
IT'S TIME TO MANDATE TEAM TRAINING IN U.S. HOSPITALS

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INTRODUCTION

In 2010, hand surgeon, Dr. David Ring, was nearing the end of a long day of orthopedic hand surgeries at Massachusetts General Hospital.¹ Prior to his next surgery, he stopped to speak to the patient, a 65 year old woman.² Because the conversation was in Spanish, the circulating nurse didn't understand what was being said and she assumed he was performing the Time Out.³ However, Dr. Ring was simply speaking to the patient in Spanish, the Time Out was not completed to verify the procedure, and this omission was not questioned by the nurse or the surgical team.⁴ The result was that Dr. Ring performed the wrong procedure on this patient by doing a carpal-tunnel release, rather than the planned trigger-finger release.⁵ Both procedures are common hand surgeries; one treating the compression of tendons and the wrist's main nerve in the "carpal tunnel" and the other treating swollen tendons in the thumb or index finger, preventing the tendons from moving properly through the sheath of tissue that surrounds them.⁶ The surgeon was devastated after making this error, so he wrote about the details of the event, which was published in the *New England Journal of Medicine*, in the hope that it would raise awareness and prevent other surgical teams from making the same type of error.⁷ Had the Time Out been performed properly with the procedure verified before the surgeon began, this error likely would not have happened.⁸

Unfortunately, errors like this cause harm or even death to patients that are being cared for every day in the United States.¹⁰ In a 2013 study published by the *Journal of Patient Safety*, the author concluded that previously-known estimates of patient harm, such as the widely-known 1999 report by the Institute of Medicine (IOM)¹¹ "*To Err is Human: Building a Safer Health*

¹ David C. Ring, James H. Herndon & Gregg S. Meyer, *Case 34-2010: A 65-Year-Old Woman with an Incorrect Operation on the Left Hand*, 363 N. ENGL. J. MED. 1951 (2010).

² *Id.*

³ *Id.*

⁴ World Health Organization, *Implementation Manual Surgical Safety Checklist* (2008), retrieved from http://www.who.int/patientsafety/safesurgery/tools_resources/SSSL_Manual_finalJun08.pdf The "Time Out" is part of the Safe Surgery Checklist implemented in 2008 by the World Health Organization. The Checklist is completed for each patient prior to the operative procedure. During the Time Out each member of the team introduces themselves. With a single individual responsible for leading the Time Out, the team will verify that they have the correct patient, correct procedure and the correct site. The team will also verify that prophylactic antibiotics have been started within the 60 minutes prior to incision time and that any applicable imaging is displayed in the room if appropriate.

⁵ David C. Ring *Supra* Note 3.

⁶ *Id.*

⁷ Stephanie M. Gancarczyk & Robert J. Strauch, *Carpal Tunnel Syndrome and Trigger Digit: Common Diagnoses That Occur "Hand in Hand,"* 38 J. HAND SURG. 1635-1637 (2013).

⁸ David C. Ring, *Supra* note 5 at 1950.

⁹ *Id.*

¹⁰ John T. James, PhD, *A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care*, 9 J. PATIENT SAF. 122 (2013).

¹¹ National Academies of Sciences, Engineering, and Medicine, retrieved from <http://www.nationalacademies.org/hmd/About-HMD.aspx> The Institute of Medicine is a private, non-profit group that provides information through research, studies and objective analysis to individual organizations and federal

System” had significantly underestimated the number of patient deaths in the United States from medical error.¹² The IOM report, which initially raised the alarm regarding patient harm and deaths from these errors, estimated that every year, medical errors cause between 44,000 and 98,000 preventable deaths in the United States.¹³ However, the more recent 2013 study from *The Journal of Patient Safety* determined that a more accurate number of patient deaths each year is at least 210,000 and might be as high as 400,000.¹⁴ These numbers of preventable deaths are very significant, as this is “roughly *one-sixth* of all deaths that occur in the United States each year [emphasis added].”¹⁵

After the IOM report was published, the federal government focused on ways to reduce error and the resulting patient harm in the healthcare setting.¹⁶ In response to the report, President Bill Clinton directed the Quality Interagency Coordination (QuIC) Task Force¹⁷ to come up with its own plans of action.¹⁸ Under the guidance of the federal agency, the Association of Healthcare Research and Quality (AHRQ), the QuIC made several recommendations focusing on a nationwide error-reporting system, including proposing mandatory reporting requirements for blood bank errors and plans to require error reporting in all Department of Defense and Veterans Affairs hospitals.¹⁹ Patient safety and quality consumer advocacy groups were concerned about the reports of patient harm and one of these groups, Leapfrog²⁰, announced that it would focus on patient harm events in upcoming surveys.²¹ While small improvements in patient safety have happened since the IOM report, consistent and widespread change has yet to be seen as a result of government and safety organization efforts.²²

During the years following the IOM report, malpractice reform was brought forward as a solution to improve error reporting and thus transparency and quality in the hospital environment.²³ However, there are critics of tort reform that feel that it hasn’t improved safety

agencies. On March 5, 2016, the IOM’s name was changed to the Health and Medicine Division (HMD) of the National Academies of Sciences, Engineering, and Medicine.

¹² John T. James, *Supra* note 10.

¹³ Janet M. Corrigan, Linda T. Kohn & Molla S. Donaldson, *To Err is Human: Building a Safer Health System*. 26 (2000).

¹⁴ David C. Ring, *Supra* note 9.

¹⁵ *Supra* note 12 at 127.

¹⁶ Laura Lin, Vol. 38, No. 2, HOSPLW Pg. 203

¹⁷ AHRQ, retrieved from <http://archive.ahrq.gov/quic/>. The Quality Interagency Coordination (QuIC) Task Force was established in 1998 by President Bill Clinton with the purpose of ensuring that all federal agencies involved in healthcare were coordinating their efforts and working toward the common goal of quality improvement.

¹⁸ Kevin A. Schulman & John J. Kim, *Medical Errors: how the US Government is addressing this problem*, 1 CURR. CONTROL. TRIALS CARDIOVASC. MED. 35–37 (2000).

¹⁹ *Id.*

²⁰ Leapfrog Group, retrieved from http://www.leapfroggroup.org/about_leapfrog Leapfrog was founded in 1998 and officially launched in 2000. Leapfrog was started by a group of large employers who were concerned about the poor quality of healthcare and wanted to use their purchasing power to positively influence US healthcare quality. Leapfrog publishes an annual survey which encourages transparency through voluntary, public reporting of hospital healthcare data. The 1999 IOM report gave Leapfrog its initial focus on reporting hospital ability to prevent patient harm and Leapfrog assigns A through F grades to the hospitals that it collects voluntarily submitted information.

²¹ H.T. Stelfox et al., *the “To Err is Human” report and the patient safety literature*, 15 QUAL. SAF. HEALTH CARE 174 (2006).

²² Mark R. Chassin & Jerod M. Loeb, *High-Reliability Health Care: Getting There from Here*, 9 MILBANK Q. 468 (2013).

²³ David A. Hyman, *The Poor State of Health Care Quality in the U.S.: Is Malpractice Liability Part of the Problem or Part of the Solution?* 90 Cornell L.Rev at 898.

and argue that tort reform may actually make safety worse by lessening the consequence to providers for their negligence.²⁴ These critics feel that the only benefit of tort reform has been to reduce malpractice insurance costs to the insurer rather than bring about the needed change of improved quality through safer systems and processes.²⁵

It has remained the goal of the U.S. healthcare industry and patient safety experts to achieve “high reliability” in healthcare, reducing patient harm or death from healthcare error to zero.²⁶ Among safety strategies used by other High Reliability Organizations (HRO),²⁷ team training²⁸ has been recognized by safety leaders in healthcare as contributing to some of the most dramatic improvements in an industry that has achieved HRO status, the airline industry.²⁹ Team training, which is not mandated for healthcare, is a key component of Crew Resource Management (CRM)³⁰ training used by the airline industry.³¹ While CRM is mandated for members of the aircraft crew and other airline team members in aviation, no comparable type of training is required for professionals working in the healthcare industry.³² If team training became required for all hospital staff and physicians in U.S. hospitals, it would have the potential to help healthcare organizations to realistically strive to achieve high reliability status, with a goal of zero patient harm events.³³ Since the time of the IOM report, patient safety leaders have urged the implementation of team training as a key strategy to significantly reduce patient harm in healthcare.³⁴ In order to make care safer for patients in U.S. hospitals, the federal government should mandate team training for all physicians and hospital staff through federal legislation with regulatory oversight by the Centers for Medicare and Medicaid Services (CMS)³⁵ through the

²⁴ *Id.* at 899.

