

Washington University Global Studies Law Review

Volume 15 | Issue 3

2016

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Rocco Giovanni Motto

Washington University School of Law, St. Louis

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Recommended Citation

Rocco Giovanni Motto, *Adverse Events: The Need for the United States and Japan to Reform Patient Safety*, 15 WASH. U. GLOBAL STUD. L. REV. 513 (2016),
https://openscholarship.wustl.edu/law_globalstudies/vol15/iss3/8

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ADVERSE EVENTS: THE NEED FOR THE UNITED STATES AND JAPAN TO REFORM PATIENT SAFETY

I. INTRODUCTION

When visiting a hospital or any medical facility, there is often a sense of nervousness and apprehension for both patients and accompanying family members.¹ Even though patients may be nervous, they know that the medical staff will work in their best interest.² But medical staffs are imperfect³: a nurse may err when administering an I.V. to a patient⁴ or a doctor may operate on the wrong side of a patient's body.⁵ When errors by the medical staff occur, it is important for the staff to identify and correct these errors.⁶

After the Institute of Medicine released a report in 1999, *To Err Is Human*, a startling discovery was apparent: between 44,000 and 98,000 hospital patients in the United States died in 1997 as a result of an adverse

1. Katherine Mikk, *Making the Plaintiff's Bar Earn Its Keep: Rethinking the Hospital Incident Report*, 53 N.Y.L. SCH. L. REV. 133, 134 (2008–09).

2. *Id.*

3. *Id.* The hospital setting can expose patients to significant risks of illnesses relating to medical examination or treatment. Barry R. Furrow, *Adverse Events and Patient Injury: Coupling Detection, Disclosure, and Compensation*, 46 NEW ENG. L. REV. 437, 445 (2012). “One early study found that more than thirty-six percent of the patients admitted to a hospital developed iatrogenic injury.” *Id.* In addition, “nine percent had major complications, and two percent of all patients died for reasons related to the iatrogenic illness.” *Id.* Many critics have commented “that hospitals lack sufficient incentives to discover and reduce their adverse event rates” because they fear that disclosure will result in more malpractice claims. *Id.*

4. *Related IV Infection*, TANGENT MED., <http://tangentmedical.com/related-iv-infection/> (last visited Oct. 31, 2014). Statistics on healthcare-associated infections (“HAIs”) show that HAIs are the most common problem associated with hospitalized patients. *Id.* HAIs cause one out of every twenty patients to acquire one or more infections and cause roughly 90,000 deaths a year. *Id.* After having a simple surgical procedure done, Bernard Reid died while he was resting. Natalie J. Kussart, *Reporting Medical Errors: The Good, the Bad, and the Ugly*, 31 S. ILL. U. L.J. 385 (2007). While recovering after surgery, a nurse made an error in the ingredients of the fluid Bernard was supposed to be given and erroneously gave a muscle relaxant intravenously to Bernard. *Id.* In the following days, Bernard “went into respiratory arrest and died five days later.” *Id.*

5. *Id.* A child was diagnosed with a hernia on the right side of his body. *Id.* Since the documents in the hospital mistakenly indicated that the boy had a hernia on the left side of his body, the doctor performed surgery on the wrong side. *Id.*

6. Mikk, *supra* note 1, at 134. “Patients who suffer adverse events, even severe ones, often do not realize what has happened, are not told about the adverse event, and often do not file a claim for compensation for serious harms suffered.” Furrow, *supra* note 3, at 440. Adverse events are as old as medicine, and being that medicine has become more complex, the amount of adverse events has substantially increased. *Id.*

event.⁷ An adverse event is an unfavorable event that is caused by a medical product rather than the primary condition of the patient.⁸ In other words, an adverse event describes any harm to a patient as a result of medical care.⁹ A later study estimated that between 220,000 and 440,000 hospital patients in the United States suffer from some type of adverse event that contributed to their deaths.¹⁰ Besides in the United States, the occurrences of adverse events are relatively high in every industrialized society throughout the world.¹¹ Even though the occurrences of adverse

7. LINDA T. KOHN ET AL., *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* 26 (2000), (discussing how adverse events are a leading cause of death and injury), available at www.nap.edu/openbook.php?record_id=9728&page=26. When using the lower of the two estimates, the Institute of Medicine (“IOM”) claims that more people die because of adverse events than motor vehicle accidents, breast cancer, or AIDS. *Id.* To reach this alarming number of patients affected by adverse events, the IOM conducted two studies, one in New York, and another in Colorado and Utah. *Id.* See also Furrow, *supra* note 3, at 439 (discussing the different forms of adverse events). As many as one-third of hospital patients are harmed. *Id.* These adverse events happen for many different reasons: staff errors, system failures of coordination and management, drug mismanagement, and many other reasons, which are discovered after the damage has been done. *Id.*

8. KOHN, *supra* note 7, at 28. Many adverse events are the result of errors. *Id.* at 29. In addition, adverse events that cause death to patients include: errors or delay in diagnosis, errors in the performance of an operation, inadequate monitoring and failure of communication among the medical staff. *Id.* at 36. The Agency for Healthcare Research and Quality (“AHRQ”) defines an adverse event as “any injury caused by medical care,” which is almost the same definition provided by the Institute of Medicine. Furrow, *supra* note 3, at 443. With the complexity of medicine, adverse events are occurring more than ever before. *Id.* at 439. “Errors in drug prescribing continue to be a major source of patient harm, as are physicians who practice medicine contrary to clear practice guidelines.” *Id.* at 440.

9. DANIEL R. LEVINSON, DEP’T OF HEALTH AND HUMAN SERVS., OEI-06-07-00470, *ADVERSE EVENTS IN HOSPITALS: OVERVIEW OF KEY ISSUES* (Dec. 2008) (discussing the key issues regarding adverse events in hospitals), available at <http://oig.hhs.gov/oei/reports/oei-06-07-00470.pdf>. An adverse event represents that the medical outcome was not caused by the underlying disease. *Id.* at 2.

10. Marshall Allen, *How Many Die From Medical Mistakes in U.S. Hospitals?*, PROPUBLICA, www.propublica.org/article/how-many-die-from-medical-mistakes-in-us-hospitals (Sept. 19, 2013, 10:03 AM) (discussing the study of John T. James and how James was able to come up with the new estimates). Because there has never been an actual account of how many patients actually experience an adverse event, these estimates are produced according to approximations. *Id.*

11. Robert B. Leflar, *Discerning Why Patients Die: Legal and Political Controversies in Japan, the United States, and Taiwan*, 22 MICH. ST. INT’L. L. REV. 777, 778 (2014) (discussing the percentage of hospital patients that suffer from adverse events in Western nation; The United States, Japan, and Taiwan). Studies conducted in certain Japanese hospitals have concluded that six to eleven percent of patients suffered from an adverse event. *Id.* At turn of the 21st century, errors within the medical field began to attract public attention in Japan because of the highly publicized mistakes at well-known hospitals in Tokyo. *Id.* at 779; see also M. Bohensky et al., *World Without Borders: Integrating Clinical Perspectives Into the Coronal Jurisdiction in Victoria, Australia*, 25 MED. & L. 13, 14–15 (2006) (discussing the various percentages of adverse events in certain countries). For instance, researchers in the United Kingdom found that 10.8 percent of the hospital patients reviewed in their study were correlated with a medical error. *Id.* at 14. Likewise, in New Zealand, adverse events are associated with 12.9 percent of hospital patients and contribute to roughly 1500 deaths per year. *Id.* at 15. While in Canada, researchers have found that adverse events from system failures are associated with 7.5 percent of hospital patients. *Id.* Finally, researchers in Australia have estimated that 16.6 percent of hospital patients deal with adverse events and 4.9 percent result in death. *Id.*

events are alarmingly high in every industrialized society, countries have treated the issue differently.¹²

In analyzing adverse events, this Note explores the advancements and regulations regarding adverse events in the United States and Japan. In doing so, this Note places particular emphasis on the different reporting practices and mechanisms each country has implemented over the years while insisting that the United States government should federally mandate reporting systems. In addition, this Note will explore Japanese initiatives and practices that may help the United States substantially improve patient safety.

