Liability Framework for Cognitive Computing in Healthcare: Standing at the Crossroad

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https://doi.org/10.24191/ajue.v17i2.13392

Received: 10 March 2021
Accepted: 5 May 2021
Date Published Online: 6 June 2021
Published: 6 June 2021

Abstract: Digitization across the healthcare industry has witnessed the advent of emerging Cognitive Computing (CC) healthcare technologies that improve diagnostic accuracy and efficiency, predict illnesses, automate routine healthcare tasks, and refine processes and care beyond human capabilities. Increased adoption of this technology can be attributed to its ability of processing enormous amounts of data promptly in addressing specific queries and producing customized intelligent recommendations. While CC's transformative technologies offer profound benefits to the healthcare industry, it also carries an unpredictable burden of risk and mistakes with damaging consequences to patients. At this juncture, CC's legal place in healthcare is largely undefined as the applicable liability framework is ambiguous. CC fits into the traditional liability rules in a piecemeal manner; however a single theory of recovery sufficiently addressing the potential liability questions arising from a computer system capable of practicing medicine and possessing the ability of parsing through enormous data for better patient outcomes is absent. The present research therefore sets out to chart the analysis of cases involving emerging medical technologies comparable to CC, in hope of examining ways in which the traditional theories of liability is projected to develop in adapting to this novel contrivance. A doctrinal and case study methods formed an integrated qualitative approach adopted by this research in opting the deployment of emerging medical technologies akin to CC and the bearing it has on the imposition of liability in the United States. CC's potential contributions to healthcare are revolutionary, however its legal repercussions are just as alarming and therefore demands for more discussion in addressing the concerns.

Keywords: Cognitive computing and law, Cognitive computing and legal liability

1. Introduction

For years, science fiction futurists have shared their depictions of intelligent machines and computers capable of learning and operating as their human counterparts. Intelligent machines have since moved beyond the lore of science fiction; today, they are a reality thanks to breakthroughs in Cognitive Computing (CC). Following the programmable and tabulating systems eras, CC represents a huge leap of computational intelligence – systems that learn at scale, reason with purpose and understand natural language, allowing them to interact with humans more naturally (Demirkan et al., 2017). In other words, CC is defined as a system capable of processing vast amounts of data at a scale to address queries

and produces customized intelligent recommendations (Behera et al., 2019). Leading organizations across industries worldwide are already capitalizing its potential to attain significant business value and help solve some of society's greatest challenges. More mundanely, CC is democratizing health knowledge, constituting a new evolution of algorithms and systems in the healthcare system (Behera et al., 2019). For instance, most profound advancement has been produced in cancer diagnosis by CC's applications in healthcare such as IBM Watson and DeepMind (Coccoli & Maresca, 2018). Cognitive intelligence features natural language processing (NLP), hypothesis generation and evaluation, and dynamic learning (Pagel et al., 2018). CC can swiftly and intelligently construe unrelated data in the data management processes and thereupon augment health information sharing for improved patient outcomes. The cognitive healthcare industry signifies a new collaboration between human beings and technology, one that is revolutionary and capable of transforming healthcare on a global scale, gaining significant traction and become more widely adopted in recent years (Daniel et al., 2017). Cognitive systems that comprehend, deduce and learn are aiding people to enrich their knowledge base, better their productivity and strengthen their expertise is projected to produce a market reach of $16.1 billion by 2022, from $2.4 billion in 2017, a 5-year compound annual growth rate (CAGR) of 45.9% (Market for Cognitive Computing, AI in Healthcare to Grow 45.9% by 2022, 2018). The potential for further rapid advances in CC technology has prompted responses from many commentators, including instigating for government coordination of CC development and constraints on CC operation. That itself is indispensable; only in 2018, an array of unexpected adverse consequences related to CC in healthcare has affected the society at many different levels. For instance, bad algorithmic decisions threaten human rights and safety as evidenced by the 'unsafe and incorrect recommendation for cancer treatment produced by IBM's Watson (Ross, 2018).