²⁵ *Id.*

²⁶ *Supra* Note 22 at 461-2.

²⁷ *Id.* According to Chassin and The Joint Commission, a High Reliability Organization is one that works in an environment of “collective mindfulness” to achieve zero patient harm events. All team members “look for, and report, small problems or unsafe conditions before they pose a substantial risk to the organization and when they are easy to fix”. They value identification of close calls and rarely, if ever, have serious errors or accidents.

²⁸ AHRQ TeamSTEPPS 2.0 What is Team Training? Retrieved from <http://www.ahrq.gov/sites/default/files/wysiwyg/professionals/education/curriculum-tools/teamstepps/instructor/essentials/coursemgmt.pdf> According to AHRQ TeamSTEPPS, “Team training involves teaching health care personnel a set of techniques initially developed to improve team coordination in aviation crews. These techniques are especially useful for health care professionals who work closely as a team in high-stress situations such as the Operating Room, Emergency Department, Intensive Care Units, and Ambulatory Care”.

²⁹ *Supra* note 27 at 469.

³⁰ Crew Resource Management: Factors for Pilots, retrieved from <http://www.crewresourcemanagement.net/introduction> Crew Resource Management (CRM) was developed in 1979 by NASA and incorporates communication, leadership, problem solving, situational awareness and decision making skills into training. Training includes instruction in the classroom and simulated training exercises.

³¹ Marck HTM Haerkens, Donald H Jenkins & Johannes G van der Hoeven, *Crew resource management in the ICU: the need for culture change*, 2 ANN. INTENSIVE CARE 3 (2012).

³² *Id.*

³³ *Id.* at 2.

³⁴ Joyce A. Wahr et al., *Patient Safety in the Cardiac Operating Room: Human Factors and Teamwork A Scientific Statement From the American Heart Association*, 128 CIRCULATION 1444 (2013).

³⁵ SearchHealthIT, retrieved from <http://searchhealthit.techtarget.com/definition/Centers-for-Medicare-Medicaid-Services-CMS> . CMS is an agency within the U.S. Department of Health and Human Services. Medicare is responsible for the oversight and administration of several federal healthcare programs, including Medicare, which administers health insurance to senior citizens and Medicaid, which administers health benefits based on financial need.

Conditions of Participation (CoPs).³⁶

THE EARLY PATIENT SAFETY AND REGULATORY LANDSCAPE

Prior to the IOM report, the early healthcare patient safety landscape was described as one which focused on the mistakes of the individual when things went wrong, rather than addressing system failures.³⁷ One of the earliest pioneers of hospital quality and standardization was Dr. Ernest Codman who, in 1910, implemented patient outcome tracking through the use of *End Result Cards* while at Massachusetts General Hospital.³⁸ *End Result Cards* included patient information as well as the patient's outcome information for at least 12 months after treatment, allowing the clinician to focus on areas of improvement.³⁹ Dr. Codman saw the *End Result Cards* as a step toward transparency and improved outcomes for his patients, but at that time it was a very unpopular concept among his fellow physicians.⁴⁰ Despite the unpopularity, Dr. Codman's work was influential in starting the Hospital Standardization Program of the American College of Surgeons in 1913.⁴¹ ⁴² The Hospital Standardization Program went on to complete its first hospital survey in 1916.⁴³ While historical data does not exist to show which criteria was used in the early surveys of the program, it is known that only 89 out of 700 hospitals with at least 100 beds were able to pass the survey.⁴⁴ While some states went on to require adherence to quality standards during those early years, federal mandates or widespread application across states did not exist.⁴⁵ The Hospital Standardization Program continued until 1952, when it became The Joint Commission on Accreditations of Hospitals (JCAH).⁴⁶

In 1965, the regulation of quality and patient safety in U.S. hospitals took a dramatic shift with the enactment of Title XVIII and Title XIX of the Social Security Act.⁴⁷ With this legislation, Medicare and Medicaid were created within the Social Security Administration and Congress gave this federal agency the ability to promulgate the CoPs.⁴⁸ In 1997, a new agency was created which took over Medicare and Medicaid oversight, called Health Care Financing

³⁶ 42 CFR 482.1, General Provisions for Conditions of Participation. Conditions of Participation (CoPs) are those "certain specified requirements" that a hospital or other healthcare entity must be compliant with in order to participate in the Medicare as well as Medicaid Programs.

³⁷ Robert M. Wachter, *The End of The Beginning: Patient Safety Five Years After "To Err is Human,"* HEALTH AFF. (MILLWOOD) 536 (2004).

³⁸ Linda Miner et al., *Practical Predictive Analytics and Decisioning Systems for Medicine: Informatics Accuracy and Cost-Effectiveness for Healthcare Administration and Delivery Including Medical Research*. 133 (2014).

³⁹ *Id.*

⁴⁰ Dennis S. O'Leary, *Performance Measures, How Are They Developed, Validated, and Used?* 33 MED. CARE 14 (1995).

⁴¹ *Id.*

⁴² Bernard R. Tresnowski, *The Current Interest in Quality Is Nothing New*, 25 INQUIRY 3 (Spring 1988).

⁴³ John W. Cashman, Pearl Bierman & Beverlee A Myers, *The "Why" of Conditions of Participation in the Medicare Program*, 83 PUBLIC HEALTH REP. 714 (September 1968).

⁴⁴ *Id.* at 714-715

⁴⁵ *Id.* at 714

⁴⁶ Bernard R. Tresnowski, *Supra* note 42.

⁴⁷ Youssra Marjoui & Kevin J. Bozic, *Brief history of quality movement in US healthcare*, 5 CURR. REV. MUSCULOSKELET. MED. 266 (2012).

⁴⁸ *Id.*

Administration (HCFA), which was later renamed CMS in 2001.⁴⁹ Today, the average hospital receives 44.3 percent of its revenue from Medicare and 12.9 percent from Medicaid and compliance in the CoPs is required to receive reimbursement from both.⁵⁰ The federal government selected JCAH's accreditation process to certify that a hospital had met the required CoPs.⁵¹ Until 2008, JCAH, today known as The Joint Commission (TJC)⁵² had the exclusive arrangement with CMS to have "deeming authority"⁵³ to certify that a hospital met certain CoPs.⁵⁴ The CoPs are what gives a Joint Commission survey "its teeth", as failure to comply puts the hospital at risk of losing its Medicare reimbursement, a significant portion of most hospitals' revenue.⁵⁵

In addition to the entities that have the authority to regulate hospital safety, there are several organizations in the U.S. that help promote quality and patient safety by setting goals and promoting performance standards for healthcare organizations.⁵⁶ National Quality Form (NQF), established in 1999, is one such non-profit organization and is well-known for its process of endorsing quality and patient safety practices.⁵⁷ Among these includes NQF "Never Events" and "Safe Practices".⁵⁸ Never Events focus on certain adverse or harm events that a patient should never experience in the hospital setting, such as a retained surgical sponge, and Safe Practices include recommendations for practices that healthcare organizations should follow to reduce adverse patient events.⁵⁹

The Institute of Healthcare Improvement (IHI), founded in 1991, is another non-profit organization with the goal of improving the safety of healthcare.⁶⁰ It launched the "100,000 Lives" campaign in 2005 followed by the "5 Million Lives" campaign in 2006 with the goal of encouraging hospitals to sign up and follow care bundles that help to prevent hospital conditions such as ventilator associated pneumonia and pressure ulcers.⁶¹ Care bundles were developed by IHI in 2001, with the initial goal of focusing on the care of patients on ventilators and with

⁴⁹ Office of the Actuary for the Centers for Medicare & Medicaid Services, Brief Summaries of Medicare and Medicaid, (2010). Retrieved from <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/downloads/MedicareMedicaidSummaries2010.pdf>

⁵⁰ Anthony Brino, *Hospitals hit a revenue crunch*, HEALTHC. PAYER NEWS, retrieved from <http://www.healthcarepayernews.com/print/22206>.

