

INTEGRATING PATIENT SAFETY AND RISK MANAGEMENT: THE ROLE OF LAW AND HEALTHCARE ORGANISATIONS

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Abstract

In creating an environment that minimises patient harm as well as avoiding the unnecessary loss of lives, there is a need for the inculcation of a safety culture in healthcare institutions. Healthcare organisations need to foster a culture that encourages continuous improvement of patient safety system within their institutions. Patient Safety is an integral part of the practice of medicine as it aims to reduce ‘the risk of unnecessary harm associated with healthcare to an acceptable minimum’ (WHO, World Alliance for Patient Safety 2009). Risk management, on the other hand, develops processes that minimise risks of harm within the organisation by identifying and analysing ‘potential hazards to prevent accidents, injuries, and other adverse occurrences through a minimum cost or minimize financial liability’ (MeSH 2009). Patient safety has the ability to support risk management efforts through new ways of understanding how things go wrong and applying new models to the problems. In supporting this, law plays a crucial role by giving health care providers incentives for delivering optimal care by preventing the risk of damage and safeguarding the legal protection of patients as well as strengthening professional discipline. Designing a model that integrates patient safety and risk management objectives requires the support of legal solutions, responsible and vigilant healthcare organisations to ensure systemic improvements in the safety and quality of the healthcare system.

Keywords: Patient Safety, Risk Management, Law, Healthcare Organisations

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Introduction

Adverse events or “injuries due to medical care” may be the result of practice, products, procedures and systems and may emerged at all the stages in the process of care-giving (WHO, 2008). The occurrence of medical error induces adverse events, which may be caused by a combination of human

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factors and system factors (Reason, 2000). However, majority of medical errors are considered preventable, particularly, those involving human errors (WHO, 2014). For instance, in majority of birth-related cases, injuries suffered by the victims may be preventable when they are due to improper handling of the birth delivery or inappropriate risk management by those involved in the birthing process. The occurrence of these kind of cases tend to trigger claims in the court of law as the injuries suffered tend to be severe, permanent and emotionally overwhelming. It is understandable for the affected families to initiate court litigation in order to alleviate the financial burden as such injuries cause life-long disabilities which require high costs of medical and nursing care. For instance, in the case of *Lim Zi Hong v Pengarah Hospital Selayang & Ors* (2013), the Government of Malaysia had to pay RM3,392,170 in specific damages and RM250,000 in general damages for cerebral palsy secondary to perinatal asphyxia epilepsy and left hemiplegia, which was the result of a preventable human error ([2013] 10 CLJ 412). Therefore, there is a crucial need for a safety culture in healthcare organisations, particularly, hospitals, in ensuring that adverse events are reported, discussed and prevented as medical errors could lead to severe physical injuries and death.

1. Patient Safety versus Risk Management

Patient Safety is an integral part of the practice of medicine. It is the “avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the processes of healthcare” (Cooper, J.B *et.al.*, 2000). It further encompasses efficiency, security of care, reactivity of caregivers and satisfaction of patients and relatives (Kohn, L.T. *et.al.*, 2000). Major reports and studies from countries around the world continue to reveal that there are real opportunities to make healthcare safer by learning about the problems within the system and using this information to generate improvement in the delivery of care. The World Health Organisation (WHO) World Alliance for Patient Safety’s Summary of Evidence on Patient Safety: Implications for Research Report (2008) surmised that patient safety is a pre-requisite for quality health care and unsafe medical care is a major source of morbidity and mortality around the world. Thus, a system of care delivery that emphasises on patient safety is one which (i) prevents errors; (ii) learns from the errors that do occur; and (iii) is built on a culture of safety that involves health care professionals, organizations, and patients (Aspden & Corrigan, J., 2004). Risk management, on the other hand, is a systemic process of identification, analysis and evaluation of actual and potential risks to estimate the costs and efforts that they request from the organisations. The main objective of risk management is to provide a safe and effective environment for patients by averting and decreasing the loss within the organisation (Dearmon, V., 2013). This is achieved by conducting activities that identifies, analyse and evaluate potential hazards in the organisation through the mapping and the analysis of the root cause. Many healthcare organisations engage the services of risk managers to execute risk management activities. The role of a risk manager focuses on (i) assessing the organisation potential risk, the ability to fund and finance the risk; (ii) claim management and the defense of malpractice claims; (iii) loss control (Napier, J. & Youngberg, B.J., 2011). Therefore, patient safety is the outcome, while risk management focuses on the prevention. Thus, patient safety has the ability to support risk management efforts through new ways of understanding how things go wrong and applying new models to the problems. Designing a model that integrates patient safety and risk management objectives requires the support of legal solutions, responsible and vigilant healthcare organisations.