First, this Note provides an overview of the history of adverse events within each country. When addressing the history, this Note will address when adverse events became a high priority within each country. This discussion will include statistics regarding adverse events before and after each country implemented some type of strategy to increase patient safety. Next, this Note is going to look at each country's reporting regulations that have been implemented over time and the advantages and disadvantages for each reporting regulation. Furthermore, this Note addresses how the United States may, or may not, benefit from the provisions and practices that are implemented to help increase patient safety in Japan. Ultimately, this Note examines what efforts each country has taken to ensure that adverse events are reduced and patient safety within hospitals increases. Finally, after analyzing each country's history of improving patient safety, this Note suggests that the United States should federally regulate adverse event reporting and determines whether or not the United States can utilize certain Japanese practices.

II. HISTORY

The report, *To Err is Human: Building a Safer Health System*, was the epiphany for many citizens and legislators in the United States that something had to be done to improve patient safety.¹³ In doing so, the

12. See Leflar, *supra* note 11, at 777.

13. Michael A. Morse, *Mandatory Reporting of Adverse Events, Near Misses, and Mistakes for Acute Care Hospitals*, 78 PA. B.A. Q. 124, 124 (2007) (discusses the famous report by the Institute of Medicine, the main changes that have been implemented by Congress throughout the years to help with patient safety). The report made it very clear that medical errors are a nationwide epidemic, which has a significant impact on hundreds of thousands of patients. *Id.* Further, not only did the report conclude that roughly 98,000 Americans died each year from medical errors, but approximately 1 million dealt with substantial adverse events resulting in around \$29 billion in annual financial costs. *Id.* The IOM report stressed that although some of these preventable adverse events may be the result of incompetence or impaired providers, the committee believes that many could have been avoided

Institute of Medicine (IOM) recommended a broad set of measures to address the problem of medical errors including a nationwide mandatory reporting system.¹⁴ Even though the 1999 IOM report strongly recommended a nationwide mandatory reporting system, no nationwide reporting system was administered; instead, federal and state statutes were implemented.¹⁵ Because many of the hospitals and healthcare providers were unaware of these federal and state statutes, there continued to be many medical errors that would go unreported.¹⁶

As this Note discusses the history of reporting in the United States, it will become apparent that not enough is being done to increase patient safety. Similarly, Japan is another well-developed country that has struggled with increasing patient safety.¹⁷ Beginning in 1999, reports of errors at hospitals of high regard filled the news in Japan.¹⁸ These errors were a result of a nurse who accidentally injected a toxic agent into her patient and a team of doctors who were not sufficiently trained.¹⁹ More importantly, in each of these errors, physicians and hospital employees altered medical records, gave deceiving information to families and investigators, or engaged in other deceitful acts.²⁰ Historically, institutions negligently monitored the quality of Japan's medical care, but at the turn

had an improved system of care been in place. The Journal's Editorial Staff, *A National Survey of Medical Error Reporting Laws*, 9 YALE J. HEALTH POL'Y, L. & ETHICS 201, 203 (2008). The IOM encouraged Congress to make many steps in order to establish better patient safety. *Id.* First, the IOM encouraged Congress to establish a national system for health care quality measurement and reporting to collect reports from states concerning the most serious errors taking place in hospitals and other health care situations. *Id.* at 203–04. The IOM also recommended that the main causes of adverse events should be available to the public, therefore reinforcing facilities' incentives to minimize errors and devote more to patient safety. *Id.* at 204.

14. Morse, *supra* note 13, at 124. According to the IOM the main goal of the reporting system was to adhere to specific reports of serious injury, hold organizations and providers accountable for patient safety, keep the public informed about unsafe conditions, and provide incentives to health care organizations to minimize the errors that cause these adverse events. *Id.* at 124–25.

15. *Id.* at 125. Many of the main targets of the federal and state statutes were completely unaware that mandatory reporting requirements existed. *Id.*

16. *Id.*

17. Robert B. Leflar & Futoshi Iwata, *Medical Error as Reportable Event, as Tort, as Crime: A Transpacific Comparison (Updated Version)*, No. 22 J. JAPAN L. 40, 41 (2006) (discussing that the issue of patient safety is unresolved in both countries), available at [http://sydney.edu.au/law/anjel/documents/ZJapanR/ZJapanR22/full%20article/ZJapanR22_07_Leflar_NEU\[1\].2.pdf](http://sydney.edu.au/law/anjel/documents/ZJapanR/ZJapanR22/full%20article/ZJapanR22_07_Leflar_NEU[1].2.pdf).

18. Robert B. Leflar, *The Law of Medical Misadventure in Japan*, 87 CHI.-KENT L. REV. 79, 81 (2011) (discussing the series of medical errors in Japan that led to a great deal of media coverage for the hospitals and medical staff). The series of events included a nurse who accidentally injected a toxic agent that killed her patient, a group of young doctors who failed to have an adequate supply of a patient's blood type before engaging in a delicate surgery, and the death of a child at a major pediatric surgery center. *Id.*

19. *Id.*

20. *Id.*

of the 21st century, administrative error and civil litigation forced Japanese medicine to improve patient safety.²¹

Patient safety remains a constant problem within well-developed countries because the traditional approach to medical errors is insufficient.²² The traditional approach involves a focus on professionalism, individual honesty, and competence.²³ The traditional approach to medical errors fails in two ways. First, the system is outdated because it targets individual accountability, and second, because it only targets individual accountability, it cannot assess today's health system, which composes of an entire medical staff providing care for a single patient.²⁴ Furthermore, the complexity of systems, not inept individuals, usually causes medical errors.²⁵ Research has indicated that highly trained individuals who are trying to do the right thing cause the majority of harm.²⁶ Thus, the strategy of punishing individual physicians who are dedicated to doing the right thing is ineffective.²⁷ It is apparent that the traditional approach to patient safety is hopeless, and a new approach to patient safety must be implemented if well-developed countries want to see patient safety improve.²⁸

A. *United States*

Throughout the years, several studies have been conducted on the nature of adverse events in hospitalized patients.²⁹ One may think with so

21. *Id.* The Ministry of Health, Labor & Welfare rarely inquired into failures of patient safety. *Id.* In addition, the medical education strongly discouraged any open questioning of practices taught by professors, even if those practices were not scientifically proven. *Id.*

22. Katharine A. Wallis, *Developing a Culture of Safety: Regulation or Education?* (May 2013) (unpublished Ph.D. thesis, University of Otago), available at <http://otago.ourarchive.ac.nz/bitstream/handle/10523/4195/WallisKatharineA2013PhD.pdf?sequence=1>.