⁵¹ Linda Miner et al, *Supra* note 39.

⁵² The Joint Commission, retrieved from

http://www.jointcommission.org/facts_about_federal_deemed_status_and_state_recognition/ The Joint Commission (TJC) is an independent, not-for-profit organization that accredits hospitals and healthcare programs in the United States. The Joint Commission has been approved by CMS as a national accrediting organization, therefore, accreditation by The Joint Commission allows the entity to meet the eligibility requirements for CMS. This allows the healthcare organization to participate in and receive reimbursement from Medicare and Medicaid.

⁵³ Robert M. Wachter, *Understanding Patient Safety*. 358 (Second ed. 2012). Deeming authority is the authority granted by CMS to an accrediting body, such as the Joint Commission, to certify that an entity is in compliance with CMS Conditions of Participation.

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ Barbara J. Youngberg, *Principles of Risk Management and Patient Safety*. 13 (2011).

⁵⁷ Robert M. Wachter *supra* note 55 at 362.

⁵⁸ *Id.*

⁵⁹ *Id.* at 362, 449.

⁶⁰ *Id.* at 363.

⁶¹ *Id.*

central lines.⁶² These bundles are sets of evidence-based interventions, with a list limited to no more than five, and are accepted as those measures that result in improved patient outcomes.⁶³

After the IOM report, AHRQ refocused their efforts to extensively investigate ways to reduce medical errors in the healthcare setting, including extensive research and policy recommendations, which has led to a significant focus on error reduction since the time of the IOM report.⁶⁴ AHRQ is an agency within the Department of Health and Human Services (HHS) and is another entity that promotes quality and patient safety by facilitating research to improve healthcare.⁶⁵

THE 1999 IOM REPORT

When the IOM report was initially published, it received wide-spread attention from both the healthcare community and the public.⁶⁶ This report was successful in sparking discussion in the healthcare community about patient safety as well as encouraging research.⁶⁷ The IOM report helped the healthcare and patient safety community to better understand error and how it leads to harm by refocusing attention away from individual blame and instead concentrate efforts on system and process issues.⁶⁸ Much of this change in focus is attributed to the work of James Reason, which was highlighted in the IOM report.⁶⁹ Reason stressed the importance of understanding the types of error as they relate to the intention of the individual.⁷⁰ This includes system failures leading to patient harm, which are usually errors that are out of the control of the individual and involve poorly structured systems or design malfunction.⁷¹ These pose the greatest threat to patient safety as they may go unrecognized, have the ability to result in multiple types of errors, and encourage providers to develop and practice “work arounds”.⁷²

The IOM report made several recommendations, including voluntary error reporting, better design of safety systems, as well as enhanced teamwork through interdisciplinary team training.⁷³ It recommended that a Center for Patient Safety be placed within AHRQ to set the national goals for patient safety and monitor and track this progress.⁷⁴ The report also called for a nationwide reporting system which would mandate reporting of errors.⁷⁵ The information would be collected at the state level and include reports on adverse events that result in patient harm or death.⁷⁶ Other recommendations included the need for health professional licensing bodies to increase attention on patient safety by implementing a patient safety curriculum and periodically

⁶² Roger Resar, et al., *Using Care Bundles to Improve Health Care Quality*. 1-2 (2012).

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ Laura Lin, *Supra* note 16.

⁶⁶ H.T. Stelfox et al. *Supra* note 21 at 174.

⁶⁷ *Id.*

⁶⁸ Robert M. Wachter *Supra* note 57 at 536.

⁶⁹ Janet M. Corrigan, Linda T. Kohn & Molla S. Donaldson, *Supra* note 13 at 53.

⁷⁰ *Id.* at 54.

⁷¹ *Id.* at 55.

⁷² *Id.*

⁷³ David P. Baker, Rachel Day & Eduardo Salas, *Teamwork as an Essential Component of High-Reliability Organizations*, 41 HEALTH SERV. RES. 1577.(August 2006).

⁷⁴ Janet M. Corrigan, Linda T. Kohn & Molla S. Donaldson, *Supra* note 72 at 69.

⁷⁵ *Id.* at 87-88.

⁷⁶ *Id.* at 88.

examining license holders on patient safety knowledge and practices.⁷⁷ The report also called for healthcare to set performance standards related to patient safety.⁷⁸ Finally, the IOM report called for healthcare organizations to implement well-understood patient safety practices and to incorporate team training programs which include simulation training.⁷⁹ To date, some of these goals have been achieved, but in a 2015 follow up report, *Free from Harm*, published by National Patient Safety Foundation (NPSF)⁸⁰ panel experts, it is noted that some recommendations still remain incomplete, including the need to further improve the safety culture within the hospital, which would begin to require “an overarching shift away from reactive, piecemeal interventions to a total systems approach to safety which is systematic and uniformly applied across the total process.”⁸¹

THE PATIENT SAFETY LANDSCAPE AFTER THE IOM REPORT

After the publication of the IOM report, the federal government responded quickly by pledging \$50 million annually toward patient safety research.⁸² The Leapfrog Group was paying close attention to the IOM report and the response from the federal government.⁸³ Having just formed in 1998, the year prior to the IOM report⁸⁴ Leapfrog notified hospitals that patient safety would be a priority for them and would be included in their future data surveys.⁸⁵

This sudden attention by several agencies and groups to the gravity of healthcare harm helped to direct significant regulatory changes toward improving patient safety.⁸⁶ CMS responded to the IOM report by requiring hospitals to develop quality assessment and performance improvement programs and mandating that hospitals track and evaluate their performance on an ongoing basis.⁸⁷ CMS also included the requirement that hospitals identify and analyze adverse events.⁸⁸ TJC took this one step further and adapted its Sentinel Event Policy, requiring hospitals to report adverse outcomes which result in harm or death, not only to TJC, but also to the patient or the family affected by error.⁸⁹

Patient safety was further strengthened several years later, with the passage of the Patient Protection and Affordable Care Act (PPACA) in 2010 when Hospital Value Based Purchasing

⁷⁷ *Id.* at 134.

⁷⁸ *Id.* at 133.

⁷⁹ *Id.* at 156.

⁸⁰ National Patient Safety Foundation, retrieved from <http://www.npsf.org/?page=historyandtimeline>. National Patient Safety Foundation (NPSF) is an independent, not-for-profit organization founded in 1997, initially sponsored by the American Medical Association, 3M, and other large healthcare associated corporations, with the mission to partner with patients, families, and key healthcare stakeholders to improve patient safety.

⁸¹ NATIONAL PATIENT SAFETY FOUNDATION, *FREE FROM HARM: ACCELERATING PATIENT SAFETY IMPROVEMENT FIFTEEN YEARS AFTER TO ERR IS HUMAN* 9 (2015).

⁸² Stelfox et al. *Supra* note 67 at 174.

⁸³ *Id.*

⁸⁴ Margaret F. Schulte, *Healthcare Delivery in the U.S.A.* 166 (2nd ed. 2012).

⁸⁵ Stelfox et al., *Supra* note 83.

⁸⁶ Barry R Furrow, *Regulating Patient Safety: Toward a Federal Model of Medical Error Reduction*, 12 *Widener L. Rev.* 1, at 2.

⁸⁷ *Id.* at 14.

⁸⁸ *Id.* at 15.

⁸⁹ *Id.* at 12, 13.

