



Review Article

Requirements of Consent and Innocence and its Impact on Medical Liability Falling

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ABSTRACT

Background and Aim: The theory of consent and innocence are two major approaches in medical law that, studying them as one of the essential conditions of medical liability, has special significance. This study aimed to analyze the discussion of consent and innocence and its impact on medical liability falling.

Materials and Methods: In the present study, keywords of consent, innocence, doctor, and liability in databases PubMed, Magiran, SID, ISC, and Google Scholar were searched and relevant literature was searched and analyzed.

Ethical Considerations: Principles of ethics and integrity in the search, citation, and literature analysis were taken into consideration.

Findings: In this study, after explaining the concept of patient consent and satisfactory and capacity conditions in its declaration and also the concept of innocence and its terms, it is emphasized that every wise and mature person has the right to decide about the treatment or medical method recommended for him.

Conclusion: Although the legislator explicitly pointed to obtain consent from the patient or his legal representatives in surgeries and medical operations and the existence of such consent in all surgical and medical operations is known as a requirement except in cases of urgent, but because in our legal system to comply with Jurisprudence, the obligation to result in surgeries and medical operations indicates the nature of the commitment of doctors and theoretical basis of medical liability, obtaining patient consent, legitimation of medical procedures and respecting the legitimacy of scientific and technical aspects of the state system are not the complete reasons of the collapse of medical liability and compensation the physician is responsible for a compensation of the damages applied to the patient unless before starting treatment acquittal is received from the patient or his representatives.

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Introduction

The theory of consent is considered as a new vision and important approach in medical law that, its study has particular importance as one of the basic conditions of medical liability. This is important because when the motionless and defenseless body of the patient, even for a short time is placed at the doctor's disposal, the patient's consent is essential. That's why the legislator

explicitly pointed to the consent from the patient or legal representatives in surgeries and medical procedures and the existence of such consents in all surgical and medical operations, except in cases of urgent is required., but since in our legal system to comply with Jurisprudence, the obligation to result in surgeries and medical operations indicates the nature of the commitment of doctors and theoretical

basis of medical liability, obtaining patient consent, legitimation of medical procedures and respecting the legitimacy of scientific and technical aspects of the state system are not the complete reasons of the collapse of medical liability. Because the Shiite jurists whose opinions and fatwas were the basis of Iranian legislator, contrary to the viewpoint of other Sunni schools with the conditions mentioned if the patient is injured still know the physician liable to compensate for damages caused to the patient, and they believe that, the doctor is responsible for a compensation of the damage, even if he does not do any fault unless before starting treatment innocence is received from the patient or his representatives. Therefore, the physician release which is followed by Jurisprudence is a new legal facility and one of the specific components of the regulatory system of Iran, is an issue distinguished of patient's consent and has different effects compared to patient's consent in medical procedures, because the permission of the patient is almost exclusively caused the permissible action of the physician in treatment and hence the patient's permission is not about the result and is just permission for treatment which is conditional and subject to the patient's health and lack of murder, prevent the proof of liability of unwanted and undesirable result that comes from practicing medicine. Thus, for lack of medical liability, in addition to obtaining permission in treatment and lack of abuse or wastage, the presumption of innocence is also necessary studied in detail in the second section of the paper, and in the end, EMS and state exceptions are studied in the third section of the paper as exceptions to the principle of consent and innocence.

Ethical Considerations

The principles of research ethics have been observed as much as possible in studies and citing the primary texts and references to the sources have been taken completely into consideration.

Materials and Methods

In the present study, keywords of consent, innocence, doctor, and liability in databases PubMed, Magiran, SID, ISC, and Google Scholar were searched and relevant pieces of literature were searched and analyzed.

Findings

1. Patient consent

1.1. The concept of consent

Consent means permission, pleasure, surrender, agreement, and delight¹ and patient consent Contentment du malade ou contentment de la victim i.e. the victim's heart's desire and agreement on the issue that, an offensive against the law, against human rights and freedoms, can be done.²

1.2. Investigation of the concept of consent:

1.2.1. Consent in the perspective of jurists:

Islamic jurists know the lack of permission in physicians to perform medical procedures as their responsibility and know him responsible for the compensation or payment of blood money in the cases.

