



The specifics of the element of error in the field of civil liability for medical experiments on the human body

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Abstract:

Medical experimentation on humans is medical interventions that cannot be avoided for the advancement of medical and surgical science. Because of these experiments scientists could reduce a large number of diseases that have cost many human lives for a long time such as syphilis, radical killer tuber culosisd is eases and others, as has become many of them in limbo and the rest of them do not pose a danger to the future of man by the fact that the treatment has now become affordable.

Medical experiments vary depending on the intention, if it is intended to treat the patient and relieve pain, the experimentation is therapeutic, but if it aims to acquire new knowledge without there being a direct personal interest in those who carried out the experiment is a scientific or non-therapeutic experiment.

With regard to civil liability arising from the use of medical experiments on human beings, they have privacy differ from the general rules of medically ability, they vary depending on the nature of the experimenter doctor commitment, if the experimentation has been therapeutic is the obligation doctor commitment of good conduct and it is his responsibility on the basis of the error is assumed, If the experiment is scientific (non-therapeutic) to happen forthwith, after which his responsibility once the damage, even if there is no fault of its part or the so-called (strict liability).

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1-Introduction:

In recent decades, medicine has witnessed significant development and progress, leading some to acknowledge that the advancements in this field over the past fifty years surpass in importance what was achieved in the twenty centuries of medical history.

Medicine continues to introduce new, even astonishing innovations across all its branches and specialties. The most notable aspect of modern medicine, from the public's perspective, is its positivity and effectiveness. This effectiveness has allowed modern medicine to extend beyond its original mission of disease prevention and treatment to also fulfill human desires in non-therapeutic fields, such as artificial reproduction, birth control, cosmetic surgeries, and especially medical experiments (J. Penneau, 1996, p. 1).

However, the increasing effectiveness of modern medicine has not concealed its harmful effects and the risks accompanying its development, which are characteristic of all scientific advancements in various aspects of human life. The progress and development of medical sciences inherently involve a high level of danger and complexity.

Consequently, this medical development and its associated risks have led to a natural increase in the number of medical practices that do not aim to treat patients but instead pose risks to those subjected to them. Among the most significant of these practices are medical experiments, which have given rise to new scientific phenomena such as cloning. These practices have resulted in a noticeable increase in the number of liability claims filed in courts seeking compensation for the resulting damages.

While the accountability of doctors for their mistakes took a long journey before being established as a principle in the early 19th century (Ali, 2004, p. 9), it is no longer in doubt today. Doctors can now be held accountable for mere negligence, similar to many other individuals (Qasim, 2006, p. 3)

Civil liability for medical errors is now established according to general liability rules in civil law.

However, if we examine the nature of the actions performed by doctors during experiments or by researchers, we find they differ from other medical, therapeutic, and surgical practices. This difference has given these practices a clear distinction, both in terms of regulations and in how the judiciary and jurisprudence address this issue. This distinction raises the following question:

- Do medical experiments fall under the general rules of medical liability, or do they have specific rules that require them to be subject to special regulations? And what are these specific rules?

This will be addressed in this paper, where we will discuss in the first section the nature of the commitment of the experimenting doctor and in the second section the specificity of medical errors in the field of medical experiments.

Discussing the specifics of civil liability in the field of medical experiments requires first examining the nature of the commitment of the doctor or medical researcher in this field and then focusing on the element of error in this context. As for the other elements, namely damage and causality, there is no need to discuss them here because they do not differ from other medical practices, whether therapeutic or non-therapeutic.

I. The First Section: The Nature of the Doctor's Commitment in the Field of Medical Experiments

Contractual obligations generally fall into two types: the obligation to achieve a result and the obligation to exert due diligence. In the former, the obligor is deemed in breach if the promised result is not achieved, and there is no need to prove fault on their part because the fault is presumed from the failure to achieve the result. The obligor can only avoid liability if they prove that the failure was due to an external cause beyond their control. In the latter, the obligor is not considered at fault unless it is proven that they did not exert the necessary care in fulfilling their obligation; thus, the failure to achieve the result does not constitute a breach of their obligation (شنوب، 1976، صفحة 9).