(VBP)⁹⁰ was incorporated into the Medicare reimbursement program.⁹¹ VBP had a long journey toward implementation, which began in 2003 after a report by the Medicare Advisory Commission (MedPAC)⁹² which found that quality improvement had been hindered in U.S. hospitals because hospital reimbursement had been budget neutral; hospitals received the same reimbursement from Medicare whether outcomes were good or poor.⁹³ This remained unchanged, so in 2009 and again in 2010, MedPAC followed up by reporting to Congress that while Medicare had increased its spending, the quality and efficiency of care had not improved and noted that providers were not being held accountable for the quality of care they gave.⁹⁴ As a result, CMS implemented VBP initiatives as part of the 2010 PPACA, and began either rewarding or penalizing hospitals, based on their performance for certain quality indicators.⁹⁵

Within the legal-civil landscape, malpractice reform has also been viewed as a way to improve the quality of care in hospitals.⁹⁶ Many groups have advocated for tort reform, stating that the fear of litigation discourages physicians and hospital staff from reporting errors.⁹⁷ Critics of tort reform, however, feel that lowering limits on damages awarded to the plaintiff will have no effect on the reporting of errors and may actually make patient safety worse, as tort reform frees providers to “serve their own economic interests instead of their patient’s interests”.⁹⁸ Additionally, studies that have been completed don’t directly support tort reform as an approach to reducing patient harm and may show that tort reform contributes to the continuation of a poorly managed and fragmented healthcare system.⁹⁹

While small pockets of improvement have resulted from the many initiatives that have been implemented since the IOM report, meaningful change has yet to happen in healthcare as it has in other “High Reliability” industries.¹⁰⁰ Fifteen years after the IOM report, the NPSF convened a panel of experts to study the progress towards patient safety that had been made to that point.¹⁰¹ The panel experts overwhelmingly agreed that because healthcare safety has lacked a collaborative approach, it has “failed to make substantial, measureable, system wide strides in improving patient safety”.¹⁰² In order to succeed at making a change in the subsequent years, the panel listed several recommendations, prioritizing leadership and culture as the most important

⁹⁰ Hospital Value-Based Purchasing, retrieved from <https://www.cms.gov/Medicare/Quality-initiatives-patient-assessment-instruments/hospital-value-based-purchasing/index.html>. Value Based Purchasing (VBP) is a program by CMS in which participating hospitals are rewarded or penalized for performance in quality of care measurements. The goal of VBP is improve the quality of healthcare in the hospital setting.

⁹¹ *How Much Does Quality Cost? Analyzing the Patient Protection and Affordable Care Act’s Value-Based Purchasing Provision and How It Could Affect the Delivery of Care By Hospitals*, 14 Duq. Bus. L.J. 69.

⁹² About MedPAC, retrieved from <http://www.medpac.gov/-about-medpac-> The Medicare Payment Advisory Commission or MedPAC was established by the Balanced Budget Act of 97. This independent congressional agency advises Congress on issues that may affect the Medicare Program including access to care, quality of care and other applicable issues.

⁹³ *How Much Does Quality Cost? Supra* note 91 at 73.

⁹⁴ *Id.* at 74

⁹⁵ PollyBeth Hawk, 22 Ann. Health L. 43 - Ready or Not: Hospital Value-Based Purchasing Poised to Transform Healthcare Reimbursement Model and Introduce New Fraud Targets Under the False Claims Act at 4.

⁹⁶ David A. Hyman, *Supra* note 20 at 898.

⁹⁷ *Id.*

⁹⁸ *Id.* at 899.

⁹⁹ *The Patient Injury Epidemic: Medical Malpractice Litigation as a Curative Tool*, L, 4 Drexel L. Rev. 41 at 106.

¹⁰⁰ Mark R. Chassin & Jerod M. Loeb, *Supra* note 27 at 460.

¹⁰¹ NATIONAL PATIENT SAFETY FOUNDATION, *Free from Harm, Supra* note 81 at 9.

¹⁰² *Id.* at 35.

and critical of the recommendations.¹⁰³

THE EFFECT OF POOR QUALITY ON HOSPITAL CARE

A poorly functioning healthcare team, which resulted in error and patient harm, as well as malpractice liability for the care providers, is illustrated in the case of *Schorlemer v. Reyes*.¹⁰⁴ In this legal case, the surgical team left a surgical sponge in the patient, Ms. Beatriz G. Reyes and this error was not caught by a proper surgical sponge count.¹⁰⁵ Reyes sought treatment from gynecologist Wendell C. Schorlemer, MD after a solid mass was found on her right ovary.¹⁰⁶ Reyes was seen and examined by Schorlemer where, after reviewing a sonogram report, Schorlemer recommended that Reyes undergo an exploratory laparotomy with biopsy of the mass and any other procedure which may become apparently necessary during the surgery.¹⁰⁷

On November 23, 1993, Reyes underwent surgery and the biopsy that was performed determined a benign cyst.¹⁰⁸ During the procedure, Schorlemer also determined that it was necessary to remove the patient's right ovary and fallopian tube due to surrounding adhesions and the inability to salvage it.¹⁰⁹ When depositions were taken, the circulating nursing and scrub tech each stated that two correct sponge counts were completed at the closing of the peritoneum and the closing skin, however, the preliminary sponge count was not documented.¹¹⁰ The medical record showed that during the postoperative period, while still an inpatient in the hospital, Reyes' temperature rose "sharply" twice and Schorlemer prescribed "fever reducing medication".¹¹¹

In December 1993, Schorlemer saw Reyes in his office three times for her post-operative care, where she complained of abdominal pain and bloating.¹¹² Reyes saw Schorlemer again for fertility issues as well as abdominal pain in April 1993 and then again July 1993 for abdominal pain and nausea, at which time Schorlemer finally performed a sonogram, finding another abdominal mass.¹¹³ Reyes saw another physician for a second opinion on the mass, who took an x-ray and discovered the surgical sponge.¹¹⁴

After having surgery to have the retained surgical sponge removed, Reyes sued the hospital, the circulating nurse, the scrub tech, as well as Schorlemer and settled with all parties except Schorlemer.¹¹⁵ Reyes prevailed during the trial and Schorlemer appealed on several points of error, including the court's giving *res ipsa loquitur* instruction¹¹⁶, legally and factually

¹⁰³ *Id.*

¹⁰⁴ *Schorlemer v. Reyes*, 974 S.W.2d 141 (Tex. App. San Antonio 1998).

¹⁰⁵ *Id.* at 143.

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

¹⁰⁹ *Id.*

¹¹⁰ *Id.*

¹¹¹ *Id.*

¹¹² *Id.*

¹¹³ *Id.* at 144.

¹¹⁴ *Id.*

¹¹⁵ *Id.*

¹¹⁶ Applicability of res ipsa loquitur in case of multiple medical defendants -- modern status, 67 A.L.R.4th 544 at 2.

insufficient evidence to support the jury's finding of negligence, and that the court "erred in failing to segregate the damages among the various theories of negligence posed by Reyes".¹¹⁷ The appellate court affirmed the trial court's decision, holding that the trial court gave "a legally correct instruction", that the evidence was "both legally and factually sufficient to support the verdict", and that damages submitted in broad form were appropriate "since the res ipsa instruction was proper".¹¹⁸

Surgical "never events"¹¹⁹, such as leaving a sponge in a patient, are estimated to happen over 4,000 times each year, and this type of event is just one example of patient harm that happens in hospitals every day in this country.¹²⁰ TJC recommends team training as a mechanism to prevent surgical events such as the retained sponge.¹²¹ Team training tools such as briefing and debriefing¹²² would have promoted an environment of open communication among the surgical team, disallowing any part of the surgical sponge count from not being completed.¹²³ Additionally team training fosters team awareness, increasing the possibility that a team member would notice and speak up about the improper sponge count.¹²⁴

AVIATION'S SUCCESS AT ACHIEVING HIGH RELIABILITY

Since the IOM report, it has been recognized that team training has the potential to significantly impact hospital safety in the same way that CRM has improved airline safety.¹²⁵ Recommendation 8.1 of the IOM report included the creation of patient safety programs which establish "interdisciplinary team training programs for providers that incorporate proven methods of team training, such as simulation".¹²⁶ Almost two decades earlier, the commercial airline

Res ipsa loquitur is generally translated as "the thing speaks for itself." Generally, the requirement for application of this doctrine are often given as: "(1) that the accident was of a kind which does not ordinarily occur unless someone was negligent; (2) that the instrumentality which caused the injury was in the exclusive control of the person charged with negligence; and (3) that the injury was not due to any voluntary action on the part of the person injured." Courts have been willing to apply the doctrine in cases involving multiple parties if "the defendants had concurrent control over the instrumentality causing the injury..."

¹¹⁷ *Schorlemer v. Reyes*, *Supra* note 114 at 147.

¹¹⁸ *Id.* at 148.

