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Civil Liability Problems Caused by Medical Decision Making Mistakes about Artificial Intelligence

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Abstract. As artificial intelligence is increasingly applied to the health care sector, it has been used for diagnosis and treatment; this results in many problems regarding responsibility. In this paper I argue that the correct classification for an AI making medical decisions is not as a new type of legal entity, but instead as an "extension" of the Medical tool. Based on it, from four aspects of the tort liability elements caused by wrong decision in medicine according to AI -unlawful act, factual damage, causality link-up, who bears a grudge- is analyzed. Furthermore, It explores these 3 types of liability; Product Liability,Medical Negligence Liability and Service Contract Liability.In addition if multiple parties' combined liabilities exist then we have to carry out sort of an Algorithm Audit in order distribute it fairly. To give theory and practice reference in order to improve the legality of AI assisted healthcare.

Keywords: AI-assisted medical decision-making, legal attributes, tort liability

1. Introduction

Currently, artificial intelligence in the field of healthcare is applied to clinical practice in medical diagnosis, treatment, nursing and health care etc. In the wake of artificial intelligence in health care being applied in clinic, all kinds of problems concerning laws will arise. When an AI system comes out with a wrong idea which causes hurt to someone, how do we decide who's responsible? Who should bear it? The developer? The healthcare organization? Or the medical personnel? The answer to this question is still unclear in the current situation. Academic community currently hold different opinions towards legal position for AI in healthcare field, with some believing it can still be regarded as just tool, meanwhile there are already works trying to treat it like a quasi-subject [1]. But such debate mainly takes place on technological aspect or ethic issue and not much study had been done systematically under tort perspective. In this article I attempt to show where AI-aided Medical Decisions fit into Tort Law by asking "What is it? " The author analyzed problems about application regarding the three elements of tort law, which are unlawful act, damage and causation and fault, then built a multi party liability framework. Through introducing some perspective like product liability, negligence liability for doctors, service contract liability and etc., then combines these ideas with the concept of algorithmic auditing, try to put forward some advice on how to regulate the legal supervision in AI-decided medicine and improve such related laws.

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2. The legal nature of AI-assisted medical decision-making

AI is really changing how we do things in health care, making it much better and more accurate. But such technological innovation has produced the complicated problem of legal liability as well. For these problems, we must first clarify what kind of law AI-assisted medical decision making belongs to. To set down some base so we can sort the whole responsibility out, let's analyze how its present-day existence as no more than "an extension" of 'medical tool" and difficulty to function independently as a legitimate person that have.

2.1. As an extension of "medical devices"

At present, AI driven medical decision applications in the medical world do not just improve doctors' ability to diagnose diseases correctly but also take part in surgeries like operation etc which greatly improves medical efficiency. Some people believe that from an appearance perspective, medical AI is just another kind of medical tool, which looks like it has no difference compared with any other surgical tools. Internally speaking, a MedicalAI is simply a machine that can carry out the procedure as programmed in advance. It's a system created and governed by people and will never perform medical duties completely on its own [2].Taking these two angles into consideration, no matter how "intelligent" the artificial intelligence may seem to be on a technical level, it must still be regarded under legal relations as another form of medical tool, an extension of the doctors diagnosis and therapy instead of a separate decision maker. At the heart of a medical decision is the meaningful expression of intent that physicians make from their professional expertise, clinical experience and particulars of the patient. Outputs from AI while on the medical process are just sources of information in decision making, not the decision itself.

Furthermore, it is incapable of engaging in emotional communication with patients in the manner of a human doctor, and may never surpass the understanding that professionals possess regarding diseases and patients' worldviews and values [2]. At the technical level, AI has indeed brought about an intelligent upgrade in medical practice. While AI provides significant assistance in medical decision-making, it merely visualises the human body's structure; the ultimate decision-making authority remains with the doctor. AI simply presents data and converts it into recommendations, whilst the final decision on whether to adopt such recommendations rests with the doctor, exercising their professional discretion.Therefore, within the current legal context, AI-assisted medical decision-making should be positioned as an 'extension of medical tools'.

