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# Compliance with Safety Assurance in Robotic Surgery: An Analytical Study in the Light of Jordanian Medical and Health Liability Law No. (25) of the Year 2018

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**ABSTRACT:** The utilization of surgical robots by medical professionals may potentially result in patient harm within the field of medicine. Consequently, it has become imperative to adopt an approach that offers adequate safeguards for individuals affected by medical errors. As a result, the realm of jurisprudence and legal practice has sought a remedy to achieve this protection, ultimately identifying it within the framework of adhering to safety assurance. From this perspective, the present study examines the notion of committing to safety assurance and its application in the context of robotic surgery, whether or not a formal agreement exists between the patient and the surgeon. Notably, the Jordanian legislature does not explicitly outline the physician's responsibility to ensure patient safety within the Medical and Health Liability Law No. (25) of ) 2018 (The commitment to ensuring safety is not directly associated with the care delivered by the physician during the patient's treatment, as responsibilities are confined to what is feasible within the scope of medical practice. Patient safety encompasses aspects that could be influenced by medical tools and equipment, like surgical robots, which are distinct from medical expertise. These aspects include issues such as sterilization failures or inadequate training for operation and usage. In this context, the physician's duty is to achieve a specific outcome. In conclusion, the commitment to ensuring safety encompasses two primary dimensions. Firstly, the obligation for safety assurance requires the party involved to anticipate and predict potential adverse events. Secondly, it entails taking proactive measures to avert or mitigate the impact of such incidents to the greatest extent possible. This commitment involves various strategies, including comprehensive training in robotic surgery and enhancing patient awareness. In light of these findings, the researcher suggests making it obligatory to provide explicit training for surgeons who operate surgical robots. Additionally, it is recommended that the physician's responsibility to inform the patient be clearly stated within the Medical and Health Liability Law.

**KEYWORDS**: safety assurance commitment, informed consent commitment, robotic surgery, surgical robot, medical artificial intelligence, medical and health liability.

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#### INTRODUCTION AND BACKGROUND

The human right to life is manifested in one of its aspects by the protection of one's body and well-being, recognizing that any encroachment or assault on safety and bodily integrity threatens this right and exposes it to danger. Therefore, legislative texts have ensured its safeguard through various means. However, the technological advancement in the field of medical sciences related to the human body, particularly in the realm of robotic surgeries, has made it possible to inflict greater harm on the right to life.

Thus, it has become imperative to establish a kind of balance between not infringing upon the right to life and accommodating the progress that comes with potential harms from medical procedures, particularly those involving robotic surgeries. This balance is achieved by imposing a legal commitment, which takes the form of a commitment to safety assurance in robotic surgeries.

# **Research Importance**

I. Theoretical Significance:

The theoretical significance of the study is manifested in the following aspects:

- i. Clarifying the nature of commitment to ensuring safety by stating its content and the necessary conditions for its implementation.
- ii. Describing the mechanisms of committing to safety in robotic surgery operations, through training surgeons on surgical robots in operating rooms and informing patients about the actual risks of using robots.

# II. Practical Significance:

Robotic work in operating rooms has become a complement to surgical work rather than a complete replacement. It cannot be claimed that robots replace surgeons, as the skilled and highly professional surgeon is the one controlling the robotic surgery. This means that robots cannot independently perform surgeries, especially given the approaching era of robotics, which compels us to focus on robotics and artificial intelligence research.

# **Research Objectives**

The study's objectives revolve around the following matters:

- III. Statement of the content of the commitment to safety assurance.
- IV. Explanation of the necessary conditions for the commitment to safety assurance to be established.
- V. Clarification of the mechanisms for training surgeons on surgical robots in operating rooms.
- VI. Explanation of the process of patient enlightenment regarding the true risks associated with robotic procedures.

#### **Statement of the Problem**

The study's dilemma arises from the fact that in traditional surgery performed by surgeons without robotic assistance, the responsible individual for any mishap is the surgeon themselves. However, in the case of robot-assisted surgery, the responsible party for the incident is not

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entirely clear, especially since the robot lacks the capacity to make judgments or predictions. As a result, it cannot be held accountable for errors in the same way a human can be.