¹¹⁹ AHRQ, *Never Events*, <https://psnet.ahrq.gov/primers/primer/3/never-events> retrieved March 12, 2016 – Never Events are those that are defined by NQF as adverse events that are "unambiguous, serious, and usually preventable". These include a list of 29 events grouped into six categories. Surgical Never Events include surgical procedures performed on the wrong body part, wrong patient, wrong procedure performed, foreign object unintentionally retained after surgery, and intraoperative or immediate postoperative death of American Society of Anesthesia Class I patient. That is a patient who is defined as normal and health, does not smoke, without any systemic disease process and minimal or no alcohol use (American Society of Anesthesia, retrieved from [http://www.asahq.org/~media/sites/asahq/files/public/resources/standards-guidelines/asa-physical-status-classification-system.pdf#search=%22asa classification%22](http://www.asahq.org/~media/sites/asahq/files/public/resources/standards-guidelines/asa-physical-status-classification-system.pdf#search=%22asa%20classification%22)).

¹²⁰ Winta T. Mehtsun et al., *Surgical never events in the United States*, 153 *SURGERY* 465–472 (2012).

¹²¹ The Joint Commission, *Sentinel Event Alert: Preventing Unintended Retained Foreign Objects*, 3 (2013).

¹²² Joyce A. Wahr et al., *Supra* note 34 at 1445. Briefing and debriefing are completed before and after the surgical procedure. Briefings allow the surgical team to "confirm the details, exchange information, ask questions, and identify problems or concerns. Debriefings allow the team to explore what went right and what they learned if any issues arose during the procedure.

¹²³ The Joint Commission, *Supra* note 121.

¹²⁴ *Id.*

¹²⁵ Mark R. Chassin & Jerod M. Loeb, *Supra* note 72 at 468.

¹²⁶ Janet M. Corrigan, Linda T. Kohn & Molla S. Donaldson, *Supra* note 79 at 127.

industry, recognizing the important role that team training could play in aviation safety, had begun to implement formal team training programs to airline crews in the early 1980's.¹²⁷ In the airline industry, the implementation of CRM is viewed by many as the turning point of meaningful aviation safety advancement, resulting in significant reductions in aircraft accidents.¹²⁸

The importance of team functioning by the aviation industry was first recognized in the 1970's when investigations into aircraft accidents revealed that more than 70 percent were due to human error that resulted from failures in team communication, rather than equipment failure or weather issues.¹²⁹ ¹³⁰ Recognizing that human error accidents could potentially be avoided, the airline industry turned to psychologists John K. Lauber, PhD and Robert Helmreich, PhD to develop training based on communication and psychology, which would become known as CRM.¹³¹ The investment by the airline industry over the last 30 years on research and psychological study has been significant and has required the industry to dramatically change the very culture that its crews operate in.¹³²

In 1981, United Airlines created the first comprehensive CRM program and was one of the first airlines to require this training of all its flight crew.¹³³ United's initial program focused heavily on requiring participants to assess their behavior and that of their peers as well as their own management styles.¹³⁴ Over the years, these programs began to shift to a more systems-focused thinking and other airlines began to adopt these CRM training programs, adapting them as each of them developed their own programs.¹³⁵

CRM was not mandated by the federal government until October 2, 1990 by the Federal Aviation Administration (FAA).¹³⁶ ¹³⁷ ¹³⁸ The progress of CRM implementation through federal mandates evolved from a voluntary system to one that was implemented and expanded through Title 14, Parts 121 and 135 of the Code of Federal Regulations (CFR).¹³⁹ Parts 121 and 135 include the training requirements for air carriers, detailing crewmember qualification requirements as well as requirements for other operations personnel, such as flight and simulator instructors, aircraft dispatchers, and check airmen.¹⁴⁰ The original crewmember qualifications

¹²⁷ Robert L. Helmreich, Ashleigh C. Merritt & John A. Wilhelm, *The Evolution of Crew Resource Management Training in Commercial Aviation*, 9 INT. J. AVIAT. PSYCHOL. 20.

¹²⁸ Thomas R. Weitzel & Henry R. Lehrer, *A Turning Point in Aviation Training: The AQP Mandates Crew Resource Management and Line Operational Simulations*, 3 J. AVIAT. EDUC. RES. at 18.

¹²⁹ Making Air Travel Safer Through Crew Resource Management, AM. PSYCHOL. ASSOC. 1 (2014).

¹³⁰ Thomas R. Weitzel & Henry R. Lehrer, *Supra* note 128 at 16.

¹³¹ Making Air Travel Safer, *Supra* Note 129.

¹³² Mark R. Chassin & Jerod M. Loeb, *Supra* note 128.

¹³³ Thomas R. Weitzel & Henry R. Lehrer, *Supra* note 130 at 14.

¹³⁴ Suzanne Gordon, Patrick Mendenhall & Bonnie Blair O'Connor, *Beyond the Checklist: What Else Health Care Can Learn from Aviation, Teamwork and Safety*. 34 (2012).

¹³⁵ *Id.*

¹³⁶ Federal Aviation Administration (FAA), retrieved from <https://www.federalregister.gov/agencies/federal-aviation-administration> The FAA was established in 1958. It is an agency within the U.S. Department of Transportation whose mission is to regulate civil and commercial aviation within the United States, to control air traffic control as well as research and administer programs related to aircraft safety.

¹³⁷ Suzanne Gordon, Patrick Mendenhall & Bonnie Blair O'Connor, *Supra* note 135 at p. 53.

¹³⁸ 14 CFR 121.404

¹³⁹ 60 FR 65940

¹⁴⁰ 60 FR 65940

began in December 1969 and no comprehensive changes had been made to these until December 1986, when safety recommendations from the National Transportation Safety Board (NTSB)¹⁴¹ prompted the FAA to address human factors and human factors science¹⁴² by incorporating aviation behavioral training into its simulator training.¹⁴³ This was done to improve “cockpit/cabin communication and coordination skills, and pilot decision-making skills.”¹⁴⁴

After a major airline accident in June 1988, involving Northwest Airlines in 1987 resulted in over 150 deaths, the NTSB analyzed the accident and determined that while both pilots had received individual-focused training during their last simulator and proficiency training sessions, they had not received team focused training and their last CRM instruction had been during ground school in 1983.¹⁴⁵ The NTSB determined that “the accident might have been prevented had the flight crew received adequate CRM training.”¹⁴⁶

The FAA solicited input from the aviation community and governmental agencies after this accident, and published a proposed Special Federal Aviation Regulation (SFAR)¹⁴⁷ in the Federal Register.¹⁴⁸ This called for replacing the current training requirements with an alternative type of training called the Advanced Qualification Program (AQP).¹⁴⁹ The AQP requirement went into effect October 2, 1990 and incorporated CRM training into evaluation flight and simulator training.¹⁵⁰

The FAA further expanded these requirements by publishing comments in the Federal Register on December 13, 1994, that to date, while the larger air carriers had adopted the AQP into their training, many smaller carriers had not.¹⁵¹ They proposed modifications to Part 121 and Part 135 to require the AQP training which incorporated CRM.¹⁵² Comments that were received

¹⁴¹ The NTSB is a federal agency that has the authority to investigate transportation accidents including civil aviation, railroad, highway, marine, and pipeline incidents. Through their investigative efforts, the NTSB is responsible for determine the probable cause of the accident and must issue safety recommendations to prevent future occurrences. The NTSB is also responsible for carrying out research studies regarding transportation safety. The NTSB also coordinates government resources to provide assistance to the victims of major transportation incidents retrieved from <http://www.nts.gov/about/Pages/default.aspx>.

¹⁴² The FAA defines Human Factors as human conditions such as complacency, fatigue and stress which may contribute to or directly cause error to happen. Human Factors Science is the understanding of the “design, development, and employment of systems and services, and the art of ensuring successful application of human factor principles”. Retrieved from https://www.faa.gov/regulations_policies/handbooks_manuals/aircraft/media/AMT_Handbook_Addendum_Human_Factors.pdf

¹⁴³ 60 FR 65940

¹⁴⁴ *Id.*

¹⁴⁵ *Id.*

¹⁴⁶ *Id.*

¹⁴⁷ According to the FAA, an SFAR is a temporary rule published in aviation “to address a temporary situation. It is generally not used to replace or enforce regulations that are to remain in effect for many years. Consequently, an SFAR has an expiration date, usually no more than 3 years from its effective date. SFARs are listed at the beginning of the most relevant Code of Federal Regulations (CFR), and may be cross-referenced to other regulations. SFARS can prohibit, restrict, or have additional requirements to operate in the airspace the SFAR applies to” retrieved from https://www.faasafety.gov/gslac/alc/course_content.aspx?cID=42&sID=244).

