

The Anatomy of Informed Consent that Provides Legal Protection for every Party

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Abstract — a doctor-patient relationship relies on two kinds of basic individual rights; right of self-determination and right to healthcare. These basic rights derive from patients' rights to get information about their medical condition. This study discusses the importance of informed consent for any parties engaged in a therapeutic agreement. It resulted in several findings. First, informed consent is useful to provide legal protection for any parties that give medical services. Second, hospitals in Indonesia, particularly in Airlangga Hospital along with its stakeholders may have better understanding on their rights and obligations in respect to providing medical treatment to their patients, as well as making decisions. This study is a normative legal research. As a normative research, it uses statute and case approaches. The data resources to be used here is primary and secondary materials, which collected through library research on legal references that related to this study. This study concluded that informed consent can be defined as the recognition on the principle of equality between doctor and patient; The procedures of providing informed consent begins since the doctor provides information about medical treatment will be given to the patient or another legal relative; and they may approve or, otherwise, refuse the medical treatment.

Keywords — informed consent, therapeutic contract, legal protection.

I. INTRODUCTION

Health is one element of public welfare, and thus, the issue of healthcare is classified into national problem that should be immediately solved, given that people may not optimally do their activities when they suffer from either physical or mental illness. Therefore, having healthcare is one basic right that every individual should have.

The more advanced a nation comes more needs of a good healthcare. Looking into the national constitution of Indonesia, healthcare is the right for every people and it is assured by the constitution. The assurance on healthcare is stressed on Article 28 H subsection (1) of the Constitution of the Republic of Indonesia 1945 (i.e., UUD 1945). This article mentions that every individual has the right to live well both physically and mentally, having a good place to live, and having a good and healthy living environment, as well as the right to get healthcare.

Having a healthy physical body is everyone's dream. To get a healthy body, many ways are used, such as implementing a healthy lifestyle (as a preventive effort) and having medical treatment from appropriate doctors due to illness (as a repressive effort). Recently, medical treatment by

doctors is an option for an individual (i.e., patient) suffering from an illness with a hope that they may get recovery from the illness they suffer through the doctors' treatment [1].

Organizing medical practices is the core of medical treatment and healthcare by doctors, and it should correspond to the standard of medical profession and have very high moral ethics, the authority and competence as experts, certifications, license, and etc. It is consistent to H. J. J Leneen that:

"De formulering van de norma voor de medische professionele standard zou dan kunnen zijn: zorgvuldigd volgens de medische standard handelen als een gemiddelde bekwaam arts van gelijke medische die in redelijke verhouding staan tot het concreet handlingsdoel" [2].

Parties that get engaged in healthcare involve doctors, patients, and hospitals. Those three components are the legal subjects in relation to both medical treatment and legal relationship. The object among those parties is healthcare itself. Doctors and hospitals provide medical treatment, while patients as the recipients of that treatment. The implementation of such relationship among those parties is organized in harmony through several regulations.

In the context of juridical field, a doctor-patient relationship is a kind of written agreement signed by patients as their consent. Otherwise, it indicates a surreptitious agreement.

A legal relationship between doctor and patient derives from a paternalistic relationship which progress involves some stages for the sake of medical treatment and based on Hippocratic and called therapeutic transaction [3].

In relation to doctor-patient relationship, it relies on two kinds of basic rights with individual nature, including the right of self-determination and the right to healthcare. Those rights carry on patients' rights to get information on their medical condition [4].

After having complete and honest information about their medical condition along with particular medical treatment they may get, patients may give their consent to get particular medical treatment from doctor, and it is called informed consent. It has been set under the Regulation of Health Ministry No. 290/MENKES/PER/III/2008 about the Consent for Medical Treatment (later called *Permenkes No. 290 Year 2008*), particularly Article 2 that every medical treatment implemented to patients should be under the

patient's consent. *Permenkes No. 290 Year 2008* is the implementation of Article 45 of Act No. 29 Year 2004 about Medical Practice (later called Act of Medical Practice).