For this reason, it is necessary to conduct investigative research and study to define the nature of the commitment to safety assurance and its mechanisms. The following questions arise:

VII. What are the conditions for the commitment to safety assurance?

VIII. What are the mechanisms of the commitment to safety assurance?

IX. Is the commitment to safety assurance about exercising care or achieving a specific outcome?

#### METHODS OF THE STUDY

The researcher adopted a descriptive-analytical methodology in their study. In this approach, the researcher will describe and analyze legislative texts, elucidate legal opinions on certain issues, engage in discussions about these opinions, extract relevant judgments, draw practical conclusions, and derive solutions. Additionally, the researcher will refine certain texts within this framework.

# **Conceptual Aspect of the Study**

Undoubtedly, the laws of medical and health liability, as well as the regulations governing the medical profession, its principles, and its regulations in general, contain numerous obligations that fall upon surgeons. In this study, the researcher will specifically focus on the surgeon's commitment to ensuring patient safety. This will be achieved by discussing the nature of the commitment to ensuring safety initially, followed by elucidating the mechanisms through which the commitment to ensuring safety is upheld in robotic surgery operations.

#### The nature of the commitment to ensuring safety

The use of robots in surgery is highly important yet also potentially hazardous. It can lead to countless damages, either due to the surgeon's inability to operate the surgical robot or because of inherent defects within the robot itself. This could result in complications affecting the patient's body and well-being, eventually leading to a series of legal issues between the surgeon and the patient. Consequently, legal, ethical, and judicial interventions are necessary to strike a balance between the imperative of protecting and ensuring the safety of human body parts on one hand, and holding the physician accountable on the other hand, particularly if the physician's negligence or failure to fulfill medical duties is proven. Accordingly, the researcher will elucidate the nature of the commitment to ensuring safety by first clarifying the content of this commitment, and secondly, by presenting the requisite conditions for fulfilling the commitment to safety.

#### The essence of the commitment to ensuring safety

The wisdom behind legislating the commitment to ensuring safety is to alleviate the burden of proof on the aggrieved party. This means that the surgeon who caused harm cannot be exempt from liability unless an external cause is present. Safety signifies a holistic physical and health condition that shields an individual from any harm resulting from the performance of agreed-upon obligations between them and the professional practitioner<sup>(1)</sup>.

Applying this concept to robotic surgery, the essence of safety entails that when a surgeon resorts to surgical robots, they must effectively control the elements that could potentially harm

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the recipient of the treatment. These elements might relate to contractual agreements between the surgeon and the recipient, and the actual control could extend beyond the scope of the contract. For instance, in situations like emergencies that prevent contract formation, during the pre-surgical diagnosis, or in the post-surgical therapeutic phase – all of which could fall outside the contractual framework between the surgeon and the patient.

The notion of committing to ensuring safety revolves around the surgeon's control over the elements causing harm. This involves the surgeon's control over the surgical robot and the objects used to execute the medical contract. This control signifies total influence and commitment to prevent any harm to the patient caused by robotic surgical intervention. Furthermore, the surgeon's responsibility includes supervising and overseeing those under their authority to maintain the patient's safety. All of this aims to fulfill the agreement between the surgeon and the patient, which underlies this commitment. The logical basis of this requirement is that the relationship between the patient and the surgeon is founded on mutual commitments. The medical contract should not impose more on the recipient – the patient in this case – than what the surgeon willingly assumed to treat them. This ensures the patient's safety.

The commitment to ensuring safety comprises two components: first, the debtor's commitment to ensure safety necessitates foreseeing and anticipating harmful incidents. Second, their commitment involves taking action to prevent the occurrence of harm or to minimize its effects at the very least. Transposing this to the surgeon's commitment to ensuring safety in robotic surgery, we observe that the surgeon must anticipate potential harm arising from the surgical robot's actions and take effective measures to prevent its occurrence. If preventing the harm is beyond their control, the surgeon should take measures to mitigate the harm's effects or at least minimize them. This includes ensuring several key aspects, such as the surgeon's qualification to perform the procedure using the surgical robot, the suitability of the device for the procedure, the patient's physical and psychological fitness for the procedure, the appropriateness of the robotic surgical procedure for the patient's condition, anticipation of post-surgery complications, and other scientific and technical considerations essential for a proper robotic surgery that guarantees patient safety.