2. The Role of Law

Law, being an instrument of social regulation, regulates behaviour within the society and protects the rights of its members. Law plays a crucial role in upholding patient safety goals and supporting risk management activities by offering (i) incentives to healthcare providers in delivering optimal care that prevents risk of damage; (ii) safeguarding the legal protection of patients; (iii) strengthening professional discipline.

Legislative Intervention in support of Patient Safety Initiatives

In several countries, legislative measures have been introduced to ensure healthcare providers respect and implement patient safety initiatives (Garel, P. (C.E.), 2013), particularly, in promoting open disclosure of medical errors and incident reporting. For instance, the introduction of the Patient Safety and Quality Improvement Act of 2005 (PSQIA) in the United States aims to provide a broader and uniform system for medical error prevention and reporting nationwide (Garvey, M.M, 2011). PSQIA establishes a voluntary reporting system designed to enhance the data available to assess and resolve patient safety and health care quality issues (Office for Civil Rights, HSS, n.d.). To further encourage the reporting and analysis of medical errors, PSQIA provides blanket confidentiality and privilege protections for such information if the information was developed for reporting to Patient Safety Organisations (PSOs), organisations that work with healthcare providers to identify, analyse and reduce the risks and hazards associated with patient care (Agency for Healthcare Research and Quality, 2008). PSQIA also authorizes the US Department of Health & Human Services (HHS) to impose civil money penalties for violations of patient safety confidentiality (Office for Civil Rights, HSS, n.d.). Similarly, patient safety initiatives in Japan had led to the amendment of the Japan Medical Care Act in 2014, which established the Medical Accident Investigation System, which came into operation in October 1, 2015. This system makes it mandatory to report adverse events to a medical accident investigation support center and to perform medical accident investigation to identify the cause of the accident. An internal investigation of a medical accident is performed, and the investigation outcome report is then collected by a private third party institution (Medical Accident Investigation Support Center) to analyze it with the aim of preventing recurrence and improving the safety and quality of healthcare (Japanese Nursing Association, 2014). Thus, under this *iryojiko cJose seido* (medical accidents investigation system), all the nation's 180,000 hospitals and clinics are mandated to investigate 'unexpected' cases of patient death themselves, regardless of their legal liability and report the results to the next of kin and third party organization (Otake, 2015). Once a hospital concludes an unexpected death has occurred, it will probe the case and the investigative teams must include outside experts to ensure impartiality. They must explain the results of their investigations to relatives of the deceased and submit a report on each case to the Japan Medical Safety Research Organisation and the organization will analyse the information and propose steps to avoid repeated fatal mistakes. This step is considered very beneficial in making hospitals more transparent and accountable in the light of the rising reported cases as according to the Japan Council for Quality of Health Care, 3194 adverse events including those that resulted in death or injury of patients were reported by 993 institutions in 2014.