As for the nature of the doctor's obligation, jurisprudence and judiciary have generally agreed that the doctor's obligation is primarily an obligation to exert due diligence, and only exceptionally, and in very limited cases, an obligation to achieve a result (علي، 2004، صفحة 405).

However, given that medical experiments differ from ordinary medical practices, does the nature of the doctor's obligation in the field of medical experiments differ from that in ordinary medical practices?

The nature of the doctor's obligation in the field of medical experiments varies depending on the purpose of the experiment. If the purpose is to treat the patient, the doctor's obligation here is to exert due diligence. However, if the purpose is to achieve a scientific benefit with no personal benefit for the subject, the doctor's obligation in this case is to achieve a result. This will be clarified as follows:

If the experiment is therapeutic, its purpose does not differ from that of ordinary medical practices aimed at treating the patient, i.e., achieving a personal benefit for the patient. Since it is not considered harmful if an ordinary doctor fails to cure the patient, whether the failure is complete or partial, because the ordinary doctor in the treatment contract does not promise to cure the patient, but is committed to exerting the diligence of a careful doctor of the same professional level to achieve a cure, it is logical that the doctor's obligation in the field of therapeutic medical experiments is an obligation to exert due diligence.

The patient who voluntarily approaches the doctor, seeking medical intervention, expects this intervention to bring direct benefit to them, whether through ordinary means or experimentation. Assuming that the doctor has informed the patient of the risks and expected outcomes of the requested intervention, and the patient has assessed that the procedure will offer them some advantages, even with known risks of potential failure or certain side effects, it is reasonable under these circumstances for the doctor's obligation to be limited to exerting due diligence, and the doctor is only held liable if they commit a technical error in performing the procedure, just like a doctor conducting a treatment through ordinary intervention (علي، 2004، صفحة 451).

As a result, the doctor is not bound by any specific outcome, whatever it may be. They are not obliged to prevent the disease from worsening, to ensure the patient's condition does not deteriorate, or to prevent the patient from suffering a severe disability or death. The occurrence

of any of these situations does not in itself indicate a breach of the doctor's obligation, as the doctor's commitment is solely to exert due diligence (فرج، 2012، صفحة 417).

This due diligence involves:

- First: The experimenting doctor's commitment to providing care consistent with humanitarian and professional ethics.
- Second: The experimenting doctor's commitment to adhering to established scientific principles.

1: The experimenting doctor's commitment to humanitarian and professional ethics entails applying the required duty according to the ethical and professional traditions, along with maintaining vigilance in fulfilling this duty. This includes accurately assessing the patient's reactions based on their condition during the experimental treatment (Mansour, 1999, p. 106).

Examples of the required diligence from the experimenting doctor include:

- The commitment to examining the patient (Mansour, 1999, p. 106).
- The commitment to acquiring the necessary scientific expertise to perform their duties efficiently and competently (Mansour, 1999, p. 107).
- The commitment to conducting necessary medical examinations before carrying out the medical experiment.

As previously noted, the primary obligation of the doctor is to exert the necessary diligence in curing the patient. This applies to ordinary medical interventions or therapeutic experiments that aim to benefit the patient. However, there are other practices where the results are certain, meaning that the doctor's care is not judged on probability, thus constituting an obligation to achieve a result. These practices are non-therapeutic, such as non-therapeutic medical experiments and organ harvesting from living donors. Our concern here is with non-therapeutic medical experiments. When a doctor undertakes a non-therapeutic experimental procedure, their obligation is to achieve a result. The rationale is that the doctor, in this case, does not intervene to benefit the subject of the experiment but promises to "provide care consistent with established scientific principles" (علي، 2004، صفحة 454).

In these instances, the doctor does not guarantee a cure or any treatment benefits to the subject. They only promise to perform a specific medical procedure without any benefit to the subject.

In therapeutic practices, the patient assumes the risks associated with medical intervention, hoping that the intervention will improve their health. This is not the case with non-therapeutic medical practices, especially scientific experiments, which should not cause harm to the subjects. Those who aim to benefit humanity by undergoing scientific experiments should not have their sacrifices result in harm to them (علي، 2004، صفحة 454).