Public jurists: In general it can be said that among the public jurists about permission for treatment there are two views:

1. Some believe the physician liability;
2. Some believe Liability is falling.

Proponents of the first theory argue that:

I. Doctor measures for the body of the patient without his permission are not permissible because the patient's organs and interests are owned by GOD to him and his right, it is forbidden to exceed someone's rights without his permission. As Imam Qrafy has pointed out, when the patient does not consent to a doctor in his treatment, physician practices for treating patients is a reprehensible act.

II. Doctor's measures to treat the patient without his permission or the permission of his representative cause that, his action becomes permissible and because his action is forbidden act is a forbidden act, the doctor must be responsible. Ibn Qudama is of the proponents of this theory. The arguments of those who believe liability falling are the following:

1. Doctor's practice in treating patients is of the examples of the cooperation in virtue that a verse has mentioned that:

«وَتَعَاوَنُوا عَلَى الْبِرِّ وَالتَّقْوَىٰ وَ لَا تَعَاوَنُوا عَلَى الْإِثْمِ وَالْعُدْوَانِ»³ because the ultimate goal of the physician's diligence in the practice of medicine is to help patients and his intention is for Allah and goodness, it turns out that he does not have the intention of aggression to the patient. So the permission of the patient or the patient's lack of consent does not affect the legitimacy and illegitimacy of the case and as a physician does not have the intention of aggression to the patient in getting permission from the patient, he does not have the hostile intention in the absence of permission.

2. Treating the patient and cooperating with him is for the good intention, so when the physician

treats the patients, his intention is for good and God denied liability from the righteous and said in the Quran «مَا عَلَى الْمُحْسِنِينَ مِنْ سَبِيلٍ»⁴ that, means the act of a righteous, benevolent person with good intention may not be punished, because the good work is in itself good and desirable.⁵

Shiite Jurists: From the Shiite viewpoint, the patient's consent is the essential condition for the treatment legitimacy, and the physician in the case of lack of consent of the patient or his family is responsible.⁶ Lack of permission for doctors in conducting medical issues in Shia viewpoint cause medical liability and in this case, physicians are required to pay blood money or compensation for damages.⁷

Therefore according to the Shia jurisprudents' opinions, it can be concluded that on Jurisprudence, it is famous that, physicians guarantee losses applied as a result of the treatment to the patient, however, the necessary precautions are given and treatment has been conducted with patient's consent. About this vote, a consensus has been taken regardless of the claim of Ibn Idris⁸, because Ibn Idris does not know the physician responsible if the physician has awareness and diligence in treatment and believes that principle is on implying innocence and unemployment, and the physician is legally obligated to treat and cure the disease and in this way, he has not been committed to achieve results and improve patient that, he is responsible to have necessary effort to treat normal patients in uncomplicated cases, otherwise, his responsibility or liability prevents medicine and then doctors refuse effective treatment. Additionally, the fact that the physician has good intention in his act according to the principle «ما على المحسنين من سبيل» and thus his liability due to patient's consent and the legitimacy of the act is fell.⁹

1.2.2. Consent from the perspective of lawyers:

Lawyers like jurists have two opinions a group believes that consent does not influence crime of medical procedures and surgeons and emphasize that in principle the consent of the victim will not affect the nature of the criminal act of physician and surgeon, but sometimes the decision of the legislative or judicial procedure considers it as crime factors.¹⁰ Like the case that the surgeon undertakes surgery with the patient's permission and consent and the patient dies during surgery without criminal intent on the patient's death. In such a case, the connivance permission of the legislator to deny wrongful death sentence for surgery, but it should be noted that the surgery should be for treatment, for

example, not for medical experience or purpose contrary to public order or good morals.¹¹ Another group of people believes that the benefit and interest of the community will not allow the consent of the injured one to be the license of injuring others. The best reason to legitimate medical practice is that he has done according to having a doctoral degree.¹²

It seems that the first group theory has more homogeneity among the principles and rules of international criminal law and medical standards. Considering the importance of consent in the validity of the legal acts, the best examples are medical surgery and operations, and Shiite jurists viewpoints that know the patient's consent as the basis of physician's liability and also according to the paragraph C of Article 158 of the Penal Code in 2013, which provides: "Any type of legitimate surgery or medical operation conducted with the permission of the person or parents or guardians or legal representatives, concerning a technical and scientific system of government" is not punishable, it can be said that the lack of consent from the patient or legal representatives in surgical and medical procedures can be considered as one of the bases medical liability as other components of criminal liability. As some lawyers also claimed that, surgery without consent is illegal and in the event of death, have considered the surgeon as the murder without elevated decision.¹³