# The necessary conditions for the commitment to ensuring safety

The foundation of the commitment to ensure safety in contracts lies in the protection of the person's body. There are conditions that must be present for the commitment to ensuring safety to be established in any contract. These conditions are:

# The presence of a danger that threatens the physical safety of one of the contracting parties.

Every individual has the right to maintain their physical safety and prevent any assault on their body. They also have the right, in the event of any attack, to seek compensation for the harm they have suffered due to such an assault. The presence of danger in a contract is the foundation for the establishment and promotion of the commitment to ensuring safety. Even though the human body falls outside the realm of commerce, it is necessary to provide the necessary

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protection for it. Therefore, the existence of danger is a condition for the establishment of this commitment <sup>(2)</sup>. The patient entrusts themselves to the surgeon for the purpose of the latter carrying out what has been agreed upon between them. Consequently, the surgeon is obligated to provide everything necessary to confront these risks or to provide preventive measures against them. The human body and its inviolability are of paramount importance. There is no doubt that all contracts involving safety commitments are based on the idea of protecting the individual's physical safety. In medical contracts, doctors commit to maintaining the patient's bodily integrity, safeguarding them from any harm arising from medications, instruments, materials, and devices they use. The doctor must adhere to scientific and professional principles to protect the patient's safety, refraining from causing the patient harm through the use of these tools and devices, or through non-compliance with recognized medical principles. This harm should not be related to a condition that the patient sought medical attention for. It is inconceivable for a patient to agree to carryailments that weren't present due to the surgeon's failure to provide the necessary care, essential for treating the patient who sought their help <sup>)3(</sup>.

# Delivery of one of the contracting parties to the other

This can be attributed to the inability of one of the contracting parties to maintain their right to bodily safety and their relinquishment of this right to the other contracting party. The patient commits themselves fully to the treating physician, enabling the latter to carry out the treatment as agreed upon, in accordance with the rules and principles of the profession, and the requirements of medical practice. The patient relies entirely on the physician, granting them complete trust, as they believe the surgeon will expend all necessary effort to treat them and take all necessary measures to protect their body. The reason for placing the patient's physical well-being in the hands of the surgeon is due to the disparity in knowledge about treatment methods and approaches between the physician and the patient. Medical knowledge is possessed by the surgeon, equipping them to perform surgical procedures <sup>)4(</sup>, thus, it becomes the responsibility of the surgeon, their assistants, and their team to ensure bodily safety. This is because the patient is unable to control themselves and completely surrenders to the treating physician due to reassurance and trust.

# The party obligated to ensure safety is a professional expert.

It is imperative that the party obligated to ensure safety is a professional expert. Professionalism is defined as: The debtor of the commitment to ensure safety engages in their profession and lives by its principles. Profession is a fundamental aspect of life, and thus, it places the responsibility on its professionals to be knowledgeable about the information related to it, whether theoretical or practical. They should take the necessary care in their conduct <sup>(5)</sup>. Professionalism, as perceived by some, becomes evident through the accumulation of work experience. It leads to an elevation in both technical and professional standards <sup>(6)</sup>, When contracting with a professional, one expects them to exercise extreme care while fulfilling their obligations. In fact, professionalism might be the basis and motive for entering into the contract. Therefore, the diligence required of the professional debtor is that of a person accustomed to similar circumstances. Hence, even a slight error from an unskilled debtor would be considered a serious error from a professional, potentially negating any clause related to liability mitigation or exemption <sup>(7)</sup>

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This condition originates from the trust that the patient places in the surgeon, given their medical knowledge and expertise. We believe that there is no place for this condition except when the commitment is to achieve a specific outcome rather than to exercise care <sup>(8)</sup>.

From the above, it becomes evident that the commitment to ensuring safety in medical practice leads to providing significant assurance for the patient. It strengthens the relationship between the patient and the surgeon, and it instills stronger trust in the patient that they will receive appropriate compensation if an accident occurs that harms them during medical procedures and surgical performance.

# **Mechanisms of Ensuring Safety in Robotic Surgical Procedures**

Human beings consistently prioritize the achievement of their bodily safety against any medical risks. Undoubtedly, this concern grows day by day, especially with the extensive advancement in medical technology and the utilization of robotic surgery in medical procedures. The potential harms resulting from insufficient training in operating and using robots by surgeons, or their newness to the medical field, and other related matters, can be damaging to individuals or even fatal. This technological progress in the field of surgical procedures has necessitated the presence of assurance or mechanisms to maintain patient safety. Examples of such mechanisms include training surgeons in robotic surgery within operating rooms and educating patients about the real risks associated with robots that they might be exposed to.

#### **Training Surgeons on Robotic Surgery in Operating Rooms**

Upon acquiring a surgical robot, surgeons should undergo training on how to operate it. However, this process is not as straightforward as it may seem. Surgeons need to learn the gestures and operational procedures of the robotic system. To elaborate on this, we will delve into the legal basis for training surgeons on robotic surgery, followed by the stages of surgeon training on robotic surgery. Lastly, we will discuss some practical errors stemming from inadequate training of surgeons on robotic surgery.