There are some instances where the commitment to certain practices involves a higher element of certainty than probability, justifying a departure from the general concept of due diligence applicable to medical practices. These practices require the doctor to achieve a specific result, applicable to all medical practices, whether therapeutic or non-therapeutic. The most significant commitments include:

1.1-The experimenting doctor's commitment to obtaining authorization from the competent authority:**

In Algerian law, the legislature requires consulting the National Council for Medical Ethics regarding all medical experiments involving humans. Non-therapeutic experiments require approval from the aforementioned council due to its oversight role (علي، 2004، صفحة 454)

- **The experimenting doctor's commitment to maintaining professional confidentiality:** (Article 4127-4 of the French Public Health Code).

1.2-The experimenting doctor's commitment to obtaining insurance for liability related to the medical experiment:

The third paragraph of Article 7/209 L of the French Public Health Code mandates that every researcher, whether a natural or legal person, must insure their civil liability and the liability of those involved with them, regardless of the nature of the relationship with the participants. This rule is explicitly stated as being of public order: "Les dispositions du présent article sont d'ordre public." This means that insurance is mandatory, and any agreement to the contrary is absolutely void (خالد حمدي، 2000،، صفحة 112)

II: The Specificity of Medical Error in the Field of Medical Experiments

While the principles of justice require that the injured party receive compensation for the damage suffered, obtaining this compensation still—legally—depends, in principle, on the existence of a fault on the part of the responsible party (the experimenting doctor). Therefore, fault is a fundamental element of liability in general and civil liability in particular.

Jurisprudence defines fault in the context of civil law as: "a breach of a prior obligation that could have been known and observed" (R.Savatier, 1951, p. 4).

.Thus, fault is a breach of a prior obligation, which in the context of a contract is a contractual obligation, and outside of it, a legal obligation. This breach would not occur from a vigilant person under the same external circumstances that surrounded the responsible party. (الطبي، 2010)

In this section, we will discuss the error in the field of medical experiments—both therapeutic and non-therapeutic—and address the specifics of this error in the field of medical experiments by examining its assessment and how it is proven in this field. Additionally, we will try to explain how error is assessed in the case of experiments conducted by a scientific research team or a medical team treating the patient by experimenting with a new treatment method.

Proving Fault in the Field of Medical Experiments

The doctor's liability in ordinary medical practices arises only if a fault by the doctor is proven, and the burden of proving this fault falls on the patient. In traditional legal principles, the doctor's fault is a deviation in conduct that would not occur from a vigilant doctor of the same degree and specialization in the same external circumstances (البيه، 1993،، صفحة 161)

However, in the field of medical experiments, due to their risk and novelty, and their difference from ordinary medical practices, the injured party often finds themselves facing a fault that is difficult to prove, making it challenging to pursue a liability claim against the experimenting doctor for compensation for the damage. This has led judges and legislators in many countries, such as the French legislator, to impose stricter liability on experimenting doctors for the harm caused to

patients or subjects. Sometimes, liability is established without fault, as in the case of non-therapeutic experiments, and other times liability is based on presumed fault, through the concept of implied or inferred fault (in the case of therapeutic experiments).

Proving Fault in Therapeutic Experiments

This means that the patient requires medical intervention (therapeutic experiment) and has voluntarily consented to this action despite the numerous potential risks associated with it. The French legislator in paragraph 7 of Article 209 of the French Public Health Code deviated from the principle of requiring proven fault to establish liability in the field of therapeutic experiments.

It established liability based on a presumption of fault but made it a simple presumption that the experimenter, who is obligated to compensate for the harmful results of the research, can refute by proving that the harm did not result from their fault or the fault of anyone involved in conducting the research.(علي، 2004، صفحة 453).