On the other hand, a doctor-hospital relationship is classified into a legal subject as well. Doctor is an individual legal subject (*natuurlijk persoon*) and hospital is a corporation legal subject (*rechtspersoon*). The relationship between those two parties reciprocally carries on rights and obligation. Furthermore, it is classified into two categories, including labor relationship and contractual relationship [5].

In terms of labor relationship, there is employer (i.e., hospital) and employee (i.e., doctors), in which doctors work as employees for the hospital and get paid. When the doctors do some errors or negligence, the responsibility belongs to the hospital. It corresponds to Article 1367 subsection (3) BW that the employer and those recruiting people as employees to represent their affairs should be responsible for any losses due to their employees' negligence.

In terms of contractual relationship, on the other hand, it has neither employer nor employee, but merely engaged based on an agreement. Article 1313 BW defines the term "agreement" as a legal action through which an individual or more get engaged themselves to one another. It makes them have rights and obligation for each to do performance to one another. Another legal consequence is that when one of the parties does negligence which may injure another party, that party should give indemnification. Therefore, when a doctor does negligence toward his patient, he should be responsible.

Patient-hospital relationship is classified into a legal subject as well. The hospital provides medical treatment and the patient act as the recipient of the treatment. The legal relationship between them corresponds to the principles of common law.

Indonesian people still give their expectation and trust to hospitals for better medical treatment. Therefore, the presence of hospitals plays an important role as the only medical institution that provides medication for patients in concrete manner. As a medical body that directly provide medical treatment to public, hospitals should not only do their functions providing medical treatment or therapeutic conduct to patients, but also giving a very serious concern on patients' rights to decide particular medical treatment they consent for [6].

In fact, it is often found that many hospitals in Indonesia do malpractices on their medical treatment, since *informed consent* is not well implemented. For instance, a case of constriction of blood vessels on Zacky Arya Pratama (8 years old) in Local Hospital Sultan Imanuddin Pangkalan Bun in West Kotawaringin Regency, Central Kalimantan, and a case of wrong blood transfusion in Arun Hospital, Lhosemawe Regency of The Autonomous Region of Aceh Province, to a patient named Badriah.

Therefore, it should be identified who will be responsible to any incident that may cause death or physical defect on a patient due to particular medical treatment, and where it finally talk about *informed consent*. The issue of non-well implemented *informed consent* as an integral part of medical treatment by hospitals in Indonesia may violate patients' rights and other stakeholders.

Research Problem

In accordance to the introduction, the research problems of this study are as follow.

1. Informed consent in providing legal protection for any parties.
2. The procedures of providing informed consent to patients in hospitals.

II. RESEARCH METHOD

This study is a normative legal research (doctrinally legal research). As a normative research, it uses statute and case approaches, therefore it didn't use any qualitative, quantitative, or mixed instrument for data collection. The data resources to be used here is primary and secondary materials which data collection is through library research on legal references that relate to this study. Library research is an instrument of collecting legal materials through written ones using *content analysis* [7].

This study uses deductive logics as data analysis technique. It process the legal materials in deductive way by explaining general things to take more specific conclusion.

III. RESULT AND DISCUSSION

A. *Informed consent in providing legal protection for any parties*

In relation to the doctor-patient relationship, the earliest model used in this relationship is paternalistic or paternal model [8]. In this models, the doctor ensures that patients receive the interventions that best promote their health and well-being, by using their skills to determine the patient's medical condition and their stage in the disease process and to identify the medical test and treatment most likely to restore patient's health condition. This model widely knowns to justified during the emergencies when the time to take the informed consent might irreversibly harm the patient, however, to this present this model rarely adopted by the doctor in doctor-patient interaction as an ideal for their interaction routine. As the development of the type of doctor-patient relationship, the current model that commonly used is deliberative model utilizing the informed consent by the patient or any parties on behalf of the patient regarding the medical treatment given to the patient [9].

The definition of *informed consent* is actually a kind of communication relationship between doctor and patient in a hospital in relation to providing information by doctor to patients as their recovery effort. This definition is also lies a therapeutic relationship between doctor and patient into a framework of doctor-patient relationship and the emphasis on medical profession in conducting their medical treatment toward their patients.