Being developed in a United States (US) affluent population setting and, on a US-based treatment guideline, IBM's Watson has failed to convince oncologists in other parts of the world to adopt its implementation (Tupasela & Di Nucci, 2020). As it is too focused on the inclinations of a few American doctors, albeit top specialists, at the Memorial Sloan Kettering by whom it has been trained, the project has been dropped altogether in Denmark as recommendations provided match with its local doctors' only in 33 percent of cases (Ross & Swetlitz, 2017). In South Korea, on the other hand, IBM's Watson has been seen to provide recommendations which are not covered by its national insurance system making it impractical to be adopted (Ross & Swetlitz, 2017). Alongside these, in countries with US-trained doctors like in Taiwan, adjustments still have to be made to IBM's Watson's recommendations as patients' requirements in Taiwan are different from their American counterparts, particularly in this case as to the drug dosages required to minimize side effects of treatments (Ross & Swetlitz, 2017). These reports signalled that Watson, once glorified as the future of healthcare, has deviated far from expectations. As CC is gathering momentum and significance in the conventional business dialogue, recognition of its potential implications has produced a new urgency to solve a host of potential ethical, legal, and regulatory challenges. At the very least, CC is expected to pose more prominent legal issues in the near future. Who will be held liable when CC medical application causes an accident? To what extent can physicians delegate the task of diagnosing medical conditions to intelligent scanning systems without revealing themselves to increased liability for malpractice if the system error occurs? Such questions regarding CC-caused harm will arise frequently as smart technologies become mainstream in various industries. The adoption of CC in the healthcare system introduces challenges in the principles underlying the rules of liability for injury caused in the delivery of healthcare. Thus, this research presents the analysis of cases involving emerging medical technologies comparable to CC, with the aim of describing ways in which the traditional theories of liability are becoming susceptible to this technology. The analysis of the case depicts the fundamentals consideration of the liability framework for CC-related harm or injuries.

2. Method

This research employed a qualitative method, combining a doctrinal approach with a case study. The process of conducting the research involved two stages which are data collection and data analysis. Prior to the case-study, the research explored the legal rules and principles pertinent to CC, whereby for this purpose, a doctrinal approach was adopted. Doctrinal research is systematic means of legal reasoning, analysing the legal propositions and instrumentalizations from both primary and secondary

sources (Kharel, 2018). This method has directed the researchers to conduct a library-based research for data collection for the analysis of case law, positioning, organizing and structuring legal propositions through legal reasoning or rational deduction relating to legal liability significant to CC. The library search was assisted by the information sources (OPAC system) for data collection from the primary sources such as case law and related legislations. In addition, the secondary data was analyzed to investigate the relevant theories, concepts and legal commentaries underpinning the study of CC. Hence, a variety of secondary sources was explored including journal articles, reports, cases commentaries and books which were also analyzed in collecting data for a doctrinal analysis.

Data analysis approaches for the doctrinal study adopted by this research include the analogy method and interpretive method. Analogy approach represents the method of exploring into identical cases within undefined situations of whether the parameter of established rules is applicable (Cassell & Bishop, 2019). Hence, through this approach, the research is able to predict the expected legal discussions and the associated principles of law in integrating CC in the healthcare system from the perspective of the adoption of its comparable medical technology predecessors such as the Da Vinci Robotic Surgical System. The qualitative case study approach on the other hand is termed as a comprehensive description of an individual case and its analysis includes the portrayal of the case and the events, not excluding the discovery process of these elements being the process of research itself (Starman, 2013). This method enabled the analysis concerning how legal rules and principles are inferred, employed, or exploited, complied with or disregarded which can influence law-related areas, such as legal and policy making processes in relation to CC. The expected outcome of the multiple case study design adopted by this research is to provide further in-depth exploration, detailed descriptions and generating the hypothesis required for a sound CC governance.

3. Results

The result of this research identifies that the principles of law precisely on the assignment of liability and responsibilities for CC-related incidents are unworkable given the complexities of this system. In deriving to this, the research affirms that the legal issues identified with the adoption of industrial robots and robotic surgical systems will likely gush into the legal analysis of CC in healthcare. Although CC is currently independent of robotic components, jurisprudence related to industrial robots and robotic surgical systems will likely act as a reference point for dealing with liability related to CC. As CC shares many attributes with these technologies, courts will likely integrate jurisprudence based on these systems in analysing and deciding lawsuits involving CC. Analysis on this matter is pivotal to this research for the purpose of distinguishing the most relevant liability framework for CC at the end of the research. In this context, robotics manufacturers face product liability lawsuits raising a number of principles, including strict liability (Mracek v Bryn Mawr Hospital , 2009) (Jones v W + M Automation, Inc , 2000) (Payne v ABB Flexible Automation, 1997) (O'Brien v Intuitive Surgical Inc, 2011), negligent design (Taylor v Intuitive Surgical Inc, 2013) , negligent failure to warn (Silverstrini v Intuitive Surgical Inc, 2012), breach of warranty, and medical malpractice (Michael Balding and Judith Balding v Thomas H Tarter, MD, Siu Physician and Surgeons Inc and St John Hospital , 2013). Using Lexis Advance Malaysia, the research reviewed legal records pertaining lawsuits involving the Da Vinci Robotic Surgical System and industrial robots from 2014-2019 across the United States as the leading enabler of both systems. The distribution of cases is not reflective of the real number of cases as adverse events for both systems are daunted by underreporting. The distribution of the cases is presented in Table 1 and Table 2 below:

Table 1 . Distribution of Lawsuits Involving the Da Vinci Robotic Surgical System

Action	Number of Cases
Strict Liability	322
Negligent Design	31
Failure to Warn	234
Medical Malpractice	94
Breach of Warranty	203

Source: Lexis Advance Malaysia

Table 2. Distribution of Lawsuits Involving Industrial Robots

Action	Number of Cases
Strict Liability	73
Negligent Design	7
Failure to Warn	62
Intentional Torts	106
Breach of Warranty	203

Source: Lexis Advance Malaysia

4. Discussion

This research observes that advanced robots equipped with autonomy, reinforcement learning and self-adaptive learning impede the establishment of standard of care in a negligence claim (O'Sullivan et al., 2019). This situation has been demonstrated in previous cases involving industrial robots and the Da Vinci Robotic Surgical System (O'Sullivan et al., 2019). In principle, under a negligent theory, a plaintiff is deemed to establish the manufacturer's duty of exercising reasonable care in the development and production of the robot system of which he has failed in his capacity, approximately resulting with damage to the plaintiff. In analysing the implications of robots to the negligence principle, it is therefore significant to deliberate on cases involving industrial robots. From the discussion, the analysis of possible legal treatments by the courts applicable to CC can be drawn. In this context, while the International Robotic Federation forecast the global application of industrial robots within the range of 2,000,000 and 3,000,000 units towards the end of 2018 alone, manufacturers are confronted with the increasing numbers of lawsuits brought by employees (Petit, 2017). These lawsuits were mostly brought on the product liability basis pertaining injuries in the workplace owing to the defectiveness of industrial robots (Hubbard, 2014). Claims by employees are often identified to be unsuccessful merely due to the implementation of safety-oriented design in a constrained factory setting (Solaiman, 2017). Revenues for workers are also restricted by the exclusivity of worker's compensation (K&L Gates LLP, 2019). Nevertheless, remedy in excess of the worker's compensation is obtainable if it is established that the employer has instigated intentional torts against the employee by way of eliminating safety controls on the machine (Passinhas, 2017). There are also relevant cases with reference to satisfying the element of duty of care and failure to exercise reasonable care for parties suing under the negligence claim. In this vein, the duty of care owed by the manufacturers refers to their compliance to the universally accepted safety standards for robot systems. It was conceded that the courts exhibited different treatments in regard to compliance to the standards by manufacturers. For instance, in the case of *Jones v. W + M Automation, Inc*, the court recognized the voluntary industry standards conformed by the manufacturer instead of the standards produced by the American National Standards Institute (ANSI), claiming that the ANSI's standards were immaterial to the system at issue (Jones v W + M Automation, Inc , 2000). Accordingly, the defendant was allowed a summary judgment due to the plaintiff's failure to produce evidence of the system's defectiveness. Similarly, in *Payne v*

ABB Flexible Automation, the court delivered that the failure to meet ANSI's standards by the defendant manufacturer was irrelevant as it was inconsequential to the cause of the accident.

The plaintiff's failure to attest that the manufacturer owes a duty of care in equipping the robot with a sensing safety device failed his claim for negligence. Instead, the court upheld the use of such sensing safety devices by the industrial community as being material to the case. Based on these cases, it is reasonable to deduce that the court's preferences of referring to different robot standards vary (Hoffmann & Prause, 2018). In this sense, unless a homogenized standard in developing CC's applications for healthcare is referred to by the courts, examining the duty of care involving CC is predicted to be futile. Apart from the product liability lawsuits, the case of *Michael Balding and Judith Balding v Thomas H. Tarter, M.D.; Siu Physicians and Surgeons, Inc.; And St. John's Hospital* also asserted that medical malpractices are also pursued by the patients injured by the Da Vinci Robotic Surgical System used in the healthcare setting. It was identified in the case of *Josette Taylor v. Intuitive Surgical, Inc* that difficulty is evident in determining the standard of care violated by the attending surgeon resulting in injury to the patient. Intriguing issues relating to the standards of care for robot manufacturers are expected to rise in the near future as opposed to the standard of care for human operators. In arriving at this analysis, reference can be made to *Arnold v. Reuther*, a case concerning a driver hitting a pedestrian while making a left turn. The court, sustaining dismissal of the suit, held that the defendant driver was incapable of having a "last clear chance" to evade the accident in his capacity as a human being. The court deliberated that:

> A human being, no matter how efficient, is not a mechanical robot and does not possess the ability of a radar machine to discover danger before it becomes manifest. Some allowance, however slight, must be made for human frailties and for reaction, and if any allowance whatever is made for the fact that a human being must require a fraction of a second for reaction and then cannot respond with the mechanical speed and accuracy such as is found in modern mechanical devices, it must be realized that there was nothing that Reuther, a human being, could have done to have avoided the unfortunate result which the negligence of Mrs. Arnold brought upon herself (pp. 596).