¹⁴⁸ 60 FR 65940 – 54 FR 7670 was published in the Federal Register on February 22, 1989.

¹⁴⁹ *Supra* note 146.

¹⁵⁰ *Id.*

¹⁵¹ *Id.*

¹⁵² 60 FR 65941.

during the comment period were supportive from the Airline Pilots Association, the NTSB, and the Coalition of Flight Attendants Unions.¹⁵³ On December 20, 1995, the FAA published the final rules which made it mandatory for all certificate holders¹⁵⁴ to comply with the revised training requirement, and explained their reasoning as “CRM training teaches crewmembers and aircraft dispatchers to use effectively all resources available to the crew (e.g. hardware, software, and all persons involved in aircraft operation) to achieve safe and efficient flight operations.”¹⁵⁵ 14 CFR 121.404 was published which stated that:

“After March 19, 1998, no certificate holder may use a person as a flight crewmember, and after March 19, 1999, no certificate holder may use a person as a flight attendant or aircraft dispatcher unless that person has completed approved crew resource management (CRM) or dispatcher resource management (DRM) initial training, as applicable, with that certificate holder or with another certificate holder.”^{156 157}

Airline safety statistics have shown continued improvement since CRM was implemented and then mandated. From 1990 to 2001, commercial airlines in the U.S. had an average of 3.9 deaths per one million flights.¹⁵⁸ Over the next decade, these rates continued to significantly decline to an average of 1.6 deaths per one million flights from 2002 to 2011.¹⁵⁹ In 2014, this continued to decrease even further to only 0.7 deaths per *ten* million flights.¹⁶⁰

CRM has been widely credited with making the most dramatic safety improvements the airline industry has enjoyed.¹⁶¹ In the current healthcare environment CRM or other types of team training are not mandated as they are in the airline industry.¹⁶² While healthcare and aviation are very different industries, both are highly technical and rely on critical decision making that requires a team to function well for optimal outcomes.¹⁶³ Team training implementation across all U.S. hospitals for all hospital staff as well as physicians has the potential to significantly reduce human error events that could harm the patient.¹⁶⁴ Many leaders within the healthcare community feel that if team training were consistently practiced by all hospital staff and physicians, with checklist processes and communication protocols being strictly followed, significant reductions in patient harm from error could be achieved.¹⁶⁵

¹⁵³ 60 FR 65942

¹⁵⁴ 14 CFR 117.3 – A certificate holder is an entity that holds an air carrier or operator certificate under part 119, referring to air carriers and commercial operators.

¹⁵⁵ 60 FR 65941

¹⁵⁶ 60 FR 65943

¹⁵⁷ 14 CFR 121.404

¹⁵⁸ Mark R. Chassin & Jerod M. Loeb, *Supra* note 137.

¹⁵⁹ *Id.*

¹⁶⁰ Airbus, Commercial Aviation Accidents: 1958 - 2014: A STATISTICAL ANALYSIS 5 (2015).

¹⁶¹ Mark R. Chassin & Jerod M. Loeb, *Supra* note 126 at 469.

¹⁶² Marck HTM Haerkens, Donald H Jenkins & Johannes G van der Hoeven, *Supra* note 33 at 3.

¹⁶³ David P. Baker *Supra* note 72.

¹⁶⁴ Marck HTM Haerkens, Donald H Jenkins & Johannes G van der Hoeven, *Supra* note 162 at 2.

¹⁶⁵ Wahr, Joyce et al at 1144.

CURRENT TEAM TRAINING STRATEGIES IN HOSPITALS

As one of the first team training programs for healthcare, TeamSTEPPS was developed in 2006 by the Department of Defense and AHRQ and has been implemented in more than 1,500 hospitals.¹⁶⁶ The team training concepts used by TeamSTEPPS were adapted from the CRM training developed by the aviation industry.¹⁶⁷ TeamSTEPPS focuses on communication tools and strategies to increase team awareness and the TeamSTEPPS framework consists of four evidence-based core competencies: “Leadership, Situation Monitoring, Mutual Support, and Communication.”¹⁶⁸

A study on the Veteran’s Administration Medical Team Training program shows that patients cared for by surgical teams trained in team training processes had an average annual 18% reduction in overall mortality and this Veteran’s Administration program also showed a reduction of 0.5 deaths per 1,000 operations for every three months of training that the surgical team received.¹⁶⁹ Event data collected by TJC shows that more than two-thirds of adverse events that happen in the Operating Room (OR) are related to communication breakdown.¹⁷⁰ The OR is a high-risk area in which extensive research has been completed, demonstrating that improvements in patient safety are consistently achieved after an organization undergoes implementation by TeamSTEPPS or other similar team training.¹⁷¹ Multiple research studies show that patient’s whose surgical teams did not work well as a team were at higher risk for experiencing complications or even death.¹⁷² In addition, the OR and other surgical procedural areas see improvements after undergoing team training such as improved compliance rates for surgical quality measures, improved surgical start time, and decreased equipment delay.¹⁷³ Many of these improvements have been directly attributed to both the preoperative briefing, when the team focuses on the preoperative preparation being complete and to the debriefing, completed after the procedure to evaluate what went right and what might have gone wrong.¹⁷⁴

HOW TEAM TRAINING MUST BE IMPLEMENTED TO BE EFFECTIVE

One of the key takeaways from team training for hospital staff is often the realization that working as a “team”, rather than as “individuals” helps to foster communication as well as trust and mutual accountability.¹⁷⁵ Team members realize that they are working toward the same goal and as a result, team members no longer consider the patient as “my” patient but rather as “our” patient, with the focus on safety for that patient.¹⁷⁶

¹⁶⁶ Susan Tullai-McGuinness, *TeamSTEPPS: A Path to High Functioning Teams*, 90 OHIO NURSES REV. 12.

¹⁶⁷ Cynthia Plonien & Marcie Williams, *Stepping Up Teamwork via TeamSTEPPS*, 101 AORN J. 465–466.

¹⁶⁸ Sheri L. Ferguson, *TeamSTEPPS: Integrating Teamwork Principles Into Adult Health/Medical-Surgical Practice*, 17 MEDSURG NURS. 122–123 (2008).

¹⁶⁹ Joyce A. Wahr et al., *Supra* note 34.

¹⁷⁰ Sheila Marie Tibbs & Jacqueline Moss, *Promoting Teamwork and Surgical Optimization: Combining TeamSTEPPS with a Specialty Team Protocol*, 100 AORN J. 477.

¹⁷¹ Cynthia Plonien & Marcie Williams, *Supra* note 167 at 467.

¹⁷² Karen Mazzocoo et al., *Surgical team behaviors and patient outcomes*, 197 AM. J. SURG. 682

¹⁷³ Cynthia Plonien & Marcie Williams, *Supra* note 171.

¹⁷⁴ *Id.* at 466.

¹⁷⁵ *Id.* at 467.

¹⁷⁶ *Id.*

To be an effective mechanism for change, team training must be rolled out to all members of the healthcare team.¹⁷⁷ In healthcare, while it can be difficult to get all staff members on board with hospital initiatives and safety programs, it can be even more challenging to get physician buy-in and participation.¹⁷⁸ Suzanne Gordon, author of *Beyond the Checklist*, took a deep look into team training in healthcare and noted the complex relationships that members of the healthcare team sometimes have that often contributes to this challenge.¹⁷⁹ One finding is that there are extensive hierarchical differences between physicians and other team members, as well as differences in the way that physicians and nurses have been trained and socialized in their work environments.¹⁸⁰ During their professional education, neither physicians nor nurses are clinically trained to work as a team and physicians are often educated to be the individual to take absolute responsibility of the patient or situation and to expect staff, particularly nursing staff, to be deferential.¹⁸¹ It is difficult for each of these integral members of the healthcare team to change the dynamics of their relationship and even more challenging for many physicians to relinquish the perceived power they have.¹⁸² The author of *Beyond the Checklist* also points out that CRM in aviation eventually worked because the FAA finally dealt with the “toxic hierarchy” in aviation by mandating CRM training.¹⁸³ The evidence in both healthcare and aviation shows that members of the team should be trained in teamwork training and be trained together, not as individuals or grouped by job role.¹⁸⁴ Without a federal mandate that requires all staff, including physician members of the healthcare team to be trained and regularly re-educated in team training, hospitals are doomed to continue to fail at successful implementation of team training and episodes of patient harm and death will continue, unchanged.¹⁸⁵

TEAM TRAINING MANDATED THROUGH CMS COPS

While there are some in healthcare that feel that the patient safety comparison between healthcare and the aviation industry have been overdone, there are many experts who recognize that there are significant lessons that healthcare could implement from what they’ve learned from aviation, but haven’t put in place yet.¹⁸⁶ One nationally-known patient safety leader, Peter Pronovost states in his book, *Safe Patients, Smart Hospitals: How One Doctor’s Checklist Can Help Us Change Healthcare from the Inside Out*, that aviation did not design safety systems until the airline industry had already accepted it’s fallibility and only then was able to accept checklists and all the tools that are part of CRM.¹⁸⁷ However the author of *Beyond the Checklist* notes that:

“the aviation safety movement started out precisely because pilots did *not* accept their human fallibility. Mistaking the end of a very long journey for its beginning, many in medicine do not seem to understand the similarities

¹⁷⁷ Robert M. Wachter *Supra* note 68 at 536.