Informed consent reveals based on a doctor-patient relationship in a therapeutic agreement. Each of the contracting parties has their own rights and obligation to fulfill. It indicates that doctors have an obligation to do diagnosis and provide the most appropriate medical treatment under their consideration, and patients along with their family have rights to decide which medical treatment to be implemented on their body [10].

A contractually legal relationship between doctor and patient does not begin when the patient come to see the doctor as everyone expects, otherwise, it begins since the doctor is available to give medical treatment through either oral or

implied statement by showing his attitude and action implying his availability, such as organizing a registration, providing registration number, as well as medical record and etc. In other word, a therapeutic relationship needs the doctor's availability, and it is consistent to the principle of consent and the freedom of making contract [11].

In relation to the dynamic of social life in societal community, the pattern of paternalistic relationship between doctor and patient shifts into partnership relationship or *patient-centered care*. It is worthy noted that patients were often considered to be too ignorant and incapable to make decisions on their own behalf [12]. Thus, doctor felt comfortable in making decisions on behalf of their patients and informing patients about the uncertainties and limitations of medical interventions served only to undermine the faith that was so essential in therapeutic success. As that model tends to widened the gap between the doctor and patients, patient-centered care came to replaced the prior model. This model centered on the partnership between doctor and patients in decision-making process related to the medical treatment given to the patient by advocate not only the doctor's technical capabilities, but also the communication between doctor and patients [13].

Basically, partnership relationship is a patient-oriented model. Patients have an absolute autonomy over themselves. They have rights to make decision on accepting any medical treatment they will get. They are free to either accept or refuse any medical treatment the doctor offers, and thus, the doctor has an obligation to provide complete information on medical diagnosis, the stage of illness, and any possible therapeutic treatment along with its risks, as well as the prognosis of illness to the patients. Through doctor-patient partnership pattern on healthcare, it may bring a synergy on doctor-patient relationship.

Furthermore, *informed consent* consists of several parts [14]. First, *Implied Constructive Consent*; an action that public has already seen and understood in prior to its implementation, and thus it does not need to be explicitly written. Patients give this consent implicitly without any further explicit statement. The doctor may see this signal from the patient's attitude and behavior. For instance, the doctor gives an injection to his patient or takes blood sample for lab test. Second, *Implied Emergency Consent*; on which the patient is in emergency, and thus the doctor needs to take immediate medical treatment to save the patient's life, while the patient and family are not available to make decision at that moment, and thus, the doctor is allowed to give the best medical treatment. Some conditions that seem possible to have this consent is when the patient is having out of breath, stop breathing, or the heart stops beating. Third, *Expressed Consent* (either oral/written with specific condition). It is necessary for a condition on which the treatment to be provided is more than just general check-up and examination procedures. In such condition (e.g., lifting out the patient's nails, or conducting surgery) the patient should be at first informed what kind of treatment they will have in order to prevent any misunderstanding.

Toward the discussion about healthcare, it is not apart from naturally human rights. That is, health is one of primary needs for human, and it is tightly related to their existence. Indeed, the theory of economy claims that human's primary

needs involve three aspects including food, clothes, and housing. However, health is another one. Without being healthy, people may not do their activities. Thus, in very broad meaning, health is considered as a human right which deals with social rights [15]. Following John Locke in his book entitled *Second Treaties of Government*; humans carry on principles as their innate rights within [16]. This book argues that the right of health is a basic right and may not be interrupted by anyone, including the state. This John Locke's argument is consistent towards Bill of Rights in Britain which was very influential for civilized society.

Therefore, the classification of human rights actually consists of two parts. First, it refers to rights that directly derives from humane aspects in an eternally universal life and be tightly related to their dignity. Second, it refers to non-basic rights that derives from interpersonal aspects which is likely to be different and classified based on particular place, time, and condition.

The principle of *informed consent* doctrine is that patients have an autonomy right to decide what they want for medication [17]. In short, patients have the right to either accept or refuse any medication, and the right to get information from the doctor before they give their consent on any medical treatment they may get. It is related to human rights. Therefore, *informed consent* is associated to two human rights, as follow.