# The Legal Basis for Training Surgeons on Robotic Surgery

Frequently, the commencement of a surgical procedure using a robot takes a longer period than the natural time required by the robot itself to perform the same operation. There might be a need for an experienced individual who is familiar with operating the robot, working alongside it. Thus, it can be deduced from this context that a significant impediment exists for the implementation and practical presence of robotic surgery, which is the training of the physician and their proficiency in operating and utilizing this surgical robot within the medical practice. The Jordanian legislator, through the Jordan Medical Association Law and its amendments, has emphasized the general training of physicians. However, it has not provided a specific provision for training physicians in operating and conducting procedures using surgical robots. This is evident from the wording in the first clause of paragraph (b) and paragraph (c) of Article 8 of the law, which states the following: [The following conditions must be met in the application for registration and licensing: (b) To have completed, after the date of obtaining the medical degree, a training period of not less than eleven months in a recognized hospital by the competent official authorities for the purpose of training. (c) To pass the examination determined according to a system issued for this purpose].

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Furthermore, the UAE legislator has reinforced this notion in paragraphs (a) and (b) of the first clause of Article 8 of Federal Decree No. (4) of 2016, by mandating that the physician performs their duties based on their scientific specialization, practical experience, degree of accuracy, and its correlation with the significance of the surgical procedure. Through this precision and specialization, greater benefit is achieved for the patient and optimal protection is provided for them. Article (13) of the Jordan Medical Association Law has been dedicated to addressing physicians under training. However, it has not explicitly mentioned the training of surgical physicians in operating and performing robotic surgical procedures. From this perspective, it would have been advisable for the Jordanian legislator to develop the medical legislative framework to keep pace with advancements. This would include the provision of legal texts that specifically address the training of physicians in the field of surgical robotics. Given that robotic surgery has begun to enter the medical arena in the Hashemite Kingdom of Jordan, it becomes essential to accompany this scientific medical progress with advanced legal provisions. This ensures the optimal protection of patients who are subject to robotic surgeries.

Undoubtedly, robotic surgery requires the training of the physician in performing these surgical procedures and how to effectively interact with the robot during the course of these tasks. Properly handling the robot is the fundamental cornerstone for the success of the surgical procedure. The Committee on Legal Affairs of the European Parliament proposed recommendations to the relevant committee on civil law rules regarding robots in Report (No. 17 issued in 2016): "The committee emphasized the importance of training and preparation for physicians and nursing assistants to ensure the highest level of professional competence and patient protection. It underscored the necessity of establishing the minimum criteria that must be met by surgeons to permit their use of surgical robots. Training aids users in understanding the technical prerequisites of this field. It's worth noting the potential for psychological diagnosis of patients using robots, as robots pose a long-term risk of potentially replacing physicians")9(.It becomes evident from the complexity of operating and conducting procedures using robots that education and prior training on robots are among the most crucial aspects that must occur before resorting to performing procedures through them. Understanding performance methods, making decisions, operating, and directing in the mind of the physician are essential prerequisites for surgical procedures. This is necessary to enhance interaction with the robot and ultimately provide protection for the patient.

#### Stages of Surgical Training on the Surgical Robot

The researcher did not find any legal decisions or judicial rulings encompassing the training of surgeons or the stages of training in robotic surgery in Jordan. This can be attributed to the recent emergence of robotic surgery in the medical realm within the kingdom, as well as the substantial cost associated with surgical robots, leading to their limited prevalence. The British company, Genesis Robotics & Motion Technologies <sup>(10)</sup>, has categorized the requisite expertise for surgical proficiency in utilizing robotic surgery systems into four stages:

# 1.Stage One: Introduction to da Vinci Technology

During this stage, the surgeon becomes acquainted with the fundamentals of the system and the robot's capabilities. Additionally, they gain direct insight into certain surgical procedures as they are performed using the robot

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Stage Two: Da Vinci Technology TrainingThis stage involves surgeons committing to completing a training program through online resources. They engage with practical training videos and participate in training at a designated center established by the robot manufacturer. This training may be conducted inperson or electronically based on available resources and circumstances.