¹⁷⁸ *Id.*

¹⁷⁹ Suzanne Gordon, Patrick Mendenhall & Bonnie Blair O’Connor, *Supra* note 137 at 91.

¹⁸⁰ *Id.*

¹⁸¹ *Id.*

¹⁸² *Id.* at 200.

¹⁸³ *Id.* at 195.

¹⁸⁴ Joyce A. Wahr et al., *Supra* note 169 at 1444.

¹⁸⁵ Suzanne Gordon, Patrick Mendenhall & Bonnie Blair O’Connor, *Supra* note 183 at 192.

¹⁸⁶ Robert M. Wachter *Supra* note 177 at 264.

¹⁸⁷ Peter Pronovost, *Safe Patients, Smart Hospitals*, 20 (2010).

between attitudes of pilots pre-CRM and those of physicians today. CRM did not succeed because in the 1980's pilots at United and other airlines threw up their hands and said, "We give up." A great many pilots, in fact, dismissed CRM as "charm school" or even a "Communist plot" to erode their authority."¹⁸⁸

When the mandates for the airlines finally happened in 1990, those working in this sector realized that the industry as a whole was finally serious about making needed change.¹⁸⁹ Many patient safety experts recognize that the most notable differences between healthcare and the airline industry is that team training is not mandated for healthcare as it is for the airline industry.¹⁹⁰ These experts also conclude that healthcare, unlike the airline industry which has the FAA to oversee and regulate airline safety, doesn't have single regulatory agency to oversee patient safety.¹⁹¹ While the authors of the IOM report had called for the creation of such an agency, today, such an agency still does not exist.¹⁹² In the United States, healthcare regulation lacks a "centralized" structure due to the influence of the various regulators at both the federal and state levels.¹⁹³

One agency that does have the authority on a federal level to regulate the safety of care patients receive is CMS.¹⁹⁴ The statutory and regulatory authority for the Hospital CoPs comes from Section 1861 of the Social Security Act, subsection (e) items (1) through (9) which designates the requirements that hospitals must meet in order to participate in the Medicare program.¹⁹⁵ Item (9) includes language that allows requirements to be included to ensure patient safety.¹⁹⁶

The Secretary of the Department of Health and Human Services (HHS) has the ability to modify the CoPs if "they are found necessary in the interest of the health and safety of the individuals who are furnished services in hospitals".¹⁹⁷ In the process to become certified to participate in the Medicare program, hospitals are "deemed" to be compliant through a national accreditation organization recognized by the HHS Secretary.¹⁹⁸ If the hospital is found to have deficiencies during a survey after qualifying as a Medicare provider, the hospital will be required to put a corrective action plan in place to correct the deficiencies.¹⁹⁹ Ultimately, non-compliance

¹⁸⁸ Suzanne Gordon, Patrick Mendenhall & Bonnie Blair O'Connor, *Supra* note 185 at 174.

¹⁸⁹ *Id.*

¹⁹⁰ Robert M. Wachter *Supra* note 186.

¹⁹¹ Suzanne Gordon, Patrick Mendenhall & Bonnie Blair O'Connor, *Supra* note 189 at 189.

¹⁹² *Id.*

¹⁹³ Robert M. Wachter *Supra* note 190 at 365.

¹⁹⁴ Centers for Medicare and Medicaid Services. Retrieved from <https://www.federalregister.gov/agencies/centers-for-medicare-medicaid-services> CMS is a subagency of the Department of Health and Human Services, CMS oversees the Medicare program as well as federal portions of Medicaid. It ensures that the programs and services that its beneficiaries receive are accessible, safe and of high quality. CMS is responsible for developing "health and safety standards for providers of health care services as authorized by Medicare and Medicaid legislation."

¹⁹⁵ 42 U.S.C. 1395x.

¹⁹⁶ 42 U.S.C. 1395x (e) (9) requiring hospitals to meet "such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution."

¹⁹⁷ 42 CFR 482.1(a)(ii).

¹⁹⁸ 42 CFR 482.1(b).

¹⁹⁹ 42 CFR 488.28 (a) which states that when "a provider or supplier is found to be deficient in one or more of the standards in the conditions of participation, conditions for coverage, or conditions for certification or requirements,

with CoPs, which can result in termination of participation in the Medicare program and subsequent loss of the ability to bill Medicare, can be a strong financial motivator for hospital facilities to maintain compliance.²⁰⁰

While the potential loss of participation in the Medicare program is a serious consequence in the enforcement of quality standards set forth by CMS, some acting as *qui tam* relators²⁰¹ and other regulators interested in enforcing quality standards in healthcare, have attempted to use the False Claims Act (FCA)²⁰² to enforce compliance.²⁰³ In the case of *United States ex rel. Landers v. Baptist Mem'l Health Care Corp.*, the Associate Chief Nursing Officer, Anne Landers brought forth a FCA action against the named hospital for several instances where it wasn't complying with the CoPs.²⁰⁴ Among these were quality of care issues where due to inadequate RN staffing in the OR, surgical techs were used as circulators²⁰⁵, with no RN present on every case.²⁰⁶ Landers attempted to use the FCA to assert that the hospital had "falsely certified compliance with applicable statutes, regulations, and rules in order to obtain payment or approval from the Government on Medicare claims".²⁰⁷ The court found that the CoPs "are not the equivalent of Conditions of Payment" and are specific to an organization's ability to participate in the Medicare program, not toward receiving payment.²⁰⁸ Baptist had requested summary judgement on the grounds that there was no genuine issue, and this was granted by the court.²⁰⁹ This court held that the FCA is not an appropriate enforcement method for the CoPs.²¹⁰

There is currently a case that is before the Supreme Court that could change this precedent.²¹¹ In this case the parents of a patient claim that a nurse practitioner who prescribed

it may participate in, or be covered under, the Medicare program only if the provider or supplier has submitted an acceptable plan of correction for achieving compliance within a reasonable period of time acceptable to CMS. In the case of an immediate jeopardy situation, CMS may require a shorter time period for achieving compliance."

²⁰⁰ 42 CFR 489.53.

²⁰¹ *Qui tam* Action, retrieved from https://www.law.cornell.edu/wex/qui_tam_action *Qui tam* is where a private individual, called a "relator" who has knowledge of a party defrauding the federal government, and brings the action forward. In these instances, the government is considered the plaintiff and if the government prevails in the case brought forward, the relator will receive a share of any award. In False Claims actions, the relator may receive up to 30% of the award.

²⁰² False Claims Act (FCA) - 31 USCS § 3729 through 31 USCS § 3733. FCA is a law that imposes penalties on entities that knowingly attempt to submit false claims to the government. The claim must have been made directly to the government or to a contractor. The FCA allows private persons to file suit, or "*qui tam*" action as a "relator" on behalf of the government. If the private individual prevails, they may be awarded a portion of the civil penalty award.

²⁰³ John T. Brennan & Michael W. Paddock, *Limitations on the Use of the False Claims Act to Enforce Quality of Care Standards*, 2 J. HEALTH LIFE SCI. LAW at 40.

²⁰⁴ *United States ex rel. Landers v. Baptist Mem'l Health Care Corp.*, 525 F. Supp. 2d 972 (W.D. Tenn. 2007).