Enacting 'Apology Laws' and 'Disclosure Guidelines' to encourage Open Disclosure of Adverse Events

In most jurisdictions, the traditional legal answer to the issue of patient safety has been brought by the tort system, i.e. the regime of professional liability (Faure, 2004). The legal rules on professional liability are supposed to fulfil two different functions (i) to fairly compensate the victim of negligent care; and (ii) to play a preventive role by giving health care providers incentives to improve care in order to prevent damage (Guillod, 2013). Undoubtedly, the inherent weaknesses in the tort regime still deny compensation even when the healthcare provider has actually erred. This is due to the problem in proving medical negligence through its substantive laws (Quick, 2012). Further, tort liability is based on personal fault. This unfortunately, encourages a culture of secrecy instead of a culture of openness. When things go wrong, it makes it more difficult to know which errors have been made and, therefore, how to prevent them in the future (Gilmour, 2006). Healthcare providers do not disclose errors because they fear of being held liable. Studies consistently show that healthcare providers are reticent about discussing errors as they believe they have no appropriate assurance of legal protection (Mariner, 2001). They also fear that an apology will be taken as an admission of guilt or liability. But in many circumstances, most injured patients mainly seek an explanation and hope for an apology rather than opting for court litigation and striving for financial compensation (McClennan, 2013). Keeping silent when something went wrong is a flawed strategy since many legal claims are due to deficits in the doctor-patient communication (Guillod, 2013). Thus, in order to encourage open disclosure more specifically by doctors, a number of countries have enacted disclosure laws mandating disclosure of medical errors under specific circumstances (McLennan, 2013). For instance, Canada, Australia and the United States have enacted so-called ‘apology laws’, i.e. laws providing that an apology given after an adverse event cannot be used in ulterior legal proceedings (Emslie et al, 2002). Generally, ‘apology laws’ mandates the disclosure of medical errors under specific circumstances, while at the same time offering legal protection to those making the apologies. The main issues embedded in these legislations include (a) apologising does not constitute an admission of fault or civil liability; (b) an apology is inadmissible in any judicial proceeding as evidence of fault or liability; and (c) the insurance coverage for the person or entity offering an apology is unaffected by an apology. For instance, in Australia, under the New South Wales Civil Liability Act 2002, section 69(1)(a) declares that apology is not an admission of fault or liability. Further, in determining fault or liability on the part of the defendant, section 69(1)(b) exclude apology from being taken into account as a relevant fact in determining fault and is inadmissible as evidence of fault and therefore, cannot be used in court against the person who gave it (section 69(2)). Thus, if ‘apology laws’ are enacted along with other norms on patient safety, they may indeed be helpful in making medical customs evolve. Eventually, by promoting better communication and open disclosure through legislations, doctors and patients will be given opportunities to find solutions outside the courtroom (Clinton & Obama, 2006).

Further, in the United States of America, new patient safety standards, including a guideline requiring disclosure of unanticipated outcome by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) were introduced to encourage disclosure. This 2004 guideline requires patients and their families to be informed about outcome of care, treatment and services including unanticipated outcome. The aim of this guideline is to create a mechanism to ensure that patients are knowledgeable and equipped to participate in current and future decision (Taft, 2005). In Australia, the development of the National Open Disclosure Standard for Public and Private Hospitals developed by the Australian Council for Safety and Quality in Health Care, which include that the giving of an ‘expression of regret’ as part of an important element in an effective disclosure was made as the reference in enacting Australian apology legislation (Australian Commission on Safety and Quality in

Health Care, 2008). This is due to the fact that, although apology is included as a part of disclosure promoted in the National Open Disclosure Standard, medical practitioners are still slow in embracing this policy due to “uncertainty about doctor’s legal and professional obligations in relation to open disclosure and concern about medico-legal risk” (Finlay *et al.*, 2013, at 445). By protecting apologies made by medical practitioners after an adverse event, more opportunities will be created for an effective disclosure and it can be made as a platform for a medical practitioner to become more responsible and accountable for their professional misconducts. Accountability will be promoted as medical practitioners will be encouraged to be more responsible for their conduct rather than such responsibility being imposed by the law when they need to pay for the compensation as ordered by the court (Cohen, 2002).