23. *Id.* at 10.

24. *Id.* In complex health systems, an individual who is working on a patient within a team may have little control over the prevention of error and injury; therefore, many of the factors attributing to medical error are outside the power of individual members of the staff. *Id.* at 10–11. Possible factors that contribute to team error include: equipment, poor organization and patient characteristics (stressed, poorly educated). *Id.* at 11.

25. *Id.*

26. *Id.*

27. *Id.* Most preventable harm is caused by flaws in the health system rather than the fault of the individual; therefore, the persistent pressure to incorporate more education and training is not likely to change the outcome of patient safety. *Id.*

28. *Id.*

29. Lucian L. Leape et al., *The Nature of Adverse Events In Hospitalized Patients*, 324 *NEW ENG. J. OF MED.* 377, 377 (1991), available at www.nejm.org/doi/pdf/10.1056/NEJM199102073240605. This study took place in 1984 in the state of New York, in which 3.7 percent of patients had injuries and that negligent care was responsible for twenty-eight percent of the injuries. *Id.* The study

many studies conducted and a country that is as technologically advanced as the United States, how can this country have so many adverse events.³⁰ Adverse events range from patient infection to unnecessary surgery.³¹ In order to increase patient safety, documentation and measurement of adverse events is a top priority.³² Thus, it is essential for hospitals to partake in reporting guidelines in order to provide an increase in patient safety.³³

Reporting is a principal element of patient safety because it can recognize medical errors, allow providers to learn from and decrease their mistakes, and monitor progress in the prevention of errors.³⁴ After the

looked at 30,195 records of patients who were hospitalized in New York in 1984. *Id.* at 378. Out of all the adverse events, forty-eight percent of them were caused from operations. *Id.* In addition, twenty-eight percent of the adverse events were caused from negligent care. *Id.* Wound infections were the most reoccurring adverse event, which accounted for nearly one seventh of all medical errors identified in the study. *Id.* The next leading medical error was drug complications, which was the most common single type of adverse event. *Id.* The study also looked at where adverse events mainly occurred and found that the majority (forty-one percent) of adverse events resulted from treatment that was administered in the hospital room. *Id.* at 379. Overall, the report found that prevention of adverse events is dependent on medical knowledge; however, the high amount of adverse events that are due to management errors suggests that many adverse events were preventable during that time. *Id.* at 377; see also Ashley M. Votruba & Michael J. Saks, *Medical Adverse Events and Malpractice Litigation In Arizona: By-The-Numbers*, 45 ARIZ. ST. L.J. 1537, 1539 (2013) (discussing that at least 20,000 adverse events occur in Arizona, and at least 1,300 result in deaths; also, the number of those adverse events that are considered to be a result of negligent care is estimated at 5,600). See also David Classen et al., *'Global Trigger Tool' Shows That Adverse Events In Hospitals May be Ten Times Greater Than Previously Measured*, HEALTH AFFAIRS, content.healthaffairs.org/content/30/4/581.full (last visited Nov. 2, 2014).

30. See Barry R. Furrow, *Regulating Patient Safety: Toward A Federal Model of Medical Error Reduction*, 12 WIDENER L. REV. 1, 3 (2005) (discussing the magnitude of medical errors within the United States). While this country flourishes in technological advancements, there are too many patients that suffer avoidable injury and death from a spectrum of adverse events. *Id.* As early as 1858, an early biostatistician, by the name of Nightingale, developed the use of statistical methodology to show the effects of unsanitary conditions in military field hospitals, which laid the groundwork for standard statistical approaches for hospital data collection. *Id.* at 441–42. Later, in the 1920s, a Boston physician had become obsessed with collecting data on every patient in the hospital with the goal of learning what worked and how doctors contributed to bad patient outcomes. *Id.* at 442. By the 1960s, medical researchers began to focus on the problem of patients harms in hospitals. *Id.*

31. Furrow, *supra* note 30, at 3–4. Infections within hospitals has increased by approximately twenty percent from 2000 to 2003 and accounted for 9,552 deaths. *Id.* at 3. In addition, unnecessary surgeries have been estimated to be responsible for roughly 12,000 deaths per year. *Id.* at 4.

32. Classen, *supra* note 29, at 1. Multiple studies have emphasized that a lot of work is needed in order to improve patient safety. *Id.* In North Carolina, a recent study confirmed that a high rate of adverse events has not decreased over time. *Id.*

33. *Id.* “This focus on sentinel events has been encouraged by the adoption of reporting safety ‘never events’ (events that should not have happened; for example, deaths from blood transfusions) in several states.” *Id.*

34. Maxine M. Harrington, *Revisiting Medical Error: Five Years After the IOM Report, Have Reporting Systems Made a Measureable Difference?*, 15 HEALTH MATRIX 329, 330 (2005) (discussing the overall change after the implementation of the reporting system to patient safety five years after the IOM report came out).

IOM released its report, it recommended a comprehensive set of measures to tackle the nationwide problem of medical errors including a recommendation to have a nationwide mandatory reporting system.³⁵ It sought, as its main goal, to ensure a response to specific reports of serious injuries, hold establishments and providers accountable for guaranteeing patient safety, implement incentives to health care establishments so that patient safety would increase, and respond to the public's right to be informed about any unsafe conditions.³⁶ In addition, the IOM insisted medical institutions comply with mandatory reporting in order for policymakers and health care administrators to grasp the root causes of medical errors and, later, implement systematic reforms.³⁷ Since the IOM report, Congress and state legislatures have actively tried to deal with patient safety.³⁸ Even though patient safety has received more attention after the IOM report, there is little improvement.³⁹ For instance, after the IOM report, instead of a nationwide reporting system a patchwork of federal and state reporting regulations exist.⁴⁰

35. Morse, *supra* note 13, at 124. See also Harrington *supra* note 34, at 330 (discussing that the IOM expected nothing less than a fifty percent reduction in errors over five years).

36. Morse, *supra* note 13, at 124–25.

37. The Journal's Editorial Staff, *supra* note 13, at 203 (discussing the recommendations of the IOM report and the overall progress of medical errors since the IOM report). The IOM recommended that the analyses of the main causes of adverse events be available to the public, thus urging facilities to minimize errors and invest in patient safety. *Id.* at 204. Additionally, the IOM recommended that the Center for Patient Safety should implement voluntary reporting for minor medical errors. *Id.*

38. Harrington, *supra* note 34, at 331. In February 2000, President Bill Clinton mimicked the IOM's plan by announcing a national action plan to reduce medical errors by fifty percent. *Id.* For the purposes of this Note, legislative activity among the states is far outside of this topic. For further information regarding states, compare Erik E. Sardiña, *Search For Truth vs. The Public Good: The Effect of The Patient Safety Act on Common-Law Discovery Rules*, 37 SETON HALL LEGIS. J. 207 (2012) (discussing the New Jersey Patient Safety Act) with Kussart, *supra* note 4 (discussing Illinois' reporting laws).