1.3. Consent condition

With the developments that emerged in ethics and medical law and the great impact these two major disciplines had on the doctor-patient relationship, it is natural, the "consent form" signed by the patient without providing information and awareness required in the field of surgery cannot provide the rights of patients. As a result, the consent with the following conditions is legally valid:

1. Consent must be provided freely (Free Consent), i.e. the patients voluntarily declare their consent to the surgery and medical operation with desire, determination, and willingly. As a result, the consent taken under the influence of coercion, force, fraud, deceit, etc., will not be treated by any legal effect.
2. Consent should be informed (Informed Consent), i.e. the patient has given their informed consent following by a series of specific information about the type of treatment and tests and its aftermath. Therefore the consent derived from ignorance and unawareness combined with incomplete and invalid information will be

necessary. As under Article 190 of the Civil Code, intention and consent of the parties, each of which is basic conditions and elements of each transaction and contract.

3. Consenting person must possess the legal capacity. So the consent of minors, insane and drunk is worthless. Article 190 of the mentioned Act considers the capacity of the parties as another condition of the accuracy of each transaction or contract.

4. Patient consent should be expressed before the surgical and medical operation or contemporaneous with it. Therefore the consent expressed after surgery, will not completely affect the justification of the act and can only be the cause of commutation of the sentence or suspended sentence.

4.1. Capacity in Patient Consent

Legal capacity is met if, following article 211 of the Civil Code the person is adult and sane. Therefore, the "consent" in the legislature in paragraph C of Article 158 of the Penal Code is the personal consent with capacity i.e. maturity, wisdom, and growth. Otherwise, in the case of insane and minors non-matures, who are not yet of legal age, the consent of "parents, guardians or legal representatives" arises.

4.2. Subject of consent and its variants

In all actions and medical procedures that the physician performs to treat and cure disease, it is required to operate in the context of the patient's consent and agreed on care and treatment. So one of the things that may create medical liability is that the doctor exceeds the limits of agreed consent and exit the area of consent subject. Naturally, patient consent is to perform certain medical or surgical treatments that physicians should rely upon or act identically to the mentioned treatment.

On this subject that if during certain surgery the patient is consenting, the doctor finds that the risk for of greater disease threatens the patient that, its surgery is inevitable, for example, if the patient refers to a doctor due to acute abdominal pain and surgeon with a diagnosis of "peritonitis" venture into the surgery and during surgery found "advanced bowel cancer" which call for surgery, can the surgeon attempt the surgery bowel cancer with the prior consent of the patient? And if the doctor does the surgery and there is a risk for the patient whether the surgeon is liable or not?

In this regard between law and medical scholars and practitioners and also between the various legal

schools there is no consensus. Considering the above, to provide a reasonable interpretation of paragraph C of Article 158 of the Penal Code, detailed provisions should be between surgery and urgent actions and practices with no emergency, and also considering given consent.

In the second operation, if there is no emergency for surgery, according to paragraph C of Article 158 of the Penal Code which provides that: "... in urgent cases consent will not be necessary", even if the doctor does not get any consent from the patient, liability is innocent, but if there is no such necessity, according to the provisions of the consent taken, two modes are imaginable:

1. If the doctor before the surgery has taken the patient's consent to do other things other than agreed surgery or an extension to the area over the site of action agreed and the patient consent has the qualifications and conditions of the law, the physician can act under the terms of the consent and in this respect, no liability is on him that, usually it is the current practice for physicians.

2. If the physician does not receive the patient's consent for the second surgery and expansion to the region over the agreed action, he is not allowed to exceed the limits of initial consent and take such action without the consent of the patient.

4.3. Type of consent

1. *Explicit consent*: Explicit or strict consent is the consent whereby the patient allows the doctor to cure with his authority.