This decision instigated the prospect of raising the standards of care for manufacturers relating to the collision avoidance mechanism once autonomous system became mainstream, given the accuracy and efficiency of the robot system. In fact, the possibility has already materialized and reflected through the previous cases of medical malpractice involving the Da Vinci Surgical System such as admitting training process for the attending physician as part of the duty of care apart from providing adequate warning to warn the user of the risk (Nik-Ahd et al., 2019). Correspondingly, the same demeanour was exhibited in the case of *Silvestrini v. Intuitive Surgical, Inc* where the plaintiff motioned a suit against the manufacturer alleging that the manufacturer's duty of care is inclusive of providing a training procedure for the hospital staff members operate the surgical robot and that the training was "totally lacking or woefully inept or inadequate". Within this framework, the standards of care for CC is set to encompass both duty to train by the manufacturer and procedures in dealing with vulnerable users, a deviation from the accepted bar of medical practices (Usluogullari et al., 2017). The hypothesis stands that given the prediction that its predecessor technology, the autonomous vehicles, will outperform human drivers' competency as mentioned above, conceivably, an omission of deploying CC in the healthcare setting will be presumed to be negligent. Indeed, in *Mracek v. Bryn Mawr Hosp*, a patient pursued a suit against a hospital for declining to use the Da Vinci Robotic Surgical System and opted for a manual surgery which consequently caused the alleged damage. Additionally, this research identifies as well that establishing the element of causation in a strict liability claim concerning CC used in the healthcare setting is seemingly onerous. The element of causation is predicted to be prejudiced by the convolution of the system, the array of potential users and handlers and its prospective uses.

In this setting, a plaintiff contending a strict liability claim against CC's manufacturers must ascertain, that the defendant retailed a defective and unreasonably dangerous product at the time it left the defendant's care, the product obtained by the plaintiff without significant changes, and the defect was the immediate cause of the plaintiff's injuries. However, the hindrance of proving this element is already prevalent and reflected in previous cases involving robots filed before the court (Laptev, 2019). For instance, in *Mracek v. Bryn Mawr Hosp*, a case involving the malfunctioning of the Da Vinci

Surgical System, the evidence confirming that the robot's malfunction and failure to operate occasioned the injuries resulting from surgery conducted by the doctors was unaccounted for. A similar fact of case surfaced in *O'Brien v. Intuitive Surgical, Inc.,* where the plaintiff claimed that a medical device developed by the manufacturer was defectively designed and impaired while the plaintiff's pancreatectomy and cell transplant surgery took place. The court in rejecting the plaintiff's claim held that the court was unable to find in plaintiff's lengthy recitation any basis for a claim against this defendant notwithstanding the fact that the robotic system's malfunctioning during the surgery was evident. Likewise, in *Michael Balding and Judith Balding v Thomas H. Tarter*, the appellate court upheld the trial court's summary judgment in favor of the defendant manufacturer as the plaintiffs were unsuccessful in producing adequate reasoning verifying that the defendant's actions were the proximate cause of their injury. Additionally, in *Jones v. W + M Automation, Inc*, a case involving a robot crushing a worker in its cell where the court maintained that the plaintiff failed to adduce evidence that a programming defect or inadequate safety features was a contiguous cause of the worker's injuries. In this case, it was recognized that the accident was instigated by the plaintiff's nonchalance, who omitted the safety measures implemented in the workplace, thus breaking the causal link. The landscape of these robotic surgery and industrial robot cases suggest the inconsistency of legal responses when something goes wrong during a procedure involving robots in the healthcare setting.

5. Conclusion

The law can either foster technological innovation or impede it. Current liability regimes are partially applicable to CC systems, depending on the setting it is deployed in. The analysis of this research contributes largely to the existing literature by purporting that a new legal action based on the enterprise liability should be introduced, incorporating the relevant aspects of medical malpractice, products liability, and vicarious liability to spearhead the use of CC in healthcare. This research, however, is only confined to the discussion pertaining the assignment of liabilities and responsibilities in CC-related cases. It is hoped that more research endeavours for CC are underway, covering the area of privacy and data protection risk, licensing, and certification requirements as well as insights from competent institutional body governing software medical devices. CC will be impugned for courts to analyse on first impression; therefore, it is suggested that substantiating a legal construct in place by the medical authorities before CC becomes prevalent in healthcare will likely stimulate the development of this advanced technology.

6. Acknowledgement

This paper is part of the research project entitled "A Framework for the Explainable Artificial Intelligence Model (XAI) in Governing Machine Learning Diagnostic Techniques for Healthcare Applications" funded by Universiti Teknologi MARA (UiTM) (Grant agreement number 600-RMC/GPK 5/3 (265/2020).

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