39. Harrington, *supra* note 34, at 331. See also The Journal's Editorial Staff, *supra* note 13, at 204–05 (discussing the progress since the IOM report). Since the IOM report, a number of state governments implemented medical error reporting systems. *Id.* at 204–05. For instance, at the time the report came out, there were thirteen states that collected medical error data. *Id.* Whereas by 2008, there were programs in twenty-seven states. *Id.* “In addition to gathering data on medical errors, state departments of health have worked with hospitals and other care facilities on root cause investigation, protocols to address known errors, and the implementation of best practices to prevent future errors.” *Id.* Besides the states, the federal government has also encouraged efforts to promote patient safety. *Id.* at 205.

40. Morse, *supra* note 13, at 125. Given that hospitals, healthcare providers, and attorneys have little or no understanding that mandatory reporting requirements exist, there continues to be a significant under reporting of medical errors. *Id.* See also Scott Jones, *Reporting Adverse Medical Events: Quality Reporting Meets Compliance*, 14 J. HEALTH CARE COMPLIANCE 53, 55 (2012) (discussing the states that maintain a current listing of adverse event reporting requirements). In addition, not every state has implemented state laws and regulations addressing reporting of adverse events. *Id.* As of right now, there are only 29 states that have implemented plans with the National Academy for State Health Policy (“NASHP”). *Id.*

Following the consistent increase of medical errors in the United States, Congress passed the Patient Safety and Quality Improvement Act (“PSQIA”) in 2005.⁴¹ The PSQIA is the first federal legislative attempt to address patient safety and develop both a new national medical error reporting system and a federal opportunity for data collection.⁴² While the PSQIA incorporated the IOM’s recommendation to design a systematic review of error, the PSQIA only established a voluntary national reporting system.⁴³ This system-based approach was set out to improve patient safety by incentivizing cooperation between health care providers and patient safety research entities.⁴⁴ One of the most revolutionary additions to the PSQIA was that it created significant protections for errors that are disclosed for the purpose of patient safety research.⁴⁵ Furthermore, under the PSQIA, information cannot be disclosed to a third party because the

41. Frederick Levy et al., *The Patient Safety and Quality Improvement Act of 2005 Preventing Error and Promoting Patient Safety*, 31 J. LEGAL MED. 397, 397 (2010) (discussing the PSQIA and its potential effects on patient safety). Before the PSQIA was implemented, the United States relied on traditional mechanisms, such as medical malpractice and peer review. *Id.* at 400. The main issue with each of the reforms is the fact that they are punitive and they do not look into fixing medical errors in the future. *Id.*

42. Levy, *supra* note 41, at 397. Even though the PSQIA was passed in 2005, the Department of Health and Human Services did not issue the PSQIA until December 2008. *Id.* The patient safety movement in health care is premised on reducing the level of adverse events. Furrow, *supra* note 3, at 441. This PSQIA, attributed to several patient safety reforms and grants the right to the Secretary of the Department of Health and Human Services to expand patient safety initiatives. *Id.* “As part of comprehensive quality management programs, patient safety compliance programs are being developed by private firms as well as hospitals.” *Id.*

43. Levy, *supra* note 41, at 407. The final legislation was completely supported in the Senate. *Id.* Shortly before signing the PSQIA into law, President George W. Bush commented that the PSQIA was a “commonsense law” that would allow others to learn from the past experiences of doctors and nurses by protecting providers who report patient safety information. *Id.* See also Kussart, *supra* note 4, at 390 (discussing the voluntary reporting system). Before the federal bill was passed, a bill similar to the PSQIA was introduced six-years prior but was never passed because of the main concerns for the protection of health care providers against liability. *Id.* Even though this prior bill failed, when the PSQIA was passed, Congress declared that this law will “be among the most significant healthcare legislation the Senate will consider during this Congress . . . because . . . this legislation will contribute immensely to the current efforts that are underway to save lives and reduce the tragedy of needless medical errors.” *Id.* (quoting 151 CONG. REC. S8741 (2005)). Even though the PSQIA does not express exactly what types of adverse events organizations are supposed to report, the PSQIA was a building point that allowed the Secretary of Health and Human Services (“Secretary”) to determine a common format for the reporting and consistent definitions. *Id.* All of the information that is collected will be used to analyze and evaluate national and regional statistics, which may ultimately lead to critical information to minimize medical errors. *Id.* at 390–91. The overall cost of the implementation of the PSQIA is estimated to be around \$58 million over four years. *Id.* at 391.

44. Levy, *supra* note 41, at 407. The PSQIA encouraged providers to discuss patient safety experiences through a series of legal protections. *Id.* Providers who voluntarily reported safety information “may qualify for both privilege and disclosure protections.” *Id.*

45. *Id.* Even though the protections are more comprehensive than any state-based protections, they are not absolute. *Id.* at 407.

information must be kept confidential.⁴⁶ The main purpose of this protection is to encourage and ensure providers to report their errors without them having to worry that the reported errors will be used against them in any type of litigation.⁴⁷

Even though reporting systems have many advantages, they contain many problems such as a lack of consistency and developing more accurate and impactful information.⁴⁸ In order to do so, the PSQIA needs to make sure that data collection is consistent and all regulations are current.⁴⁹ When Congress enacted the PSQIA, the purpose was to provide steadiness within the system;⁵⁰ however, “[c]ongress diverged from that purpose when they made the reporting system voluntary.”⁵¹

However, the Food and Drug Act (FDA) has enforced regulations that provide a framework for the timing and content of adverse event reports.⁵² Facilities, such as hospitals, surgical centers, and nursing homes are required to report any type of death or severe injury that was caused by a device within ten business days to the FDA and manufacturer.⁵³ While this is a tremendous step in the right direction for patient safety, the implementation of a framework needs to cover more than just device-related deaths if the United States wants to see a dramatic increase in patient safety.

46. *Id.* at 408.

47. *Id.* After the providers report the medical errors, the error information will be sent to Patient Safety Organizations (PSOs), where the information will be compiled and analyzed. *Id.* at 407–08. After analyzing the error information, PSOs are able to make recommendations for avoiding errors and improving overall patient safety. *Id.* at 408.

48. Kussart, *supra* note 4, at 395 (2007) (discussing the problems of the PSQIA).

49. *Id.*

50. *Id.* at 396.

51. *Id.* There is no way for consistency to be achieved when states can decide whether or not they want to report. *Id.* The data received is not going to be much different from the data that is already in place because essentially nothing has changed. *Id.* Therefore, the trends and estimates will not be an accurate reflection of the nation because not all states or providers will be included. *Id.* In addition to the inconsistency, the PSQIA did not establish what type of events should be reported. *Id.* Instead, the PSQIA states that “the Secretary may determine common formats for the reporting . . . [and] common and consistent definitions.” *Id.* (citing 42 U.S.C. § 299b-23).

52. Daniel B. Kramer et al., *Ensuring Medical Device Effectiveness and Safety: A Cross-National Comparison of Approaches to Regulation*, 69 *FOOD & DRUG L.J.* 1, 9 (2014) (discussing the adverse event reporting guidelines that have been implemented by the FDA).