2. *Implied consent*: Implied consent is consent that the patient indicates it with the act or talk and common law implies on it, like the case that, a patient does not allow appendicitis has surgery on him and the physician during surgery faces with high fat or observes inflation that if he does not act to perform, in addition to further suffering, the patient must pay high costs for intra-operative, however, the patient consent is insufficient here, but there is no doubt that surgery is to remove excess fat and eliminating swelling to the lives and survival of the patient's health. "Jurists stated on the validity of the permission and liability falling for the physician".¹⁴

In implied consent, the patients would declare their consent with act or speech. "In a common law system silence does not mean consent"¹⁵, but in the Iranian common law system if silence is an expression of the sense of consent will never lead to the goal. For example, if a surgeon after initial tests

examining the patient determines the date of surgery and the patient without expressing his consent explicitly, will be present on the date for the surgery, his behavior seems to imply consent. Patient consent, whether explicit or implied consent, can be in writing or orally. The patient consent signed to perform any medical measures and actions is an example of written consent, however, oral consent in terms of the law is like the written consent has equal value, but the main advantage of the written consent is that in the case of problems and earlier refusal of the disease is provable and the patient cannot be denied his consent. It seems that obtaining oral consent from the patient, especially in the presence of a valid witness has the same value as written consent.

The IPC regarding how and the type of consent of the patient is silent and does not refer to a particular form of consent, however, according to Articles 193 and 194 of the Civil Code that know the expression of parties in any form, including writing and words, gestures and any other actions that are an expression of intention and the pleasure permissible, it seems that the consent required by the legislator in paragraph C of Article 158 of the Penal Code, is not limited to any particular type and form of consent, and includes any type of consent including written, oral, explicit or implied. Some jurists explicitly confirmed this opinion.¹⁶

The question that arises here is that in the event of a dispute between physician and patient according to the existence or absence of consent, how conflict resolution can be achieved? In this case, since on the one hand, consent is the condition of the permissibility of medical practice and medical surgery, on the other hand, a doctor can use the facts and circumstances to prove the consent, even use the silence of the patient after informing him to prove the consent, therefore, prove of the consent is the responsibility of the physician and proof of lack of consent is the responsibility of the patient is a defensible and logical theory and consistent with the Sharia and law.¹⁷

2. Physician innocence

2.1. The concept of innocence

In the legal definition of innocence it has been said that: "Innocence is the release of the committee for a certain person, mainly the personal commitment or other certain person is not employed or engaged from the beginning and he will be free innocence."¹⁸ and, on the legal definitions it is said that, "non-

residual obligation, whether financial or non-financial obligation, such as the right to nemesis".¹⁹ Thus, according to the above definition, it can be said that the innocence of the physician is that, the patient or legal representative before treatment, releases the obligation of the physician for consequences of surgeries and medical operations. In this regard, Article 495 of the Islamic Penal Code of 2013 provides that: "If a doctor caused the loss or injury in treatment, it causes the blood money unless the operation is under medical regulations and technical standards or that the innocence has been obtained before the treatment there is no depreciation".

2.2. Principles of innocence

Among Shiite jurists about the impact of innocence on the physician liability falling, two theories have been proposed:

2.2.1. Shi'a jurists' theory: Shi'a jurists have the opinion that the doctor's innocence causes the liability to fall. First, due to Imam Sadiq (AS) quoted from Imam Ali (AS) "who conducts veterinary medicine, should take innocence and consent from the patient's representative otherwise he is liable".²⁰ Secondly, physician innocence is a conditional contract requirement that according to the rule of «المؤمنون عند شروطهم» the doctor in the contract admitted to the liability falling and according to this condition the patient is committed that in case of an incident during the operation, does not claim damages from the doctor;²¹ thirdly needs and requirements of people to the doctor and doctor refrainment from treating, in the event of a claim for damages, it is necessary that justifies the need to explain the physician's innocence .

In masalek Alafham it is claimed that this idea is from jurists and in Aghnia the claim of consensus is on it.²² And most Shiite clerics, including Saheb Sharaie Eslam²³, Javaher kalam [24] Ayatollah Khoei²⁵, and Imam Khomeini²⁶ are also the proponents of this theory.