1) *The right to self determination*

After the doctor provided information that dealt with patient's medical condition, the patient may give his/her consent. This consent is a manifestation of the right to self-determination. Based on the Regulation of Health Ministry of the Republic of Indonesia No. 585 Year 1989, the parties that give the consent are: a) legal-age patients in conscious condition and mentally good; b) the parents or relatives of under-age patient; c) the relative or curator of legal-age patient who is under amnesty; d) the parents or relative or curator of legal-age patient with mental illness; and e) the closest relatives of under-age patient and orphans, or the family is unavailable to give consent.

Patients do not have to agree with any medical treatment their doctor offers, as they have the right to refuse. However, the refusal is often due to particular factors such as their incompetence to pay the bill or the patients are afraid of the medical treatment they are going to have. Responding to such refusal, doctors have no right to force their patient. In this case, they should appreciate the patient's right to self-determination.

2) *The Right of Information*

In this case, the one who is responsible to provide information to the patients about their medical condition along with its treatment is doctors. It means that doctors should provide their patients' medical information, whether requested or not. The Regulation of Health Ministry No. 290/MENKES/PER/III/2008 about the Informed Consent, especially in Article 1 subsection (a) that *informed consent* for medical treatment is a consent the patient or the closest family of the patient gives after having a complete information about particular medical/dental treatment the patient will have. And,

looking into Article 1 subsection (b), medical treatment involves preventive, diagnostic, therapeutic, and rehabilitative treatment by doctor or dentist to patients. The information about medical treatment is at least involves Article 7 subsection (3) that is 1. Diagnosis and the procedures of medical treatment; 2. The objective of medical treatment to be conducted; 3. Another alternative treatment along with its risks; 4. Any possible risks and complications; 5. The prognosis of the treatment; and 6. Cost estimation.

The explanation of that Article should be informed in detail and easy to understand. Additionally, patients should have chances to ask in order to appreciate their autonomy as a legal subject, which J. Guwandi classifies into [18]: 1. the risks of the treatment; 2. any possible side effects; 3. another alternative treatment (if any); and 4. Another possibility that may happen if the treatment is not implemented.

Toward *informed consent*, it is defined as recognition of equality between patient's and doctor's rights. To reach harmony in a doctor-patient relationship, it needs an equal communication between both parties. Hence, both doctor and patient have equal rights to express their intention and expectation. The relationship between doctor and patient is not a kind of "employer-employee" relationship. No superior and inferior between them. Therefore, doctors may not treat patients as the object of their job. This equal relationship significantly affects the process of information exchange between doctors and patients. Doctors are expected to give chances to their patients to express and accept information clearly and conveniently in order to have an effective and efficient communication. In addition to shifting doctors' paradigms, it needs to organize socialization and education to create smart patients. It is expected that, later, the position of patients will be equal to doctors'. According to Indonesia Medication Counsel, there are some types of doctors for medical treatment, especially those that bring effect on the communication between doctor and patient, however they emphasize on type of doctor is willing to ask and provide additional information that may fit their patients' health [19].

Informed consent is defined as recognition to the principle of equality between doctor and patient. This recognition is not solely on legal relationship with private nature (i.e., individual), but also reaching a broader context that emphasizes the government's participation in the implementation of health programs to reach higher level of health. Hence, *informed consent* does not only put the responsibility of medical professionalism in individual manner, but also in relation to the consistency of government's responsibility that corresponds to the constitutional mandate which is attempting to reach the assurance of equality in healthcare as the basic right of every people of Indonesia.

B. *The Procedures of Providing Informed Consent toward Patients in Hospital*

Informed consent is basically a process of sustainable communication [20]. In addition to communication, informed consent seems abstract and ideological. In ethical context, informed consent is the attempt to implicitly ask the

patients' consent, and with their autonomy, the patients accept that the aim of medical treatment conducted to them is their own choice, not under other's pressure. In this case, *informed consent* shifts the paradigm of making decision from doctor-oriented to patient-oriented. It requires a disclosure, and thus, doctors should get very clear information by, for instance, tracking the medical record of patient's family.