2.2. The challenge of 'legal subjectivity'

The AI is deeply involved with the medical area; it brings changes of medical diagnosis and treatment method: From doctor taking charge of everything to share rights of managing algorithm or even make independent decision. Though this change greatly improves the efficiency of medical services, it causes problems for laws to regulate. In terms of the main obstacles to clinical use, it is mainly due to the fact that the legal definition is unclear. If it's classified as a "medical device", the technological ability and practical effect of this kind of system are much more than common medical equipment; if classify it as a"virtual doctor",it can't realize the ethical judgment or legal personality. Being neither a person nor an object makes it hard to say if AI in medicine is legal or not. In AI-assisted medical decisions, deep learning model's characteristics are unforecastable and have a biased algorithm, therefore it is very hard to remove the possibility of being wrong. When there is damage done, it is hard to apportion blame legally; AI cannot be blamed for damages that

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occur when harm happens; if medical people just watch over things, they should not be charged with mistakes resulting from complicated autonomous logical errors within the algorithm; though producers may shoulder some product responsibility, the faults arising from changes in algorithms caused by autonomous learning after being deployed are outwith this kind of responsibility.

3. Elements of tort liability for AI medical decision-making errors

AI Medical Decisions come across as Patient Harm and old Tort Liability gets in trouble with it. In this section we will carry out a legal evaluation about wrong acts, facts of harm, causality and subjective fault regarding to errors on AI medical decision making giving some rules for responsibility determination.

3.1. Element of wrongful act

Unlike traditional medicines, when a person uses A.I. medicine makes decisions, it's not them doing the act – their algorithm is taking in some input data and churning out some diagnosis suggestions. Therefore, the element of wrongful act in an AI medical decision is where the process of algorithm operation goes awry and produces an incorrect diagnostic recommendation. If the process does not follow the technical rules and does not perform statutory responsibilities of care, then there is a wrongful act under tort law [3].

Algorithmic mistakes are key parts of this wrongdoings. Deep Learning Models are like having its own personal black box that we do not understand why the model suggest one particular person a treatment over another. The automatic form of learnings gives out some results that no one really knew about. If someone makes a suggestion, doctors don't know what plan is suggested in for them and this cause confusion [4]. Deep inside their minds, Doctors will feel trapped with either accepting AI Medical Decisions which may result into Making Mistakes or Rejection from AI Which may Hurt Some People. It's not that there is no wrongness in the inexplicable itself, but if the algorithm outputs something different from basic medical knowledge or diagnostic standards because of poor design, then it turns into a wrongdoing.

Data bias is also quite serious: AI's decision making is only as good as the data it makes use of. If there are mistakes with medical data employed to train an algorithm, it might produce skewed conclusions on some people. This bias is not some kind of accident happening to technology, it's a system's internal error inside the algorithmic model which can happen over and over again, thus doing harm more than once.

3.2. Element of facts of damage

Facts of damage is the objective fact of tort liability. Liability's most important feature is blameworthiness. Without it, actors will not be held responsible for illegal behavior [5] – in other words: only if there has been some kind of damage that can be compensated for. And hence defining what the damage is, becomes very important.

Personal injury is the most direct and serious kind of harm. The misdiagnosis of AI Medical Decision Making can delay the treatment for patients which they could have received at an ideal time window; Wrong surgical suggestions or surgeries will damage their physical tissues, lose organs and even be dead. Personal injury due to the decision-making mistake of AI compared with traditional medical negligence shows the characteristics of being sudden and irreversible; [6] it has certain significance in tort law.

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Property damage is the economic cost borne by the patient and family because of a wrong diagnosis and treatment. And includes resubmission of examination fees due to wrong diagnosis, medical cost for a bad treatment made in mistake after getting better sometimes include funerals cost Also if people can't work because of AI's medical decision mistakes, we need to add up the money they lost by not working.

Psychological harm is less real than person-injury or property-damage, but it is an outcome of tort consequence which should not be neglected. The psychological suffering endured by patients and their families due to AI misdiagnosis is difficult to quantify, but tort law should not overlook it merely because it is non-physical.

3.3. Element of causation

We need to show a specific tie between the robot's medicine mistakes and someone getting injured for this to happen. AI medical decision making, although indirect but assistive one, causality can't be figured out easily like the previous cases, we need to consider what's within tech permission than what's in law permission.

First we need to figure out what part AI deciding played in making that harm happen. In terms of diagnoses now, what data analysis and conclusions by AI are like doing a blood test or ultrasound for traditional medicine – they just help doctors do disease diagnosis. The final call is always made by the doctor.Human-AI collaboration means that if there's any wrong conclusion from AI, no harm would be done as long as you have medical knowledge to correct it. If doctors accept the wrong machine judgment and make medical decisions according to such judgments, then AI medical decision-making is an important link in causing harm. If doctors judge completely on their own, without considering AI's outputs, then there is no harm caused even if there was an error in AI.