However, the doctor cannot negate this liability by proving the fault of another party or the voluntary withdrawal of the subject from the experiment)Article 4127-4 du code de la santépublique français(. This paragraph of Article 209 demonstrates how the French legislator has tightened civil liability for doctors, making their fault presumed to relieve the patient of the burden of proving this fault, contrary to the general rules that usually place the burden of proof on the claimant. Moreover, the signs of tightening civil liability for the doctor conducting such experiments are evident in depriving them of the opportunity to negate the presumed fault by proving the fault of another party or the fault of the patient due to voluntary withdrawal from the experiment before its completion, all contrary to the general rules of negating civil liability. In the judiciary, this concept has been adopted under the notion of implied or inferred fault as follows:

The Judiciary's Adoption of the Concept of Implied or Inferred Fault

The essence of this concept is to infer the doctor's fault from the mere occurrence of harm, contrary to the general rules of civil liability that require the claimant to provide evidence of the defendant's fault. It necessitates the existence of a causal relationship between the doctor's fault and the harm suffered by the patient. The claim is dismissed if the claimant fails to provide evidence that the harm is directly caused by the doctor's fault.

The French judiciary has resorted to this concept—implied fault—by inferring fault from the mere occurrence of harm, as the harm would not have occurred without a fault from the doctor (قاسم، 2006، صفحة 94). This concept can be applied to therapeutic experiments, considering them a type of medical practice aimed at treating the patient. Simultaneously, due to their difficulty and risk, it is challenging for the patient to provide evidence of a fault on the part of the experimenting doctor.

Therapeutic experiments can also be compared to cosmetic surgeries, as they are considered non-therapeutic practices that provide a benefit to the subject. The Egyptian Court of Cassation adopted the concept of inferred or implied fault in a case concerning the liability of a cosmetic surgeon, ruling that it suffices for the patient to prove the cosmetic surgeon's fault by presenting a fact that suggests negligence, thereby establishing a judicial presumption of the doctor's failure to fulfill their obligation. The burden of proof then shifts to the doctor, who must prove the necessity that justified the grafting procedure and that would negate the description of negligence (ص1075، 2015، صفحة 1075).

The concept of implied or presumed fault is not the only method the judiciary has used to alleviate the burden of proving medical fault. While this concept has been successful in the field of therapeutic experiments, it is insufficient in the field of scientific experiments (non-therapeutic) due to their risk and the impossibility of proving fault in some cases, even through presumptions or inferences, as in the case of implied fault. Therefore, the judiciary, supported by jurisprudence, has resorted to other legal tools with a broader impact in the field of non-therapeutic (scientific) experiments, such as the concept of liability without fault, which will be discussed in the second branch.

Eliminating the Concept of Fault in Non-Therapeutic (Scientific) Experiments

We have understood that non-therapeutic (scientific) experiments are conducted on individuals without providing any direct material or therapeutic benefit to them. Instead, the goal may be to benefit humanity in general or achieve a scientific breakthrough, regardless of the potential risk of such experiments. Therefore, paragraph 7 of Article 209 of the French Public Health Code has determined the liability of the doctor conducting such experiments, considering the doctor's liability in this case as liability without fault. This means that the doctor's civil liability exists even if no fault is proven, which is one of the cases of civil liability not based on fault. The doctor is obligated to compensate for the harm suffered by the injured party, even if no fault is proven on their part, thereby depriving the doctor of the opportunity to negate civil liability by proving the absence of fault or the fault of another party or the injured party due to voluntary withdrawal from the experiment (Art).

This, in itself, constitutes a tightening of the doctor's liability in this type of medical experiment, which does not aim to provide direct benefit to the subject. (هاشم، 2002، صفحة 134).

Legal jurisprudence defines liability without fault as: "Liability that is realized as a result of the harm suffered by the injured party, independently of the presence of proven or presumed fault on the part of the person to whom the action that caused the harm is attributed. (منصور، 1999، صفحة 403)"

Liability without fault is a type of civil liability adopted by the French administrative judiciary regarding the liability of public hospitals in France through a ruling issued by the Lyon Administrative Court in 1990 (Trib. Lyon, 1990), followed by the French civil judiciary in 1999. Consequently, the doctor cannot negate their liability for the harm suffered by the subject under any circumstances (1999).