Stage Three: Initial Case Series Plan

In this stage, the trainee is required to perform a number of procedures under the guidance and supervision of experienced surgeons who are proficient with the system. The supervisor evaluates the trainee's readiness to independently conduct surgeries using the system. Some believe that training might take several years. They suggest that a trainee surgeon should perform around 200 supervised surgical procedures before conducting a surgery independently using the robot. In certain delicate surgical procedures, a surgeon may require supervised training on approximately 200 to 250 cases before proceeding independently. In essence, the surgeon should be qualified to operate the robot unassisted. The effectiveness of surgical intervention using surgical robots is entirely contingent upon the extent of training the surgeon has undergone in utilizing and operating the robotic surgical system )11(.

Hence, the researcher perceives that proper training on the system is not limited solely to the theoretical aspect, but also encompasses practical experience under the guidance of experienced surgeons proficient with the system. This approach is imperative due to its implications in mitigating robot-associated risks, leading to a reduction in the occurrence of complications stemming from robotic surgery.

# Stage Four: Continuous Development

In this stage, there is an ongoing connection between the company and the trainee. The surgeon maintains continuous awareness of the advancements made to the surgical robot system. This is essential for participating in new training programs prepared for these developments.

**Surgical Errors Resulting from Inadequate Training on the Surgical Robot** Given the absence of legal precedents in Jordan addressing the training of surgical doctors on surgical robots and the errors resulting from inadequate training, we proceed to present some practical examples of negative occurrences reported by the FDA)<sup>12()</sup> due to insufficient training as follows)<sup>13()</sup>

Regarding the emergency tracheal opening cases in 2008, the robotic system displayed an error on its screens. The doctor attempted a reboot, but the error persisted. Consequently, the doctor disabled the endoscope camera and manually manipulated it for a duration of (5-6) hours. As a result, the patient's heart entered the endoscope multiple times, leading to an injury that required manual stitching. Despite the error being evident, the doctor continued to work with the robot as if it were an inert tool. The responsibility in this case falls personally on the surgeon for all damages inflicted upon the patient.

Energy release from the robotic device caused patient burns in 2016. After a patient underwent a hysterectomy procedure, doctors informed her that the surgical robot did not stop operating. This resulted in a significant tissue incision, burning in one of the channels. The surgeon had to perform sutures to prevent leakage. The medical team noted a "considerable"

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distance" between the surgical site and the damaged tissues, implying an error in the robot's guidance and surgery measurements.

# **Patient Informed Consent Regarding the Risks of Robotic Surgery**

in practical reality, non-specialist doctors often perform the initial assessment of patients on many occasions, despite this process primarily falling within the purview of specialized physicians. Ultimately, surgeons bear the responsibility for making surgical decisions, even though non-specialists may carry out the initial evaluation. Surgeons inquire about ensuring the patient's safety before, during, and after the surgical procedure. They are also responsible for ensuring that no erroneous procedures are carried out. Therefore, surgeons shoulder several obligations, notably including the informed consent of the patient regarding the true nature of the robotic system and the associated risks. This achieves a legal balance between the parties involved in the relationship since the patient, as one party, is often unfamiliar with medical procedures, while the other party (the surgeon) is a professional and expert in the field. Therefore, the researcher will proceed to present the concept of patient informed consent regarding the risks of robots. Subsequently, the legal foundation of the physician's obligation to inform the patient about the risks of robots will be clarified. The stages of the physician's obligation to inform the patient about the risks of robots will be outlined. Finally, the outcomes resulting from the physician's compliance with informing the patient about the risks of robots will be addressed.

# **Concept of Patient Informed Consent Regarding the Risks of Robots**

Patient informed consent is defined as the act of a physician truthfully conveying to their patient an understanding of their health condition, enabling the patient to make an informed decision regarding their treatment. This empowers the patient with the option to either accept or decline the proposed medical intervention. Moreover, the patient is made aware of the potential outcomes of the treatment or surgery <sup>114(</sup>. It's important to note that the information provided by one surgeon to the patient doesn't necessarily have to be identical to the information provided by another surgeon. In terms of legislative definition, the Jordanian legislator has not directly defined the physician's obligation to inform the patient. Instead, this obligation is mentioned in the provisions of the Medical and Health Responsibility Law No. (25) of (2018). The law emphasizes its obligation without delving into its specifications and scope. Article 7, paragraph (d) of this law stipulates that: [The service provider is obliged to adhere to the rules, standards, and procedures of practicing the profession according to their degree and field of specialization, documenting that in the service recipient's file. The physician, in particular, is obliged as follows: (d). To inform the service recipient about the available treatment options, except for emergency medical cases that cannot tolerate delay].