53. *Id.* In 1993, the MedWatch program established a more streamlined adverse reporting mechanism for consumers, which collects voluntary submissions from health care providers and patients together with required reports from user facilities, importers, and manufactures. *Id.* These reports may be submitted in multiple ways, which makes it easier to volunteer the adverse event reports. *Id.*

B. Japan

Around the same time *To Err is Human: Building a Safer Health System* was presented in the United States, the Japanese public was dealing with a similar event.⁵⁴ In 1999, medical error was brought to the public's attention by the mass media when a lung patient at Yokohama City Medical University Hospital mistakenly had part of his heart valve removed and a heart patient had surgery on his lung.⁵⁵ In the years following, numerous accounts of medical errors continued to be reported at well-known hospitals across Japan.⁵⁶ In order to address and take control of this matter, the Ministry of Health, Labor and Welfare (MHLW) set up a small patient safety office in 2000, which conducted a study that examined the occurrence of adverse events in Japanese hospitals.⁵⁷ This study found that adverse events had occurred in 6–7% of hospitals, and that 23% of those adverse events were avoidable.⁵⁸

In distinguishing the limitations of the court system as a regulator for medical error, the MHLW launched several administrative proposals to address patient safety issues.⁵⁹ One of the most notable proposals is the “Model Project for the Investigation and Analysis of Medical Practice-

54. Robert B. Leflar, *Public and Private Justice: Redressing Health Care Harm in Japan*, 4 DREXEL L. REV. 243, 245 (2011) (discussing the problem of medical error that first appeared within the Japanese public). Hereinafter Leflar, *Public and Private Justice: Redressing Health Care Harm in Japan*. See also Robert B. Leflar, *Unnatural Deaths, Criminal Sanctions, and Medical Quality Improvement in Japan*, 9 YALE J. HEALTH POL'Y & ETHICS 1, 6 (2009) (discussing the particular instance that resulted in two physicians getting arrested). “A twelve-year-old girl died during heart surgery at Tokyo Women's Medical University Hospital in 2001 due to improper functioning of a heart-lung machine.” *Id.* During another medical error, the CEO of a well-known Tokyo hospital, along with two nurses, were arrested after the patient died from an accidental injection. *Id.*

55. Leflar, *Public and Private Justice: Redressing Health Care Harm in Japan*, *supra* note 54, at 245.

56. *Id.* “The media played a important role in the public awakening: reporters competed to dig up the details of the tragedies . . . and embarrass the health ministry.” *Id.*

57. Leflar, *Public and Private Justice: Redressing Health Care Harm in Japan*, *supra* note 54, at 246. The health ministry drafted guidance manuals advising hospitals to employ risk management personnel and started a voluntary adverse reaction reporting system *Id.*

58. *Id.*

59. *Id.* at 251. See also Leflar, *supra* note 11, at 793–94 (discussing Japan's model project for the peer review). This project for peer review “[I]aunched in four urban prefectures and subsequently expanded to ten.” *Id.* at 793. This model project was an effort to improve the quality of hospital case reviews and regain the public trust in their objectivity, while channeling case reviews away from police. *Id.* The model project was impactful because it brought “independent specialists to investigate in-hospital deaths upon participating hospitals' request, and to report results to the hospital, the family of the deceased, and . . . to the public.” *Id.*

Associated Deaths.”⁶⁰ This system allows hospitals to submit cases of questionable deaths to an independent review panel of outside experts.⁶¹ After the experts review a case, they provide methods that will prevent similar events from happening in the future.⁶² Even though this is a step in the right direction, the number of participating hospitals and the number of cases submitted are substantially smaller than what was expected in the beginning.⁶³

Medical Authorized Holders (MAHs) are required to report adverse events directly to the MHLW.⁶⁴ Even though most of the adverse event reports come from the MAHs, it is also possible for other stakeholders, such as facilities and providers, to submit reports either to MAHs or directly to the MHLW.⁶⁵ “After receiving the adverse event reports, [Pharmaceuticals and Medical Devices Agency (PMDA)] analysts evaluate the relationship between the device and the reported injuries or outcomes, trying to assess whether the outcome was related to user error,

60. Leflar, *Public and Private Justice: Redressing Health Care harm in Japan*, *supra* note 54, at 252. At the suggestion of four major medical societies, in 2005, the ministry set up the Model Project for the Investigation and Analysis of Medical-Practice-Associated Deaths [(“Model Project”).] *Id.*

61. *Id.* The review panel of outside experts would conduct an autopsy, “review the medical records, interview the participants in the patient’s care, and compile a report for both the family and the hospital.” *Id.* The experts would then evaluate everything that happened and explain what measures should be taken to prevent similar events in the future. *Id.* The review process involves medical specialists, attorneys, nurses, and health officials. *Id.*

62. *Id.* While the Model Project is a great step in the right direction for patient safety, it is important to know that there are limitations: it only addresses death cases, not cases dealing with serious injuries. *Id.* In addition, these case reports have been known to take longer than expected, which slows the process and angers the families who are anxious to hear the cause of death. *Id.*

63. *Id.* See also *Japan Establishes Programs to Address Medical Errors*, WORLD HEALTH ORG., www.who.int/patientsafety/news/japan_programs/en/ (last visited Nov. 5, 2014) (discussing the programs that the Japanese health officials administered to address medical errors). The health ministry created a trial malpractice database, which provides information on unexpected hospital deaths and serious after effects of treatments. *Id.* These prominent health officials are expecting that this information will be provided to roughly 250 national and university hospitals in Japan, with the overall goal to help better educate nurses and doctors on how to prevent accident and near-accident patterns. *Id.* Furthermore, health officials are dedicated to addressing errors made by pharmacists, since it is a significant contributor to medical errors. *Id.* The Japan Pharmacist Association is planning to certify pharmacists who develop expertise with the nearly 300 kinds of anticancer medicines that are available in Japan. *Id.* In order to receive certification, pharmacists have to demonstrate that they are fully aware of the medical properties that deal with all relevant drugs. *Id.*

64. Kramer et al., *supra* note 52, at 11–12 (discussing adverse event reporting within Japan). The MAHs must report the adverse events to the MHLW within 15 or 30 days; this is all dependent on how serious the problem is. *Id.* at 11.

65. *Id.* Other parties involved in the manufacturing and supply of devices, such as distributors, also must report to the MAHs adverse events or events that otherwise factor into overall safety and effectiveness judgments. *Id.* “Health care providers are required by law to cooperate with MAHs during active investigation of safety problems.” *Id.* Most importantly, when providers “learn of cases of diseases, disabilities or deaths suspected to be caused by the use of medical devices, and they confirm that it is necessary to prevent the spread of hazards, they must report to the MHLW.” *Id.*

the underlying disease, or a device malfunction.”⁶⁶ When it comes to device malfunction, MAHs track and report events that occur outside Japan for similar or related devices—not just devices specifically sold in Japan.⁶⁷

Unlike United States hospitals, Japanese hospitals are not required to perform self-critical analyses; however, many Japanese hospitals are beginning to complete self-critical analyses using the references from the National University Hospital Presidents’ Conference and with guidance from the MHLW.⁶⁸ With the continuation of medical errors, the MHLW adopted a broader principle, which made it a mandatory requirement to report accidents.⁶⁹ Although this was an improvement from the past, MHLW’s original reporting program was unsuccessful.⁷⁰

In 2003, MHLW changed its direction and determined that accidents causing harm to patients, in addition to near-miss events, would be the concentration of the redesigned reporting system.⁷¹ Similar to the United States, and since 2004, the reporting of accidents causing harm has become mandatory (only under the FDA), rather than voluntary.⁷² Instead