2.2.2. Right falling theory before proof: this theory is one of the examples of "إبراء ما لم يجب" and is attributed to Ibn Idris; is based on this issue that, physician innocence before treatment does not know the reason of liability falling, because it would mean the right falling before its proof.²⁷

The main reason for proponents of this theory in the ineffectiveness of innocence is because, it is said that, the innocence of the physician is the right falling before its proof that this is not correct. In addition, these jurists consider the requirement

practice enough for the liberation of legislation and referring the innocence and in addition, it's believed that inertia is too weak, because it is through it, and in this sense the narrative document is weak.²⁸

Although Iranian legislator referred to in Article 145 of the Penal Code, adopted in 2013, knows the doctor responsible for all losses resulting from the treatment, however, he is permitted, but consequently according to Shi'a jurists, under Article 495 the same law says that patient innocence before the treatment destroys this liability on condition of fault. However, the same article notes that: "In the absence of negligence or fault of the doctor in the science and practice for him there is no guarantee, however, he has not obtained the innocence".

2.3. Nature of innocence: the purpose of liability innocence for the physician in law is not both criminal and civil absolute liability, but a rather only financial and civil liability. Because innocence does not prevent crime and punishment, in other words accepting such inclusion is incompatible with public order and good morals. Because eliminating this liability removes a part of social guarantees of the rights of individuals and in that regard, it is contrary to public order, secondly, in cases where the person intentionally causes damage or knowingly does something tantamount, innocence condition cannot reduce his commitment to compensation, because in the regular community no one has the right to be free to damage others under the shelter of the contract obtained by himself [29] So the patient who gives innocent of liability for his physician absolves the physician from the harmful consequences of his action arising from the nature of medical procedures. Therefore, concerning the legal nature of innocence, it must be said that innocence is one of meaning exclude of liability and it shall remain in force until doctors do not have depreciation in their actions.³⁰

Thus the essential condition for removing the criminal liability of doctors considering the mentioned subject depends on the following:

1. Legitimacy of surgery or medical
2. Observe technical and scientific norms of government regulations
3. Patient consent

If any of the above conditions is not fulfilled, it is obvious that the physician cannot be exonerated from criminal liability, because these general principles govern all practices and medical measures and innocence condition is effective and

pervasive as long as the doctor does not have depreciation and error in their actions and it is only in the case that innocence before treatment removes the civil liability of the physician. Due to this fact, Article 158 of the Penal Code of 2013 that knows the patient consent as one of the causes of modal mass and criminal liability and does not have a word of the doctor innocence and Article 495 of the same law that considers the need to obtain innocence from the patient to resolve civil liability of the physician necessary are collected. So the physician's medical liability treating with patient's consent is not absolute and also the innocent condition entirely removes the liability from him.

It should be added that there is the need for legislation on the doctor-patient relationship and the provisions of the commitment of both sides and the responsibilities due to violation of them so that the ethics and practices be able to create appropriate "medical law" in one of the most sensitive human relationships and social issues.

2.4. Terms of innocence

The physician's innocence by the patient as consent is one of the things with the same conditions and rights that the legislator has considered for the consent. Of course, the legislator regarding the innocence based on Clause 2, Article 495 of the Penal Code in 2013, stipulates that: "In cases of absence or unavailability of specific representative, chairman of the Judiciary seeking permission from the Supreme Leader and the relevant prosecutors to grant authority takes action for giving the innocence to the physician." Although this is expressed for innocence according to what was stated in that article "the patient's representative includes to specific representative like parents, and the general representative as leadership." It can also be expressed on the "consent."

3. The exceptions of consent and innocence

State of necessity and urgency and criminal responsibility as a result of that is one of the issues that has long preoccupied lawyers' minds so far. In case of necessity and urgency, two factors forced humans to commit a crime; the first is the factors that human usually does not affect in their emergence and are due to the forces of nature, such as floods, storms, earthquakes, fires, etc., which they are called «force majeure» (Cairo force). The other class includes factors that are relevant to humans and are results of the necessities of self-

defense as the case of necessity that the physician to save the mother is forced to abort her fetus.³¹

Some experts believe, there is a general doctrine of necessity whereby, lack of doing necessary measures to save the life of the patient and recovery, is like neglecting compensable benefits applied to another as a result of committing a crime.³² The doctrine of necessity is based on implicit consent of the patient or based on "emergency hypothesis". Because based on implied consent, it is assumed that just as the patient normally gives consent for salvation from serious physical injury, he wishes to be solved by the physician.³³

The important point is that in the state of necessity and emergencies, the measures taken must be such that any conventional physicians in a similar situation, do the same actions. In other words, the question which must be determined on a state of necessity and urgency is that, is it necessary or not and if so, action is taken at the right time or not? In addition, the patient's specific condition should be added to the above options.