Creating Non-Delegable Duties of Healthcare Organisations to ensure Accountability

In early histories, healthcare organisations, particularly, hospitals, were considered as charitable institutions and were afforded absolute immunity from any legal liability. Hospital authorities could not be vicariously liable for the negligence of members of their medical staff, whether professionally qualified or not, as being a charitable institution, the element of control over the method of working was lacking. However, in the present times, the development of the ‘doctrine of corporate law’ creates duties for hospitals to be legally responsible for the safety and security of patients, employees and visitors (Dearmon, V., 2013). The provision of a wide range of medical services is considered an integral and essential part of the operation of any hospitals, which provide medical treatment to the patients. Although the negligent act may be committed by a particular individual but the act is considered to be a part of the overall medical care provided by the hospitals. It is the medical care that is sought by the patient and it is proper medical care that should be provided. Thus, it would only be in the interests of justice that the primary responsibility for the provision of medical care lies with the hospital authorities and they should not be allowed to delegate that responsibility to others as to relieve itself of such liability. As stated by Denning in *Cassidy v Ministry of Health* [1954] 2 QB 66, 82, “...the hospital authorities are responsible for the whole of their staff, not only for the nurses and doctors, but also for the anaesthetists and the surgeons. It does not matter whether they are permanent or temporary, resident or visiting, whole time or part time. The hospital authorities are responsible for all of them.”

The doctrine of vicarious liability imposes liability on employers for the torts committed by his employees who are acting in the course of employment. However, the doctrine does not impose liability on employers for torts committed by independent contractors, whom are considered as “independent”, in the manner on how they execute their duties. Consequently, to insulate themselves from liability, healthcare organisations are constantly finding ways and methods to classify their staff as independent contractors and thus, abdicate legal responsibilities to them. This practice has been argued to be against the notion of fairness and justice. The reason being that as the employee advances the economic interests of their employers, healthcare organisations should be made to bear the corresponding losses and as an organization, they can easily distribute the losses they had suffered. The creation of non-delegable duties arose as the courts tried to create exceptions under the doctrine of vicarious liability. In some circumstances, a hospital will still be found liable for the negligence of a nurse, doctor or other health care professional even though that nurse, doctor or other health care professional is not an “employee” of the hospital (Fox., P. 2007). This arises in circumstances where the hospital owes the patient a non-delegable duty of care. The exception on

non-delegable duty owes its origins in the common law case of *Dalton v Henry Angus & Co* (1881) 6 App Cas 443, in which Lord Blackburn in the House of Lords stated that “a person causing something to be done, the doing of which casts him a duty, cannot escape from the responsibility attaching on him of seeing that duty performed by delegating it to a contractor.” Since then, the interpretation of non-delegable duties has evolved through judicial cases and provisions under various statutes. In the context of provision of care by a hospital, a non-delegable duty of care is a legal duty of a hospital owed directly to the patient which cannot be divested by delegation. This was reiterated by Lord Denning in *Cassidy v Ministry of Health* [1951] 2 KB 343, 363, in which his Lordship stated that “where a person is himself under a duty to use care, he cannot rid of his responsibility by delegating the performance of it to someone else, no matter whether the delegation be to a servant under a contract of service or to an independent contractor under a contract for services.” Further, in *Wilsher v Essex Health Authority* [1986] 3 WLR 801, 833, *Browne-Wilkinson VC* commented that “...a health authority which so conducts its hospital that it fails to provide doctors of sufficient skill and experience to give the treatment offered at the hospital, may be directly liable in negligence to the patient.” The Australian case of *Kondis v State Transport Authority* [1984] 58 ALJR 531 has also held that a hospital authority is under a duty to take reasonable care of its patients. Such a duty cannot be delegated to its staff or to independent contractors, even if such persons are chosen with reasonable care. The hospital authority will therefore be directly liable for negligence on the part of its staff, as a breach of its non-delegable duty has occurred. (Bettle, J. 1987). Thus, the hospital may be liable for the breach of duty by any health care professional, whether or not they are an employee. It is a duty which, because of the particular nature of the relationship between the hospital and the patient, cannot be delegated to the health care professional who are at all times with the hospital (Fox, P. 2007). Further, according to Buchanan., V.M. et al (2003)., “the fact that a contract classifies a healthcare provider as an independent contractor is not dispositive, particularly where the contract contains conflicting facts or different inferences can be drawn from the contractual terms about the relationships of the party.” For instance, a non-delegable duty of care was held to exist in the case of *Albrighton v Royal Prince Alfred Hospital* [1980] 2 NSWLR 542, in which the hospital was found liable for the negligence of its honorary medical officers as the hospital had undertaken to provide reasonable care for all the needs of the patient, who had approached the hospital directly for treatment, and whom it had admitted. The court held that “...whatever legal duties were imposed upon those who treated, diagnosed or cared for her needs from time to time, there was an overriding and continuing duty upon the hospital as an organization”. This means that a hospital owes a non-delegable duty to ensure that the treatment which it undertakes to provide to a patient is performed with reasonable care. (Fox, P. 2007). Many lessons can learned from the rationale of the judgment in the US case of *Simmons v Tuomey Regional Medical Center* which held that hospitals have a non-delegable duty to render competent services to patients even if the hospital appoints independent contracted physicians as the hospital’s duty has “evolved into an absolute duty that is incapable of being delegated.” Thus, although the hospital may freely transfer its duties to an independently contracted medical staff, liabilities accompanying some of the duties cannot be delegated. Further, whether hospital’s responsibility is non-delegable depends on whether it is “so important to the community that the employer should not be permitted to transfer it to another.” The court concluded several factors to support this absolute non delegable duty. Amongst them are, firstly, public reliance on hospital imposes a non-delegable duty on the part of hospitals to those who utilize its services. Secondly, the public recognize a hospital as a single entity providing multifaceted medical services and thus, doctors working in the hospital are the instrumentalities; regardless of the nature of the