In Algeria and Egypt, as in the case of the first type of medical experiments (compensation claims against the administration for medical errors made by doctors in public service fall under ordinary courts, similar to other compensation claims, the Egyptian judiciary abandoned the requirement of gross fault for establishing doctors' liability in general, including the administration's liability for errors made by its doctors, after previously requiring it for holding doctors or the public administration accountable for such medical errors (Cass. civ).

The abandonment of the gross fault theory seen in the French, Egyptian, and Algerian judiciaries has beneficial effects. An error made by a public or private doctor, which might be considered slight or minor, can still cause severe damage to the patient. The distinction between gross and slight fault is based on the severity of the error, not the damage suffered by the injured

patient, which is unfair to the latter. Such a judicial approach, recently adopted by the French administrative judiciary and the ordinary judiciary in Algeria and Egypt, could be significantly relevant in this context, especially when a public doctor conducts a non-therapeutic experiment on a person, given the associated risks. However, this might not be sufficient to compensate the injured patient for the damages suffered due to the medical experiment, especially if it is a scientific (non-therapeutic) experiment. Although the judiciary has abandoned the requirement of gross fault, liability here is still based on fault, which is often difficult for the injured patient to prove and frequently fails, even if the fault to be proven need only be slight. Moreover, medical experiments, especially scientific (non-therapeutic) ones, involve significant risks and damages that might not be related to any error made by the public or private doctor, despite being the result of the doctor's experimental intervention on the patient's body. In such cases, the concept of civil liability based on fault, even if slight, is unable to meet the need of these injured patients

Conclusion

Medical experiments on the human body raise numerous questions regarding their legality, regulations, and the responsibilities arising from them.

Medical experiments are among the most dangerous situations a person may face while receiving medical services, as these experiments inherently carry significant risks. Through our study, we concluded that medical experiments on the human body are an unavoidable necessity for verifying the effectiveness of new medications tested on humans. This necessity is dictated by societal needs and has been practiced since ancient times, contributing significantly to the reduction of diseases that claimed countless lives over extended periods. These experiments remain the sole refuge for addressing new diseases and their catastrophic consequences.

Medical experiments have also played a pivotal role in expanding scientific knowledge, advancing medical sciences, instilling hope in patients, and alleviating fears of epidemics and diseases, as was the case in earlier times.

The scientific importance of medical experiments on the human body is undeniable, especially considering the fundamental physiological and biological differences between humans and other organisms. While initial experiments should ideally be conducted on animals, and despite the anatomical similarities between humans and certain animals (e.g., chimpanzees), there are instances where the efficacy of a drug or treatment can only be conclusively determined through human testing to obtain accurate results regarding the substance or treatment being examined.

Through this study, we reached several conclusions:

1. Informed and Voluntary Consent

Consent must be free, informed, and devoid of any defects in will, such as fraud, coercion, or deception. Coercion in this context may manifest as dependency (e.g., patients or students), economic incentives (financial compensation), or other forms of dependency, such as prisoners and individuals with mental illnesses.

2. Authorized Facilities

Experiments may only be conducted in licensed facilities authorized for such activities, following approval from the competent administrative authorities and specialized regulatory bodies established for this purpose.

3. Civil Liability in Medical Experiments

Civil liability arising from medical experiments on the human body exhibits distinct characteristics, particularly concerning the element of fault. Establishing fault in medical experiments differs from general legal principles. In therapeutic experiments, liability is based on presumed fault (a fault presumption) that the experimenting physician cannot escape unless they prove that the damage was unrelated to their error. For scientific experiments, however, the experimenter cannot avoid liability, even in the absence of fault, as liability in this context is based on a strict liability principle. This theory, developed by the French judiciary and adopted by French legislation, deviates from general legal rules that require fault to be proven for liability to arise.

4. Physician's Obligations in Medical Experiments

A physician's obligation in medical experiments differs from that in other medical procedures. In therapeutic experiments, the obligation is to exercise due care. However, in non-therapeutic experiments, the obligation shifts to achieving specific results, as the participant derives no direct benefit from such experiments.

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