In the idea of Islamic jurists based on the verse 'Allah of "فمن اضطر غير باغ و لاعاد فان الله غفور رحيم"³⁴ and hadith "رفع عن امتي الخطاء والنسيان و... و ما اضطرروا اليه" as well as the legal rule "الضرورات تبيح المحظورات"³⁶ crime in the state of necessary and medical practice has been justified as a result of emergency and paragraph (c) of Article 158 and Article 497 of the Penal Code in 2013 derived from the arguments of Jurisprudence, has known the doctor in case of necessity and urgency that there is no possibility of obtaining consent and innocence, innocent of liability. As well as a legal rule "الضرورات تبيح المحظورات"³⁶ for crime in necessity and medical practice as a result of emergency justified, and paragraph (c) and Article 497 Penal Code Article 158 derived from the arguments of Jurisprudence in 2013 or accordance with it considers the doctor innocent of reliability in case of necessity and urgency that there is no possibility of obtaining consent and innocence of the patient.

The urgency and necessity of exceptions to the principle of consent and innocence of surgical and medical procedures can be examined in two categories:

1. Medical emergencies: Article 1 of the Penal Code Regulations defined the refusal to help injured and elimination of physical risks approved in 1985 of medical emergency as follows: "Medical emergency are cases of medical procedures that can be immediately examined and treated the patient

and if immediate action is not taken there will be the possibility of life-threatening complications, deformity or incurable or irreversible effects" and Article 2 of mentioned regulations has investigated the eleven enumerating instances of medical emergency; but, as understood from paragraph 12 of the article mentioned, the medical emergency instances will not be restricted to the provisions referred to in Article 2 of these Regulations, but these are examples and any other diseases that take fast action needs to prevent risks to life, disability or irreversible trauma is included in medical emergency, and in accordance with paragraph 2 of the Penal Code, refusal to help injured and eliminating physical risks, adopted on 1976" The doctors are required in the case of observing such patients, do what they can, otherwise, he is the offender and is sentenced to imprisonment from six months to three years".

2. Government Exceptions: In addition to emergency and urgent cases, there are some other scenarios that legislators based on reasons such as protecting the social system and health of the individuals, physicians are obliged to take measures against individuals and patients without the need for consent, even if he disagreed doctors should do their remedial action. For example, according to Article 5 of the rule of the way to prevent sexually transmitted and infectious diseases approved in 1941 and amendments in 1968, in those cases where the condition of the patient and the quality of communicable disease is a cause for concern the clinic forces the patient to be treated until resolving the risk of contagion in one of the hospitals and about the treatment of minor or an idiot or insane sexually transmitted diseases, considered as the legal obligations of a parent or legal representative, Article 6 of the Act provides penalties for negligent parent or representatives.

This case is true for compulsory vaccinations, anti-tetanus vaccine before marriage for women, examining the students, travelers, and suppliers of food, pharmaceuticals and cosmetics, and

In this case, also, the same rules on medical emergency are true about liability the current medical liability, with the difference that here the legislator decision will be replaced by the patient's consent and innocence, and consequently, the doctor will not responsible for the damages.

Conclusions

What the doctor commits to doing is the patient's treatment which is directly related to the life that,

this liability is sometimes based on the treatment contract between the physician and patient, and sometimes it is coercive and according to the rule of law. But in any case, whenever the committed physician disobeys the ethical and legal obligations that are considered as the cause of the medical liability falling, and causes damage to be patient, is responsible for all life and property loss and damage, these requirements include:

1. Doctor has scientific and practical expertise;
2. Doctor considers medical, scientific, and expertise standards in doing medical and hygiene procedures;
3. Physician has not committed a fault and medical error in medical affairs;
4. Physician attempted to cure with the patient's informed consent, except in government urgent cases;
5. Physician obtains innocence before beginning treatment for possible damage.

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Conflict of Interest Statement

The author declares that they have no conflicts of interest.

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