66. *Id.* This assessment can lead to two different routes: it may conclude that further investigation is required by the MAHs or that the evaluated data is going to need additional safety measures, such as a change in labeling. *Id.*

67. *Id.* Collecting foreign data is particularly important for Japanese regulators because most medical devices used in Japan are sold in other countries prior to being used in Japan. *Id.* If there were to be a recall or if a safety alert was issued in another country, the MAHs must notify PMDA and analyze whether there is a possible impact on domestic devices or patients. *Id.* For instance, “[i]f a recall . . . is determined to relate to a manufacturing problem limited to devices sold outside of Japan, the MAHs still must submit the root cause analysis and evaluation, and determine whether systems in place are sufficient to prevent a similar problem from arising domestically.” *Id.* at 11–12

68. Leflar, *supra* note 17, at 56. Part of the caution is attributable to the concern by Japanese medical leaders, which is also a concern to the leaders of the United States, regarding the possibility that this information could be used to the detriment of medical defendants’ civil malpractice actions. *Id.* There are four sources of legal obligation which raise some concern to the Japanese hospitals and physicians: “(1) national and local Freedom of Information rules that apply to public hospitals; (2) the liberalized discovery rules under Article 220 of the civil procedure law; (3) an asserted contractual obligation . . . to investigate hospital accidents and report the results to patients; and (4) the requirement for reporting to the police of ‘unnatural deaths’ in Article 21 of the Physicians’ Law.” *Id.*

69. *Id.* at 58. This reporting requirement was brought into effect with the help of the court’s decision. *Id.* Facing a similar controversy as the United States, Japan faced a major issue in structuring its patient safety programs. *Id.* Initially, MHLW set standards to establish safety management systems including systems for internal reporting to hospital patient safety committees of accidents involving injury. *Id.*

70. *Id.* at 59. The “near miss” reports, which officials hoped would contain great amounts of information to help identify specific problems, were unhelpful and left the officials figuring out the root causes of these accidents. *Id.* A small amount of the staffers were available to read and analyze the reports to give feedback. *Id.*

71. *Id.*

72. *Id.* This included an additional 272 larger and specialized facilities, including all national and university hospitals. *Id.*

of the reports being made to a governmental entity with enforcement powers, the reports are now sent to an independent quasi-public entity, which has the sole purpose of collecting and analyzing medical accident data and determining the remedial measure.⁷³

1. *The Use of Medical Prosecutions and the Media in Japan*

Unlike the United States, during the initial recognition of medical errors, Japanese hospitals and physicians worry about the probability of a police investigation and criminal prosecution.⁷⁴ In addition, the Japanese engage in several legal strategies that are not present in the American legal system.⁷⁵ For example, “professional negligence causing death or injury” is a common charge brought against medical personnel—a type of crime not found in the United States.⁷⁶ Furthermore, the prosecutorial culture in Japan is much more different than that found in the United States.⁷⁷ After the Supreme Court of Japan’s landmark conviction of the Hiro General Hospital director in Tokyo, many physicians and hospitals have chosen to file “unnatural death” reports whenever a patient dies in circumstances where possible professional negligence was involved.⁷⁸

Even though there is a constant worry about criminal prosecution, the more significant impact on medical errors is the amount of media coverage

73. *Id.* This type of reporting structure is similar to the air safety reporting system in the United States. *Id.* See also *Aviation Safety Reporting System (ASRS)*, NATIONAL BUSINESS AVIATION ASSOCIATION, <http://www.nbaa.org/ops/safety/asrs/> (last visited Jan. 12, 2015) (discussing that the Aviation Safety Reporting System (ASRS) was implemented to improve aviation safety by providing a venue where pilots, air traffic controllers, flight attendants, mechanics, ground personnel, and others involved in aviation operations can share information about unsafe situations that they have encountered or observed). *Id.* Additionally, these reports are held in strict confidence. *Id.* When a report is made to ASRS, all information about the submitter is not taken away before the report is posted. *Id.*

74. Leflar, *supra* note 17, at 65. Even before the media provided mass coverage of the medical errors taking place within hospitals, an average of two to three prosecutions per year were brought in medical cases in Japan—a frequency much higher than is reported in the United States. *Id.* at 65–66. In the past few years, medical prosecutions have continued to increase in Japan. *Id.* at 66.

75. *Id.*

76. *Id.* at 66. The few convictions in the United States consistently involve charges of recklessness or intent, which requires a higher level of *mens rea*. *Id.* at 67.

77. *Id.* at 72. The Japanese prosecutorial culture focuses on determining the exact facts of each case, and when prosecutors consider possible charges, they consider whether the victim has received compensation or an apology. *Id.* In contrast, American prosecutors neither need nor consider the doctor’s remorse or whether or not there was an apology, which is imperative in the Japanese prosecutorial culture. *Id.*

78. *Id.* at 68–69. Because of this particular case, the number of reports to police has increased eight-fold since 1998, the year before the case became public. *Id.* at 69.

that these medical errors receive.⁷⁹ The media coverage has portrayed hospitals and physicians negatively, which creates the need for patient safety, induces patients to seek criminal prosecution, and encourages police investigations.⁸⁰

III. ANALYSIS

To say that Japan's model for increasing patient safety will eliminate the occurrence of medical errors in hospitals across the United States would be inappropriate. Given that humans are imperfect, there will always be medical errors present within the medical field.⁸¹ However, it is appropriate to expect well-developed countries to significantly increase patient safety over time by implementing and understanding different methods and solutions. After much consideration, it is clear that applying Japan's model to the United States is not realistic. Nevertheless, the United States may benefit and increase their patient safety by adopting certain characteristics found in Japan's system.⁸²

A. Why Mandatory Reporting Will Improve Patient Safety

As discussed in Section II, after enacting the PSQIA in 2005, the United States encouraged facilities to voluntarily report medical errors.⁸³ The current approaches to tracking adverse events can be very intimidating; however, these approaches include voluntary, sentinel event and never event reporting systems, which are often mandated by state regulators.⁸⁴ These voluntary methods of gathering adverse events fail because they do not detect the majority of adverse events and, therefore,

79. *Id.* at 66. Because of the amount of publicity that hospitals and physicians were receiving during that time, the medical profession was on edge and had helped create a public expectation that the police and prosecutors will play a significant role in medical errors. *Id.*

80. *Id.* The relentless media coverage depicts hospitals and physicians in a negative way, by showing the people the harm and the amount of lying within hospitals. *Id.*

81. See Bryan A. Liang & Steven D. Small, *Communicating About Care: Addressing Federal-State Issues in Peer Review and Mediation To Promote Patient Safety*, 3 HOUS. J. HEALTH L. & POL'Y 219, 223 (2003) (discussing the complexity of systems used within hospitals). Some of the characteristics that make these systems complex include: technical needs, long hours, long operations, and trade-offs between employees. *Id.* at 224–25.

82. *E.g.*, Leflar, *supra* note 17, at 66.