Based on the above, we can define the obligation of informed consent as follows: It is the duty of the physician to provide their patient with truthful, comprehensive, and adequate information regarding all aspects of medical treatment throughout its various stages. This equips the patient with full knowledge and awareness, enabling them to make an informed decision about their health condition and obtain an enlightened consent. Therefore, this obligation serves as a legal

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guarantee for safeguarding the patient's health and preserving their will, considering the patient's position as the weaker party in the contractual relationship. The physician's adherence to this obligation contributes to maintaining the trust between them and their patient. In robotic surgery, obtaining consent does not merely rely on obtaining consent based on free will. It goes beyond that by requiring informed and insightful consent. This means that the patient consents with full insight and understanding of all implications of the surgical procedure, including all the risks and potential outcomes. As a result, the physician is obligated to ensure that the patient is well-informed about their medical condition, the seriousness of the upcoming robotic surgical procedure, as well as any available options and alternatives, if applicable.

# The Legal Basis for the Physician's Obligation to Inform the Patient About the Risks of Robots

Due to the novelty of robotic surgery, there has been no specific provision or application of the physician's obligation to inform the patient in the field of robotic surgery. Therefore, the researcher will approach the physician's obligation to inform the patient in its general sense, considering it as a mechanism within the broader commitment to ensuring safety in robotic surgery. There is a divergence in determining the legal basis for this obligation. Some argue that it is grounded in the law as a source of obligation, while others contend that it is based on the medical contract. This is elaborated as follows:

1.The Perspective Advocating that the Legal Basis of the Physician's Obligation to Inform the Patient is the Law: Supporters of this perspective believe that the physician's obligation to inform the patient is a legal duty. It obligates the physician to provide the patient with information about the nature and type of their illness, medical interventions, treatments, potential health outcomes, and the expected risks if the patient declines medical intervention)<sup>15()</sup>.

2. The Perspective Advocating that the Contractual Basis of the Physician's Obligation to Inform the Patient is the Medical Contract: Advocates of this perspective assert that the source of the physician's obligation to inform the patient is the medical treatment contract entered into between the physician and the patient. They argue that the medical treatment contract, which involves parties with differing levels of technical and professional knowledge, compels the physician to inform the patient's will and enable them to make a decision about accepting or refusing medical intervention. Despite acknowledging the pre-contractual nature of the obligation to inform, they consider it to arise from the medical contract of the physician's obligation to inform. The first is liability for harmful action, based on the existence of a prior commitment to establish a medical contract that obligates the physician

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to inform and inform the patient about their condition. Alternatively, based on contractual liability, if the physician fails to fulfill their obligation to inform the patient about matters that are contractually mandated for disclosure.

In Jordanian legislation, this commitment finds its foundation in the Medical and Health Liability Law of the year (2018). The legislator articulated it for the first time in clauses (d, h, w, z) of Article 7 thereof. This is due to the inadequacy of general rules in protecting it. The legislator has obligated physicians to inform their patients before surgical procedures about complications, whether expected or not. The law also emphasized the necessity of obtaining the patient's consent in cases involving assisted reproductive technologies or embryo implantation, as well as any procedure related to female sterilization. Moreover, the legislator prohibited conducting any medical experiments on a patient without their written consent. All of these measures are geared towards safeguarding the patient's interests. On the other hand, some assess this commitment on an ethical basis that falls upon the surgeon, in accordance with the principle of good faith in transactions. Surgeons are deemed as professional practitioners, and this commitment is seen as a general professional obligation (17). And some argue that the source of this commitment is the medical practice itself, as it is a field of expertise that surgeons possess more than patients. Therefore, the responsibility of informing the patient about the medical procedure rests upon the surgeon (18).

# Stages of Physician's Obligation to Inform the Patient about the Risks of Robots

The physician's work begins with diagnosing the patient's illness, which is the most precise stage among all stages of medical practice. The Jordanian legislator emphasized the necessity of using effective means in diagnosis and established the physician's liability if ineffective methods are employed or if their effectiveness testing is incomplete, as stated in paragraph (c) of Article (8) of the Medical and Health Liability Law.

