite DHS' current trend analysis efforts, the cost of such a system must be considered within limited fiscal resources.