contractual relationship that may exist between them. It can be seen that from their case, the main justification for imposing a non-delegable duty on hospitals is not through the ordinary workings of tort law but mainly based on public policy considerations. Patients' expectations and safety were paramount considerations in deciding the case. Under the common law, the circumstances in which a non-delegable duty will be imposed is relatively fixed, without any guiding principles which determine precisely how and when such a duty arises. (Jones, M.A. 2008). In many common law jurisdictions, in addition to the common law, non-delegable duties are often created through statutes. In the United Kingdom, for instance, the Occupiers' Liability Act 1957 stated in section 2(4)(b) that in certain circumstances an occupier may be liable for dangers due to the faulty execution of any work of construction, maintenance, or repair, even when this has been done by an independent contractor (Dias R.W.M. & Markesinis, B.S. 1989). There are also numerous Commonwealth, State, and Territory statutes in Australia which govern the contractual relationships of employees-employers and independent contractors-hirers. Each Australian jurisdiction has a raft of statutes covering labour relations e.g. industrial relations, occupational health and safety, workers compensation, privacy, workplace surveillance, public sector employment, and administrative review of government action legislation. (Wilson, J. 2011). For instance, the Independent Contractors Act 2006 (Cth) excludes any law conferring or imposing rights, entitlements, obligations or liabilities that would be considered "workplace relations matters" in an employment relationship. (Independent Contractors Act 2006 (Cth) section 7(1)(b).