In this stage, the physician is required to provide clear, truthful, and sufficient information to the patient for diagnosing their condition. There is no specific form for informing in the diagnostic stage; it can take any form through which the physician communicates the results they have reached and extracted from examinations and medically used methods. It is not obligatory for this information to be in written form. The Jordanian legislator emphasized in paragraphs (w, z) of Article (7) of the same law the necessity of informing the patient about the nature and seriousness of their illness, or informing their family members in exceptional cases. The physician is also obligated to inform the patient or their family about potential complications that may arise from the diagnosis before initiating treatment. There are situations where the obligation to inform the patient is not mandatory for the physician, as stated in paragraph (w) of Article (7) and paragraph (a) of Article 8 of the same law. These cases include instances of necessity and urgency, patient's waiver of informed consent, loss or impairment of patient's capacity, and based on the patient's psychological

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condition. The Jordanian legislator exempted the physician from informing the patient if it would have a psychological impact on the patient's condition. Instead, the duty of informing falls on the patient's relatives, family members, or companions. The disclosure must be honest and accurate, provided in advance before the intervention of surgical robotics. It should be comprehensive, detailed, understandable, and appropriately tailored to the patient's cultural background and medical condition. In addition to the physician's obligation to inform the patient during the diagnosis stage, the legislator has imposed the same obligation on the physician during the treatment stage, all in the interest of patient protection. Surgeons are required, prior to any robotic surgical procedure, to provide the patient with the information necessary for them to make an informed decision about their condition. This division of the treatment stage can be categorized into two parts: the initiation of medical action and the subsequent stage of presenting the current and anticipated future results, risks, and complications of the medical intervention. We elaborate on these two stages as follows:

# I. Informed Consent in the Case of Initiating Medical Action.

After diagnosing the patient's condition and identifying the illness they are suffering from, the physician's responsibility is to provide informed consent during the treatment phase, which is one of the most critical stages of medical practice. The physician is obliged to present the patient with information about the proposed treatment, its suitability for their condition, the methods involved, and any alternative treatment options. The patient is given the freedom to choose what suits them best; they might opt for robotic surgical treatment or find a better alternative. The researcher believes that the physician should not choose or impose a specific treatment or an alternative on the patient. Instead, the physician should present the advantages and disadvantages of each option, along with the potential consequences. This approach ensures that the patient is well-informed and can make an educated decision. By not imposing a treatment, the patient is given the opportunity to consider other available treatments and take into account their personal circumstances, such as choosing a cost-effective solution that may be less effective for their medical condition.

# II. Informing About the Results, Precautions, Risks, and Complications of Medical Action.

The physician is obligated to inform the patient about the anticipated outcomes of robotic surgery, providing a comprehensive explanation of them. The physician should also refrain from conducting a robotic surgical procedure if its outcomes do not align with the patient's desired medical treatment goals. Additionally, the physician is responsible for clarifying whether the risks and disadvantages of the procedure outweigh its benefits and advantages. And the Jordanian legislator addresses the matter of precautions before commencing medical action, as stated in paragraph (h) of Article (7) of the Medical and Health Liability Law, which reads as follows: '[The service provider is obliged...: to describe the treatment, specify its

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quantities and usage method in writing and clearly, with their name and signature, the date of the prescription, and to notify the recipient of the service or their family members, as appropriate, of the necessity to adhere to the method specified for the treatment]. Therefore, the physician should inform their patient about the required behaviors and precautions that need to be taken into account before commencing robotic surgery. As for informing about the risks of medical action, the Jordanian legislator has addressed it in a general manner. In paragraph (z) of Article (7) of the Medical and Health Liability Law, it states: [Informing the recipient of the service or their family members about the complications that may arise from the diagnosis, medical treatment, or surgical intervention before its implementation, monitoring and taking the initiative to treat them whenever possible].' This underscores the importance of notifying the patient or their family members about potential complications that may arise from the diagnosis, medical treatment, or surgical intervention before it is carried out, and taking steps to address these complications whenever feasible. Hence, building trust between the physician and the patient obliges the physician to fully inform the patient about all aspects of the medical procedure, whether in the diagnosis or treatment stage, in a clear manner that fosters a complete and comprehensive understanding in the patient. This information should be tailored appropriately to the patient's physical and psychological condition, enabling them to express their will freely, based on clear knowledge and informed understanding.