²⁰⁵ 42 CFR 482.51 (a) (3) states that "Qualified registered nurses may perform circulating duties in the operating room. In accordance with applicable State laws and approved medical staff policies and procedures, LPNs and surgical technologists may assist in circulatory duties under the supervision of a qualified registered nurse who is immediately available to respond to emergencies". This hospital was located in Tennessee, which requires that an RN be present to circulate and that an LVN or Scrub Tech may assist the RN, but the RN must be present. 2001 TN Regulation Text 4533 1200-8-1-.07 (1) (e).

²⁰⁶ *Supra* note 204.

²⁰⁷ *Id.*

²⁰⁸ *Id.*

²⁰⁹ *Id.*

²¹⁰ *Id.*

²¹¹ *Universal Health Servs. v. United States*, 2016 U.S. LEXIS 2002 (U.S. Mar. 21, 2016).

off-label seizure medication to treat their daughter's bipolar disorder, was not properly qualified and treatment of the medication caused a new onset of seizures that later caused the death of their daughter.²¹² The parents brought a *qui tam* action forward alleging that defendant, Universal Health Service Inc., violated the False Claims Act.²¹³ The United States District Court for the Court of Massachusetts held that the initial allegations brought forward "raise serious questions about the quality of care provided to the Plaintiffs' daughter. But the False Claims Act is not the vehicle to explore those questions."²¹⁴ This was appealed to the United States Court of Appeals for the First Circuit.²¹⁵ The court reversed the decision of District Court, excluding a portion of the ruling that pertained to the employment of psychologists.²¹⁶ The court held that the Relators "appropriately stated a claim under the FCA."²¹⁷ This case is set to be heard by the Supreme Court on April 19, 2016.²¹⁸

THE QAPI COPS

The CoPs that focus on quality and patient safety are found in section 482 of title 42 in the CFR.²¹⁹ These are the Quality Assessment and Performance Improvement Program (QAPI) CoPs which requires hospitals to implement a quality and performance improvement program and this would provide a logical location for CoPs that focus on the mandate for hospitals to require their physicians and hospital staff to have initial and recurrent team training.²²⁰

On December 19, 1997 proposed rules to add the QAPI CoPs was published in the Federal Register.²²¹ The QAPI CoPs are intended to focus the provider on the quality of care delivered to patients as well as "the performance of the hospital as an organization, and the impact of treatment furnished by the hospital."²²² While the CoPs exist to "protect patient health and safety and to ensure that high quality care is provided to all patients"²²³, the QAPI's focus on quality and patient safety efforts makes it an ideal location for CoPs that mandate team training.

²¹² United States ex rel. Escobar v. Universal Health Servs., Inc., 2014 U.S. Dist. LEXIS 40098 (D. Mass. Mar. 26, 2014).

²¹³ *Id.* at 8.

²¹⁴ *Id.*

²¹⁵ United States ex rel. Escobar v. Universal Health Servs., 780 F.3d 504 (1st Cir. Mass. 2015).

²¹⁶ *Id.* at 517.

²¹⁷ *Id.*

²¹⁸ Supreme Court of the United States, retrieved from <http://www.supremecourt.gov/Search.aspx?FileName=/docketfiles/15-7.htm>.

²¹⁹ 42 CFR 482.21.

²²⁰ 42 CFR 482.21 which establishes a Quality Assessment and Improvement Program and states that "The hospital must develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program. The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS."

²²¹ 68 FR 3435.

²²² *Id.*

²²³ *Id.*

The Administrative Procedure Act, which governs federal agencies' procedures and process of rulemaking, would be used to make changes to the CMS CoPs.²²⁴ ²²⁵ In order for CMS to put forth new rules in the CoPs, it would be required first to give notice in the Federal Register about the proposed rule.²²⁶ This notice would need to include the substance of the rule and the legal authority under which the rule is proposed.²²⁷ While 5 USCS § 553 does not specify an amount of time for a comment period, CMS would be required to inform the public through this notice in the Federal Register of the date for any comments to be submitted through "submission of written data, views, or arguments with or without the opportunity for oral presentation."²²⁸ Once the comment period had concluded, the final rule would then be published in the Federal Register and would be required to be published at least 30 days before the rule's effective date.²²⁹

On the final rule's effective date, American hospitals would be required to comply or face termination of participation in the Medicare program, including billing Medicare for services provided by the facility for covered patients.²³⁰ As in the airline industry, a mandate of team training would require specified training and implementation of a team training program, such as TeamSTEPPS. As the success of CRM has been evident in the airline industry, with respect to the dramatic reduction of airline accidents, so too would be the success from team training implementation in decreasing preventable harm to patients from medical error.

CONCLUSION

Since the IOM report, *To Err is Human: Building a Safer Health System* was published in 1999, there has been an increased focus by the federal government and patient safety community to solve the issue of patient harm and death, as the result of healthcare error.²³¹ The IOM report helped healthcare to begin to shift the focus from placing blame on the individual involved in error, toward a focus on addressing system and process failures.²³² Federal action began with formation of the QuIC task force, by President Bill Clinton, to put action plans in place to improve patient safety.²³³

While there have been some successes in the initiatives that have been implemented since the IOM report, it is a frustrating realization by the healthcare community that within the U.S., we have been unable to achieve the same success as other High Reliability industries.²³⁴ The IOM report itself, having made several recommendations that it saw as essential to improve the safety of healthcare in America, had included the recommendation for hospitals to implement

²²⁴ Vanessa K. Burrows & Todd Garvey, *A Brief Overview of Rulemaking and Judicial Review*, <http://www.wise-intern.org/orientation/documents/crsrulemakingcb.pdf> (January 4, 2011).

²²⁵ 5 USCS § 553.

²²⁶ 5 USCS § 553(b).

²²⁷ *Id.*

²²⁸ 5 USCS § 553(c).

²²⁹ 5 USCS § 553(d).

²³⁰ 42 CFR 489.53.

²³¹ Mark R. Chassin & Jerod M. Loeb, *Supra* note 145 at 460.

²³² Robert M. Wachter, *Supra* note 37.

²³³ Kevin A. Schulman & John J. Kim, *Medical Errors: how the US Government is addressing this problem*, 1 *CURR. CONTROL. TRIALS CARDIOVASC. MED.* 35–37 (2000).

²³⁴ Mark R. Chassin & Jerod M. Loeb, *Supra* note 232 at 460.

team training programs.²³⁵ Team training has been widely recognized by safety leaders in healthcare as having the potential to bring about the same improvements in safety for healthcare that it has been credited for in the airline industry.²³⁶ Among the many regulatory initiatives that have been implemented after the IOM report, team training has yet to be properly implemented, let alone mandated, in U.S. hospitals.²³⁷

It is clear that team training must not only be implemented to be an effective instrument of change, but it must be a part of the initial and ongoing training that all members of the healthcare team, including physicians should receive.²³⁸ It also must be mandated, because without a federal mandate, the extraordinary safety results that the airline industry has seen, and the promising results that a few hospitals have begun to see, will not happen for healthcare as a whole.²³⁹

In order to mandate team training, implementation must be achieved at a federal level, which CMS would have the authority to accomplish.²⁴⁰ CMS would be able to achieve enforcement through the CoPs, which U.S. hospitals would be motivated to comply with in order to participate in the Medicare program and receive this reimbursement.²⁴¹ Non-compliance by participating hospitals would mean that a facility would ultimately risk termination of its participation in the Medicare program, losing a significant source of revenue.²⁴² In order to significantly improve patient safety in U.S. hospitals, the federal government must mandate team training and should use the Medicare CoPs as a path to do so.

²³⁵ Janet M. Corrigan, Linda T. Kohn & Molla S. Donaldson, *Supra* note 126 at 156.

²³⁶ Mark R. Chassin & Jerod M. Loeb, *Supra* note 235 at 469.

²³⁷ Marck HTM Haerkens, Donald H Jenkins & Johannes G van der Hoeven, *Supra* note 164 at 3.

²³⁸ Robert M. Wachter *Supra* note 193 at 364.

²³⁹ Suzanne Gordon, Patrick Mendenhall & Bonnie Blair O'Connor, *Supra* note 192 at 192.

²⁴⁰ 42 U.S.C. 1395x.

²⁴¹ 42 CFR 482.1.

²⁴² 42 CFR 488.28 (a).