3. The Role of Health Organisations

The increasing awareness of patients' rights and rising public's expectations has prompted healthcare organisations to improve quality and patient safety. Undeniably, the present trend amongst healthcare organisations, particularly hospitals, is focusing more and more on patient safety improvement activities (Meersman, P, 2011). As emphasised by Miller and Bovbjerg (2002) that there are two determinants of success in improving patient safety, that is a demand for safety from external factors (legal, market, and professional) and appropriate organisational responses that depend on internal factors such as leadership and governance, professional culture, information-system assets, and financial and intellectual capital (Garel, P. (C.E), 2013). Thus, the promotion of the safety of care requires a management commitment and leadership, collaboration and cooperation of all the professionals within the organisation (Patient Safety and Risk Management Guidelines, 2008). The organisation needs to ensure compliance with current regulatory standards as well as policies and supports the transparency and reporting of adverse events and accidents in an open environment without fear of sanction or blame. For instance, Recommendation 7 of the Council of Europe Member states asserts that although error is inherent in all fields of human activity, it is however possible to learn from mistakes and to prevent their re-occurrence. Healthcare organisations have the capacity to acknowledge errors, adverse events and 'near misses' and learn from them. According to the Australian Commission on Safety and Quality in Health Care, healthcare organisations should create an environment in which the members are encouraged and able to recognise and report adverse events; prepare through training and education to participate in open disclosure processes (Runciman, 2002). The Recommendation also spells out the main features of such a system, which should be, inter alia, non-punitive in purpose, voluntary, anonymous (Council of Europe, 2006). This will encourage healthcare workers to actively report through the establishment of a reporting environment which is

open, fair and non-punitive. At the same time, it states that the appropriate response to a problem must not exclude individual responsibility, but should focus on improving organizational performance rather than on individual blame (Council of Europe, 2006).

Healthcare organisations should therefore, be active in (i) participating in the review of clinical policies and procedures; (ii) supporting a non-punitive reporting environment; (iii) rewarding staff for reporting unsafe practices; (iv) prompt reporting of potential liability; (v) identifying potential areas of risk/liability; (vi) ensuring all staff are being educated on risk management and compliance issues (Patient Safety and Risk Management Guidelines, 2008). The promotion of the safety of care requires a management commitment and leadership, a collaboration and cooperation of all the professionals who are well trained not only on risk management but also on the hospital and medical practice change. Healthcare organisations in various countries in Europe have recognised the importance of creating awareness on patient safety and risk management in their organisations. Various organisational measures have been taken, particularly at hospital level, to ensure the identified patient safety initiatives are implemented. For example, the Danish Safety Hospital Programme 2010-2013 encourages hospitals to achieve identified goals which include (i) reducing mortality and harms by a certain percentage; (ii) commitment by leadership and staff; (iii) creating a good working environment; and (iv) learning from data. Danish hospitals had also introduced, among the risk management tools, a reporting and learning system for adverse events in order to analyse all information related to these events and to reduce the risks that they could happen again. The data collected are not used to apply penalties measures to the employees but transformed into measures implemented at hospital level in order to guarantee a proper patient involvement and transparency in the complaining system including, the introduction of a digital process that allows the citizens to access their electronic health records (Garel, P. (C.E), 2013).

4. Conclusion

Undeniably, the implementation of risk management and full-disclosure programs has resulted in the decrease in litigated claims as well as improve patient safety standards. This is because a well aligned risk management program can be able to provide the suitable infrastructure by applying continuous monitoring, internal and external audits of varying degrees and reassessments of its tolerance limits for risk events (Cupryk, M, 2011). It can be seen from a research conducted by the Michigan Health Services reported that since the introduction of their disclosure programs, ‘per case payments’ had decreased by 47% and the settlement time had reduced from 20 months to 6 months (Boothman, Blackwell, Campbell Jr., Commiskey, & Anderson, 2009). Although the research was only conducted at hospital level, it can be seen that disclosure and transparency do not only have ethical benefits but also financial & economic benefits as well (Boothman et al., 2009). In the state of Kentucky, after seventeen years of introducing a policy of full disclosure of adverse events, only three cases have gone to trial, with an average settlement of \$16,000 (Joerling, 2009). Thus, it can be seen that globally, the healthcare industries are moving towards embracing a culture of patient safety and transparency in response to adverse events. Disclosure policies and procedures are the first step toward identification and prevention of system failures. Healthcare organisations as well as legislators should strive to accomplish widespread change in the constantly developing healthcare setting.