From law, it's whether any intervening factor breaks the chain; [7] doctors can be seen as supercausal agents for example if they acted out in gross negligence - like not catching what is clearly wrong with what the machines say, then you might call those people supercausal and break up this link. On the other hand, when medical professionals are cautious enough yet still cannot discover algorithmic mistakes and they should not suffer from causality interruption. To get it shared with developer as well, so that technical risk doesn't shift fully on Medical Professional.

3.4. Element of fault determination

Determining fault is most basic to assigning torts. Different people have different duties of care; hence, the standards for attributing fault also vary.

Developer fault mainly lies on the product design and warning. And AIs have some short-coming too. It can be judged by reasonableness which algorithms satisfy in the same field of technique's use rather than the difficulty developers put in. Developers might use greatly imbalanced information, not sufficiently testing an idea, or be uninformed about specific matters of systems and still fall short on design oversight if: Warning duty: developers do not bear fault responsibility due to the failure to reasonably warn and enable others to misunderstand about what kind of performance systems have, making some inaccurate judgment according to it.

Medical professional fault is judged by whether they exercised reasonable care [8].Although AI possesses high autonomy, at the current stage it remains an auxiliary tool, and medical professionals should retain ultimate judgment authority and responsibility. If medical professionals blindly trust machine output, failing to verify obviously questionable conclusions, or miss correct diagnoses due to non-use of AI medical decision-making, negligence may be found. If medical professionals make

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reasonable judgments after comprehensive comparison, even if the final erroneous conclusion harms patients, fault should not be readily ascribed.

Medical institution fault primarily manifests as organizational and managerial negligence. As introducers and managers of AI equipment, medical institutions bear duties of care to ensure normal equipment operation, accurate data input, and adequate personnel training. If institutions fail to establish regular equipment maintenance systems, provide systematic operational training to medical personnel, or cause data entry errors through management confusion, leading to AI medical decision-making errors, organizational fault should be established.

4. Subjects of tort liability and imputation pathways for AI medical decision-making errors

Once AI medical decision-making is put into practice, the ambiguity surrounding the definition of liable subjects and the lack of clear procedural rules become practical challenges. This section aims to clarify the legal liability boundaries of various parties and construct a systematic imputation system.

4.1. Product liability pathway

The core of this section, and also the prerequisite for holding manufacturers liable under product liability, is whether AI can be characterized as a product. Although medical AI constitutes pure software, its function lies in assisting or even substituting medical professionals in making professional judgments. Essentially, it functions as medical equipment with diagnostic and therapeutic capabilities and should therefore fall within the scope of product liability law [9]. Furthermore, Article 2, Paragraph 2 of the Product Quality Law defines a product as one that is processed and manufactured for sale; software naturally falls into this category. Thus, it is clear that manufacturers, as the designers, producers, and sellers of products, shall bear corresponding legal liability for medical harm caused by product defects.

Product defects include three categories: manufacturing defects, design defects, and warning defects. Manufacturing defects primarily refer to deviations from the original design during production, creating unreasonable dangers, and are relatively easy to judge [10].Design defects mainly involve the rationality of the internal logic of the AI medical decision-making algorithm model, the quantity and quality of training data, and the rigor of the validation process. Due to the technical characteristics of medical AI, such as autonomy, learning capability, and the "black box" algorithm, patients often find it difficult to prove the existence of a design defect. Therefore, a "reasonable algorithm" standard can be established, meaning that the performance of diagnostic and therapeutic AI should conform to the level expected of a reasonable algorithm; otherwise, an unreasonable danger exists [11].

Regarding warning defects, given the potential risks associated with using AI medical decision-making, manufacturers have a duty to fully inform users about product performance, applicable scope, known risks, and precautions. If a manufacturer fails to provide reasonable warnings, causing medical professionals to form incorrect expectations about the product and subsequently make inappropriate decisions, a warning defect should be found. If the manufacturer has fulfilled its warning duty, but a medical professional, due to their own fault, fails to fulfill the obligation to inform the patient, then a warning defect should not be found. For a medical professional's breach of the duty to inform, the patient can claim liability for damages resulting from the failure to inform against the medical institution based on the special duty of medical personnel to inform under Article 1219 of the Civil Code.