83. See Levy, *supra* note 41, at 407.

84. Barry R. Furrow, *Adverse Events and Patient Injury: Coupling Detection, Disclosure, and Compensation*, 46 NEW ENG. L. REV. 437, 452 (2012) (discussing the issues with collecting adverse events data).

we do not have enough information to properly attack this problem.⁸⁵ In addition, underreporting is a significant issue when there is not a mandatory system to report adverse events because without data there is no way to know what to change about the current method.⁸⁶ If the federal government made the disclosure information about adverse events a requirement, competition could be created among hospitals to decrease patient safety risk, ultimately leading to higher patient safety standards.⁸⁷ Even though the federal government has moved in the right direction by requiring hospitals to publicly report deaths and certain bad outcomes, the United States should define bad outcomes more broadly in order to trigger more disclosure requirements.⁸⁸

Allowing individual states to adopt their own rules on disclosure is a step in the wrong direction because only a little more than half of the states adopted rules requiring hospitals to disclose certain medical errors.⁸⁹ Without consistency among the data collected, the chances of increasing patient safety are very slim.⁹⁰ Consistency cannot be achieved when states have the power to decide whether or not they want to report certain medical errors.⁹¹ Therefore, the trends and estimates that are provided by the states will in no way be an accurate representation of the nation

85. *Id.* at 452–60. Studies gathering the actual incidence of negligent events in hospitals found that many adverse events were not reported in hospital records as required, which occurred more often when the main person responsible for the error was a senior physician. *Id.* at 460. In order to stop hospitals from concealing adverse events, strong sanctions should be enacted and a new government agency or department should be appointed to focus solely on adverse event detection, measurement and reduction. *Id.*

86. The Journal's Editorial Staff, *supra* note 13, at 213.

87. Stephen D. Sugarman, *Outcome-Based Regulatory Strategies for Promoting Greater Patient Safety*, 15 THEORETICAL INQUIRES L. 573, 583 (2014) (discussing numerous strategies to increase patient safety within the United States). Determined to improve the frequency and quality of patient-provided information regarding adverse events, federal officials have recently considered asking for patients who think they have suffered from some type of medical error to report their experience to the government. *Id.* at 588.

88. *See id.* Hospitals must include death rates from heart attacks, heart failure and pneumonia, as well as readmission rates. *Id.* at 583.

89. *Id.* at 586. Certain state websites are more helpful than others in terms of overall information and user friendliness. *Id.* While information provided by other states can be quite useless and a waste of time. *Id.* A problem is that patients may want to know how well a hospital has eliminated preventable adverse events, "but also how well it does in achieving the positive goals the proposed patient treatment aspires to." *Id.* at 587.

90. Kussart, *supra* note 4, at 395. Additionally, the purpose behind the PSQIA was to provide consistency within the system. *Id.* at 396.

91. *Id.* Data received from voluntary reporters will not be of much use, especially because there is a chance that the report is incomplete. *Id.*

because not all states will be included.⁹² Even though a mandatory system may improve patient safety, there is no guarantee that medical personnel will follow the law.⁹³ Finally, by making a national reporting system mandatory, more states and providers will participate, which will ultimately lead to more accurate statistics.⁹⁴

B. What Can the United States Implement from Japan?

Because of a strong history of stringent criminal prosecutions in Japan, Japan has substantial benefits regarding patient safety compared to the United States.⁹⁵ Without question, these two countries have differences within their legal structures, which has forced each country to take different approaches to improving patient safety.⁹⁶ The criminal prosecution system in Japan has helped motivate the medical profession to commence internal system improvements.⁹⁷

In the past two decades, there has been an estimated twenty-five to thirty-five cases of criminal prosecution for medical negligence in the United States.⁹⁸ Multiple factors have contributed to this low amount of prosecutions.⁹⁹ Additionally, even though there is a high frequency of civil medical malpractice actions in the United States, the threat of criminal prosecutions does not give much concern to American physicians or hospitals.¹⁰⁰

92. *Id.* See also Bryan A. Liang, *Collaborating on Patient Safety: Legal Concerns and Policy Requirements*, 12 WIDENER L. REV. 83 (2005) (discussing the importance of how collective learning would increase and promote patient safety across the United States).

93. Kussart, *supra* note 4, at 396. For example, even though speed limit signs are posted on roads, they are not going to ensure that everyone obeys that law.

94. *Id.* In any event, accurate statistics will lead to a greater chance of an increase in patient safety. *Id.* Since the PSQIA did not establish the type of events that must be reported, the PSQIA data collected is going to be a surplus of irrelevant information. *Id.* In order to achieve consistency, all health care providers must know precisely what to report. *Id.* at 397.

95. Leflar, *supra* note 17, at 75.

96. *Id.* at 74.

97. *Id.* at 75. In response to the criticisms of the extent of the criminal justice system's involvement in the patient safety arena, the MHLW launched a "model project" in 2005. *Id.* at 73.

98. *Id.* at 64. Based on these cases, convictions were obtained on the basis of the defendants' reckless disregard for a patient's safety. *Id.* The reason for such a low amount of prosecutions is the fact that these matters are so complex, with such a high burden of proof that makes it impractical for anyone to pursue a case. *Id.* at 64–65. Additionally, the need for medical experts and the length of time required for a case makes the prosecution of medical personnel a costly and difficult task. *Id.*

99. *Id.*

100. *Id.* Injured patients and their families rarely seek to have the negligent physicians prosecuted. *Id.*

In comparison, a major worry of Japanese hospitals and physicians is the possibility of police investigation and criminal prosecution.¹⁰¹ Additionally, the Japanese prosecutorial system in Japan allows for a larger number of causes of action than that found in the United States.¹⁰² Because there may be an issue of liability considerations, there is a demand for suspicious medical errors to be communicated to some neutral entity outside of the hospital.¹⁰³ Accustomed to Japan, the police and the media have become popular external entities who can effectively respond to adverse events.¹⁰⁴ In other words, Japanese individuals who are affected by a medical error are more inclined to call for police and seek prosecutorial involvement than Americans.¹⁰⁵

While it would not be ideal or beneficial for the United States to adopt a system that would create fear in its doctors,¹⁰⁶ it may be beneficial for the media to get involved with reporting medical errors. After considering the differences between Japan and the United States, it is apparent that if the media in the United States would be as fierce as the Japanese media after medical errors, then legislators, hospitals, and physicians may be more inclined to increase the safety within facilities.¹⁰⁷ If the United States media portrayed medical error issues as international issues, much more would be done.¹⁰⁸

Throughout this Note, it has been mentioned that communication among medical staff is a vital component to patient safety. Therefore, it is fundamental for there to be constant communication between nurses and

101. *Id.*

102. *Id.* at 66.

103. *Id.* at 68.

104. *Id.* Even though the police are not medical experts, it is understood that some might favor a system that encourages reporting to the police as a public accountability mechanism. *Id.*

105. *Id.* at 71. One of the main reasons the Japanese are inclined to seek the police is that they look to public authorities to resolve disputes that Americans would resolve privately. *Id.* Additionally, patients who suffer from a medical error go to the police because of the practical difficulties and delays in obtaining civil law remedies through malpractice actions. *Id.*

106. David A. Hyman & Charles Silver, *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. 893, 896 (2005) (discussing how liability will hinder the overall quality of healthcare). When doctors are punished for their decisions, it may discourage them from reporting errors. *Id.*

107. Leflar, *supra* note 17, at 45. See also Rachael Lee Burgess, *The Effect of Media Bias on Legislation: A Case Study of Arizona's Senate Bill 1070 on Immigration* (June 30, 2011) (unpublished thesis, Rowan University) (discussing when Arizona enacted the *Support Our Law Enforcement and Safe Neighborhoods Act* in April 2010.) Following the enactment, media from all over the country gave their opinions on whether or not the immigration bill should be implemented. *Id.* at 1.