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The only real mistake is the one from which we learn nothing – John Powell

References

- Agency for Healthcare Research and Quality. (2008). The Patient Safety and Quality Improvement Act of 2005. Retrieved September 5th, 2016 from <http://www.ahrq.gov/qual/psoact.htm>.
- Aspden P, Corrigan J, Wolcott J, et al., editors. Patient safety: achieving a new standard for care. Washington, DC: National Academies Press; 2004.; Clancy CM, Farquhar MB, Sharp BA. Patient safety in nursing practice. *J Nurs Care Qual.* 2005 Jul–Sep;20(3):193–7.
- Australian Commission on Safety and Quality in Health Care. (2008). Open Disclosure Standard: A National Standard for Open Communication in Public and Private Hospitals, Following an Adverse Event in Health Care. Retrieved from <http://www.safetyandquality.gov.au/wp-content/uploads/2012/01/OD-Standard-2008.pdf>
- Bettle, J. (1987). Suing Hospitals Direct: Whose Tort was it Anyhow?. *New Law Journal.* 137 : 573.
- Boothman, R. C., Blackwell, A C., Campbell Jr., D. A, Commiskey, E., & Anderson, S. (2009). A Better Approach to Medical Malpractice Claims? The University of Michigan Experience. *Journal of Health & Life Sciences Law,* 2(2), 125.
- Buchanan, V.M. & Papantonio, L. (2003). When the Hospital has to pay for a doctor's mistakes. *AFTL Women's Caucus Journal.* September issue, Florida.
- Cooper, J.B, Gaba, D.M., Liang, B, Woods, D & Blum, L.N. (2000). The National Patient Safety Foundation Agenda for Research and Development in Patient Safety. *Disclosures Medscape General Medicine.* 2(3).
- Cupryk, M (2011). Standardising Patient Safety Risk Management. *Pharmaceutical Engineering,* March/ April 2011, Vol. 31. No. 2, 1-10.
- Dearmon, V. (2013). Risk Management and Legal Issues, Chapter 15, in *Management and Leadership for Nurse Administrators,* Sixth Edition, edited by Linda Roussel, Jones and Bartlett Publishers.
- Dias R.W.M. & Markesinis, B.S. (1989). *Tort Law.* 2nd ed. Oxford : Clarendon Press.
- Garel, P. (C.E), 2013, Patient safety in practice - How to manage risks to patient safety and quality in European healthcare, *Report On Hope Agora The Hague,* 11-12 June 2013, at p. 5.
- Garvey, M.M. (2011). The Patient Safety and Quality Improvement Act: Tension Between Improving Quality of Care and Acknowledging Responsibility for Error, Chapter 8 in *Principles of Risk Management and Patient Safety,* Edited by Barbara J. Youngberg., Sudbury: Jones & Batlett Learning.
- Finlay, A. J. F., Stewart, C. L., & Parker, M. (2013). Open disclosure: Ethical, Professional and Legal Obligations, and the Way Forward for Regulation. *Medical Journal of Australia,* 198(8), 445–448.
- Office for Civil Rights US Department of Health & Human Services (HSS)., Retrieved from <http://www.hhs.gov/hipaa/for-professionals/patient-safety/statute-and-rule/>.
- Clinton, H.R. & Obama.B. (2006). Making Patient Safety the Centerpiece of Medical liability Reform. *New England Law Journal.* 2205-2208.