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4.2. Medical negligence liability pathway

Even when AI medical decision-making participates in medical diagnosis, medical institutions and professionals remain the leaders of the diagnostic and treatment activities, and their duty of care is not lessened by AI involvement.

On the contrary, if it is a human-machine collaboration model which requires that the medical staff has more professional judgement on it and the standard of being negligent also should be adjusted according to this mode.

The heart of the medical profession's responsibility is the choice and use of the output results from AI medical decision making. Even though a medical AI has a lot of self-determination, it is still just an assistant—only the doctor will decide on the end treatment. In this case, doctors have to check out every single machine judgment and finally make their decisions for themselves [10]. If a doctor accepts an incorrect advice without any consideration and causes harm to patients, it is considered as lack of reasonable attention, which also belongs to medical negligence. On the contrary, if a medical person makes reasonable judgments according to his knowledge and experience, taking into account the patient's condition and the reliability of the AI recommendation, just because the result is wrong, negligence can not be easily found. In judging for negligence, it must look at the diagnostic process as opposed to the result; acknowledging that medical decisions are complicated and uncertain.

The duty of care for medical institutions mainly comes from the organization itself. Medical institutions are the introducers and administrators of AI medical equipment. They shoulder organizational and managerial duties like guaranteeing that the equipment operates safely and steadily, transmits data accurately, trains enough people etc. An organization could still be held responsible if they fail to do routine maintenance on the machinery and inspections or if they do not train the medical staff properly.

4.3. Service contract liability pathway

Service contract liability occurs when a service provider is unable to meet their end of the agreement. Here's not just about selling equipment, there also has to be a following series of data updating and maintenance to guarantee that the whole AI medical decision making system will run continuously, safely and stably.

Service contract liabilities differ depending on what is agreed to, but there must still be a baseline for the market in order to provide clarity on who has what rights when producing and using AI medical decision making software. Regarding to the output of an intelligent diagnosis give me, stabilize and secure it; solve this problem on time; update the system at any given moment; when there's a failure like that one; offer prompt technical assistance. If a service provider does not live up to these duties which results in wrong data from the AI medical making decisions causing harm to people they are responsible for breaking their deal with you.

But it's hard for people to apply service contract liability. In most cases, no direct contract relationship exists between the patient and the AI service provider; rather, it is usually the medical institution that has a contractual relationship with the AI medical service provider. That is to say, they receive the service indirectly via a medical institution which makes it hard for them to claim any breach of contract directly from the service provider, hence jeopardizing their rights and interests. Faced with this problem, people in charge should set up patients' defense. Author also proposes to draw upon the concept of contracts for the benefit of third parties and give patients direct rights of action against the service providers in certain cases.

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4.4. Mixed liability of multiple parties

AI Medical Decisions involve many people such as the company, hospital, doctor and also some services. In particular in practice there is usually more than one cause of a negative outcome. Therefore, it will be important for this section of allocating liability among such different entities is also a challenge in real life.

The main thing about mixed liability is picking the right form of liability. If it's both the manufacturers' product defect as well as hospitals' organization error causes personal injury of patients,then they will all bear joint & several liabilities. (Wrong) So, this means that the patient can demand all compensation from either of the liable parties and then who gives compensation will go for reimbursement according to what part they caused. If it cannot be determined which of the harm resulting from a product defect or medical fault occurred first, we can also look at rules governing joint dangerous acts: The manufacturer and the hospital will bear responsibility for both [12].

AI's "black box" makes it hard to point out who should be blamed for the liability, [13] so in that case I think we need to add a kind of algorithmic check to let us look back at how an AI medical system has made decisions. The results of the algorithmic audit will be able to take up the role of proof for proving products and causalities and make up for the insufficient evidentiary capacity of the parties.

5. Conclusion

The deep integration of artificial intelligence into medical decision-making, whilst delivering precise diagnosis and treatment and enhancing efficiency, also challenges traditional legal frameworks. As artificial intelligence technology continues to evolve, its legal attributes and liability framework must also be dynamically adapted. Legislators should plan ahead, safeguarding technological innovation whilst balancing fairness and efficiency, clarifying the boundaries of rights and obligations for all parties, and promoting the healthy, orderly and sustainable development of artificial intelligence in healthcare.

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