108. Leflar, *supra* note 17, at 48. Once the public is informed on the issue, more will be done to help resolve it. *Id.*

doctors, and for facilities to figure out how to improve communication.¹⁰⁹ Within the United States, there is a nurse shortage, and it is expected to continue throughout the next eight to ten years.¹¹⁰ Similarly, Japan has a deficiency in nurses too,¹¹¹ however, because of particular studies conducted in Japan, facilities are able to adjust to the main causes that attribute to medical errors.¹¹² Additionally, in Japan, the amount of small to medium-sized hospitals plays a crucial role because the workplace is less strenuous on the entire medical staff.¹¹³

The United States may want to consider the development of smaller hospitals and an overall increase in medical staff.¹¹⁴ If the United States does not increase nurses within hospitals, it will increase the stress level of current nurses, encourage nurses to leave the profession, which would eventually lead to an increase of medical errors.¹¹⁵

C. What Can Be Done to Further Improve Patient Safety Within the United States?

It is impossible for an institution to improve patient safety without first knowing its deficiencies; therefore, the primary goal is to learn about the institution.¹¹⁶ After learning about the causes within the hospital, it is important to address the mistakes by providing leadership with the tools to fix the mistakes.¹¹⁷ Safety improvements can only be implemented within

109. Linda L. Lindeke & Ann M. Sieckert, *Nurse-Physician Workplace Collaboration*, ONLINE J. ISSUES NURSING, Jan. 21, 2005, http://www.nursingworld.org/MainMenuCategories/ANAMarketplace/ANAPeriodicals/OJIN/TableofContents/Volume102005/No1Jan05/tpc26_416011.html.

110. Robert J. Rosseter, *Nursing Shortage Fact Sheet*, AM. ASSOC. COLLEGES NURSING, Apr. 24, 2014, <http://www.aacn.nche.edu/media-relations/NrsgShortageFS.pdf>. The lack of nurses is not because of the lack of interest in the field but because of constraints such as the lack of classroom and budget constraints. *Id.* at 2. Furthermore, according to AACN's report in 2012–2013 U.S. nursing schools turned away over 79,000 qualified applicants from nursing programs. *Id.*

111. *Nursing in Japan*, JAPANESE NURSING ASSOC., <http://www.nurse.or.jp/jna/english/nursing/employment.html> (last visited Feb. 21, 2016).

112. See generally, e.g., Yasushi Kudo et al., *Safety Climate and Motivation Toward Patient Safety Among Japanese Nurses in Hospital of Fewer than 250 Beds*, 47 INDUS. HEALTH 70, Oct. 14, 2008, available at https://www.jstage.jst.go.jp/article/indhealth/47/1/47_1_70/_pdf. This study showed that reporting, nursing conditions, and communications with physicians had significant impacts on preventing mistakes. *Id.* at 74.

113. *Id.*

114. See *id.*

115. Rosseter, *supra* note 110, at 3. More than seventy-five percent of resident nurses believe the nursing shortage presents a significant problem for the quality of patient care. *Id.*

116. Furrow, *supra* note 3, at 458. Overtime, hospitals have been described as “obtuse” institutions—they fail to learn from experience and data due to their culture and structural features embedded within history. *Id.* at 458–59. In order for hospitals to discover errors and their causes, money, time, and participation is going to be needed. *Id.* at 459.

117. *Id.* at 459.

a facility that is adequately staffed and funded.¹¹⁸ Money must be spent on electronic medical records and staff that can identify adverse events within these medical records.¹¹⁹

When it comes to monitoring adverse drug events, infections and other kinds of harm, there needs to be a boost in computerized detection tools.¹²⁰ One approach is to detect adverse event patterns by using the Institute for Healthcare Improvements' Global Trigger Tool, in conjunction with the use of data mining software.¹²¹

Mandating public adverse event disclosure would allow for an increase in patient safety because important information will be provided to address adverse event needs.¹²² While many critics argue that mandatory reporting would suffocate errors and deter critics from reporting, evidence for this assumption is not strong, and there is evidence that supports the contrary.¹²³ In addition, "[p]hysicians who are not exposed to liability are no more likely to report errors than physicians who are exposed to liability."¹²⁴ Over time, adverse events have been viewed as a waste product of hospitals, a product that is both harmful and inefficient.¹²⁵ The consistent waste of adverse events demands regulation towards an increase to patient safety.¹²⁶

118. *Id.*

119. *Id.*

120. *Id.* A health care system should use a multitude of tools, including tools that are not human. *Id.* In other words, hospitals need a boost in various computerized detection systems to identify adverse events. *See id.*

121. *Id.* at 460. These tools are programmed to detect outlier problems in care that may otherwise be unnoticeable to medical staff and administrators; however, these programs are unlikely to pick up the range of adverse events that nurses, doctors, and other providers would detect during patient care. *Id.*

122. *Id.* at 461.

123. *Id.* Evidence has been provided that insists that full disclosure in a properly designed system reduces litigation risk, settlement and payout costs. *Id.* "Tom Baker and Timothy Lytton observe that the claim that medical malpractice liability discourages error reporting has never been documented by empirical research, and a recent, careful review has thoroughly discredited this conventional wisdom." *Id.* (quoting Tom Baker & Timothy Lytton, *Allowing Patients to Waive the Right to Sue for Medical Malpractice: A Response to Thaler and Sunstein*, 104 NW. U. L. REV. 233, 244-45 (2010)).

124. *Id.* at 462. "Reporting hospitals' comparative outcomes would be valuable. Public reporting may stimulate quality-improvement activity by hospitals, although a strong correlation between public-reporting obligations and clear evidence of safety improvement is not yet established." *Id.* This collected data is more than likely to improve over time because of the constant pressure from private and government payers. *Id.*

125. *Id.* at 463. "Ernest Codman first used the term waste to describe patient harms. He argued that hospitals must track their practices and evaluate outcome of their patients, since he felt that patient harm due to infections and unnecessary or inappropriate operations was a hospital waste product." *Id.*

126. *Id.* at 464.

IV. CONCLUSION

While it is apparent that both the United States and Japan have long realized that medical errors are a significant problem within their nations, neither country has figured out a way to minimize these errors and increase patient safety. Overtime, both nations have developed new regulations to improve patient safety, but none of these improvements have left a significant impact. It is clear to see that the numbers support the fact that patient safety has not improved. In order for either nation to increase patient safety, the collection of data is a necessity. With more data collected and analyzed, the more likely each nation will have a better understanding on how these medical errors occur within medical facilities. Finally, in order for this data to be gathered, the United States must federally mandate medical error reporting in order to properly attack this demoralizing issue.

*Rocco Giovanni Motto**

* Associate Notes Editor, *Washington University Global Studies Law Review*; J.D. (2016), Washington University in St. Louis; B.A. in Ethics and Public Policy (2012), The University of Iowa. Rocco would like to thank Grace Polzin, his mother and father, and his invaluable friends for their unending support.