# The Result of the Physician's Obligation to Inform the Patient about the Risks of Robots.

Informed consent is considered the result of the physician's commitment to informing the patient, and it forms the foundation for strengthening the bond between the patient and the surgeon. This bond leads to better care and monitoring for the patient and achieves the desired outcomes of robotic surgery. The surgeon should provide all relevant information about the treatment, therapy, alternatives, medical condition, symptoms, and potential complications in a clear and transparent manner, adhering to scientifically accepted medical principles. The decision of the patient, whether to consent or decline, is left in their hands and is based on informed consent and free will. In this regard, it's worth noting that the American College of Surgeons has outlined the elements that should be included in the discussion between the surgeon and the patient for the purpose of obtaining informed consent. They have specified these elements as follows (19):

- I. The nature of the disease and the natural consequences of the treatment.
- II. The proposed medical procedure, including any associated risks or potential reasons if present.
- III. The most common complications, which must be clarified and explained. The patient should be informed about the potential benefits of the medical procedure and the associated risks

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involved in the proposed surgical operation. Additionally, the potential outcomes in the post-treatment stage should also be addressed.

- IV. Alternative forms of treatment, including non-surgical techniques and methods.
- V. Informing the patient about the diagnosis and care before surgery, educating them about the risks and benefits of the procedure, and explaining the nature of post-operative care.
- VI. Discussing the nature of qualified healthcare providers who will be involved in the surgical procedure and outlining the roles of each in the process.

The surgeon must not exaggerate the deceptive advantages of the proposed robotic surgery. In cases where the patient is a minor or legally incapacitated, parents or legal guardians must participate in the discussion of informed consent and sign the agreement, if consent is given, for the surgical procedure to be conducted. Ultimately, the decision to proceed with the surgery or not rests with the patient, their family, relatives, or caregivers, as necessary and in the best interest of the patient. The patient is at the center of the surgical process and is the most crucial element therein.

#### THE MAIN FINDINGS AND DISCUSSIONS OF THE STUDY

In this study, the researcher presents many important results that he reached, which can be used in future studies in this field.

- I. The commitment to ensuring safety encompasses two aspects: firstly, the obligation of the obligor in ensuring safety necessitates foreseeing and anticipating harmful incidents, and secondly, the obligor's commitment to act in order to prevent harmful incidents or minimize their effects to the lowest extent possible.
- II. When considering the commitment to ensuring safety as the basis for liability regarding things, it is not possible to absolve oneself from liability by exercising due care; as the commitment to ensuring safety is a commitment to achieving a goal, not merely exercising care.
- III. The conditions of the commitment to ensuring safety involve the presence of a danger that threatens the physical safety of one of the contracting parties, the delivery of oneself by one of the contracting parties to the other, and the obligor of ensuring safety being a professional, such as the surgical doctor in this study. The commitment to ensuring safety includes mechanisms in robotic surgery processes, including training surgeons on the surgical robot in operating rooms and informing the patient about the risks of robots from the beginning of the contract until the end of treatment.
- IV. The commitment to informing the patient is considered one of the mechanisms of the commitment to ensuring safety, and it is the foundation of the Law on Medical and Health Liability for the year 2018. The legislator included it for the first time in paragraphs (d, h, w, z) of Article )7( of Law )No. 25 of 2018( due to the limitations of general rules in its protection.

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V. Building trust between the physician and the patient requires the physician to inform the patient about all aspects of medical practice, whether in the diagnostic or treatment phase, in a clear manner that generates a complete and comprehensive will in the patient. This information should be suitable for the patient's health and psychological condition, enabling them to express their will freely, based on clear knowledge and enlightened insight.

# RECOMMENDATIONS

- I. We recommend that the Jordanian legislator introduce a mandatory legal provision for the purpose of training surgeons in operating surgical robots and conducting surgical procedures using robots. This is especially important considering the promising future of this technology.
- II. We recommend that the Jordanian legislator explicitly include the commitment to ensuring safety in Article )7( of Law )No. 25 of 2018( as part of the specific obligations of physicians. This would serve as the foundation upon which the judge can establish the surgeon's liability in robotic surgery cases, providing a significant guarantee for patients to obtain compensation.
- III. We recommend emphasizing in medical conferences the need for a paradigm shift in the approach and mindset of the medical profession. This shift should transition from traditional practices to modern and advanced medical thinking, which involves embracing advanced technological methods, including surgical robots, in medical practice.

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considered one of the most significant and influential entities in the field of robotics and artificial intelligence. For more information, please visit the company's website through the following link: <a href="https://www.genesisrobotics.com">https://www.genesisrobotics.com</a> [11[ Ibrahim, Khaled Mamdouh. (2022) Legal Regulation of Artificial Intelligence. Dar Al-Fikr Al-Jami'i, Egypt, p. 25.

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