- Cohen, J. R. (2002). Legislating Apology: The Pros and Cons. *The University of Cincinnati Law Review*, 70, 819.
- Council of Europe Recommendation (2006) of the Committee of Ministers to member states on management of patient safety and prevention of adverse events in health care. Adopted by Committee of Ministers on 24 May 2006 at the 965th meeting of the Ministers' Deputies. Available from: <https://wcd.coe.int/ViewDoc.jsp?id=1005439>.
- Emslie, S, Knox, K. & Pickstone, M. (2002). Improving Patient Safety: Insights from American, Australian and British Healthcare. Department of Health, National Patient Safety Agency.
- Faure M. (2004). Economic observations concerning optimal prevention and compensation of damage caused by medical malpractice. in: Dute J, Faure M, Koziol H, eds. No-fault compensation in the healthcare sector. Wien. New York: Springer.
- Fox. P., (2007). Medico-legal issues. Rural Collaborative Practice Project. HW01 :1-56. Victoria, New South Wales. <http://www.health.vic.gov.au/ruralhealth/downloads/dla-phillips-fox.pdf>.
- Gilmour, J.M. (2006). Patient Safety, Medical Error and Tort Law: An International Comparison. *Health Policy Research Program*, Canada.
- Guillod, O. (2013). Medical Error Disclosure and Patient Safety: Legal Aspects. *Journal of Public Health Research*. Vol 2:e31: 182-185.
- Japanese Nursing Association. (2014). Nursing and Patient Safety in Japan. Retrieved August 11th from <https://www.nurse.or.jp/jna/english/pdf/safety-01.pdf>
- Joerling, J. (2009). Does Sorry Work? The Power of Full Disclosure in the Healthcare Setting Introduction. Washington University Law. Retrieved from https://law.wustl.edu/Faculty_Profiles/Documents/haley/SeminarPapers/JillJoerling.pdf.
- Kenichi Yoshida et al. (2005). New Investigative Organisation will be enacted for potentially therapeutic deaths in Japan. (Unpublished paper).
- Kohn LT, Corrigan JM, Donaldson MS, eds. (2000). *To Err is human. Building a safer health system*. Washington: National Academy Press.
- Larizgoitia, I., Bouesseau, MC. & Kelley, E. (2013). WHO Efforts to promoting of adverse events and Global Learning. *Journal of Public Health Research*. Vol.2:e29: 168-174.
- McLennan S, Truog R. (2013). Apology laws and open disclosure. *Med J Aust*.198:411-2.
- Meerman, P. (2011). The Role of Governance in Hospital Risk Management and Patient Safety, Chapter 9 in *Principles of Risk Management and Patient Safety*, Edited by Barbara J. Youngberg., Sudbury: Jones & Batlett Learning.
- Napier, J. & Youngberg, B.J. (2011). Risk Management and Patient Safety: The Synergy and the Tension, Chapter 1 in *Principles of Risk Management and Patient Safety*, Edited by Barbara J. Youngberg., Sudbury: Jones & Batlett Learning.
- Otake, Tomoko (2015), Shortcomings identified in new reporting system in hospital deaths, The Japan Times, 1-5, <http://www.japantimes.co.jp/news/2015/10/05/reference/shortcomings-identified-new-reporting-system-hospital-deaths/>.
- Quick, O. (2012). Patient Safety and the problem and potential of law. *Professional Negligence*. 28(2):78-99.
- Reason J. (2000). Human error: models and management. *British Medical Journal*. 320: 768–770.
- Taft, L. (2005). Apology and Medical Mistake: Opportunity or Foil? *Annals of Health Law*, 14, 55-94.
- Runciman WB. (2002). Lessons from the Australian Patient Safety Foundation: setting up a national patient safety surveillance system-is this the right model? *Qual Saf Health Care*. 11:246–251.
- Takasugi, Norihisa & Yokorura, Yoshitake, (2012), Japan Medical Association's Basic Proposal Towards the Establishment of a Medical Accident Investigation System, *JMAJ*, 55(2): 139-141.
- Wilson, J. (2011). Independent Contractor or Employee –Skating on Thin ice. unpublished paper written by partner in legal firm Williams Love & Nicol. <http://www.netlawman.com.au/info/independent-contractor-or-employee-australia.php>

- World Health Organisation (WHO) (2014). Guide for Developing National Patient Safety Policy and Strategic Plan. Patient Safety Unit /Health Systems and Services Cluster, WHO African Region.
- World Health Organisation(WHO) (2008). World Alliance for Patient Safety Summary of the Evidence on Patient Safety: Implications for Research.Geneva, Switzerland.
- Todtlinga, F., Lehner, P., & Kaufmann, A. (2009). Do different types of innovation rely on specific kinds of knowledge interactions? . *Technovation*, 29(1), 59-71.