A doctor-patient relationship is never apart from the process of transparent communication. Technically, however, it is not as expected due to distortion on language and culture. In this case, patients are passive ones with no good and systematic communication. Therefore, doctors may feel difficult to give appropriate answers as expected. When this happens, the doctors will ask for help from the patients' family. However, it seems ineffective since, in particular culture, it is still taboo to share the history and medical condition of family member transparently to others (including doctors), and it is assumed as an intervention from private domain.

These facts show that not all patients are available to give information about their family and relatives. Understanding and realizing this problem, misunderstanding between doctor and patient can be avoided, and the final decision of this communication always relies on the ethics of medication. On the other hand, there is another objection against *informed consent*. Onora O'Neill, from Newnham College in Britain, argues that *informed consent* is only for patients who are physiologically and psychologically mature [21]. Toward the public policy in health sector, O'Neill argues that *informed consent* may inhibit the legislation for health sector since the policy should be publicly applied rather than personal. Whereas, *informed consent* should actually be personally applied.

Essentially, the difference between doctor-patient relationship and others is in the juridical nature. This relationship is a kind of agreement (i.e., *verbinten*) which characteristics involve (1) *consensual or agreement*, that both parties (doctor and patient) agree to one another on medical treatment, and (2) *fiduciary*; this relationship is trust-based to one another [22], and thus, *informed consent* is classified into agreement.

Due to this categorization, *informed consent* leads to organizing a contract. An agreement is considered legal if it satisfies the terms and condition set under regulation, as mentioned in Article 1320 BW, otherwise, it may not be recognized by law although all the contracting parties has dealt with that. Based on the provision of Article 1320 BW, the terms that make an agreement legal involve (1) consent among parties, (2) proficiency, (3) particular issue, and (4) rightful cause.

Responding to this unequal condition between doctor and patient, it may take the principle of proportionality into account as the basic position between both parties. According to Agus Yudha Hernoko, the principle of proportionality in the process of organizing and implementing commercial business contracts has several functions. First, in the process of pre-contract, the principle of proportionality gives chances for negotiation among parties to do fair exchange on their rights and obligation. Therefore, we need to avoid any negotiation with no good

faith. Second, in the process of organizing a contract, the principle of proportionality ensures that the equality of rights and freedom to define/ set the proportion of rights and obligations among parties can be fairly implemented. Third, in the implementation of contract, the principle of proportionality ensures the realization of exchanging rights and obligations based on the consensus within. Fourth, in case of a contract failure, it should be seen proportionally whether the failure is fundamental (i.e., fundamental breach) that disturbs the implementation of contract in most part or merely trivial one (i.e., minor important). Therefore, a test on the principle of proportionality is a determinant factor to define the proposition of contract failure. Hence, it should not be misused by one of the contracting parties to take benefits from such condition (i.e., the failure of the contract) for the sake of their personal interest which may violate another party. Fifth, in case of contract dispute, the principle of proportionality is useful to set the proportion of fault as the attempt to solve the dispute based on the principle.

The concept of proportionality as discussed above, the pattern of position between doctor and patient is proportional. Patients as ones that need doctors' skills and expertise. This proportional position between doctor and patient corrects the contractual relationship between them, as it should be equal.

The content of a therapeutic agreement contains the statement of consent from patients or their family with full of consciousness and without any coercion toward particular medical treatment on them. The statement clarifies that the patient has been informed by the doctor about the characteristics, goal, risks, and the importance of a medical treatment the doctor will conduct to the patient. In addition, the pertinent parties (i.e., patient/the family, doctor, and hospital) should also sign the consent. It is to get the legality of the agreement for conducting medical treatment toward the patient, clarifying that both parties; doctor and patient, agree to what is contained in the consent.

The fixed procedures of implementing *informed consent* in hospitals contain several conditions [23].

First, in prior to the process of consent, the doctor should provide information to the patient/the family/the legal relatives that represent the patient about a set of medical treatment he is going to conduct, including diagnosis, the basis of diagnosis, medical treatment, the indication of the treatment, the goal, procedures, the risk of complication, prognosis, and another alternative risk.

Second, the explanation or information should be provided by the doctor that conducts the examination and treatment using a simple language with less technical terms in order to make sure that he will get an appropriate consent.

Third, the patient or the legal relative of the patient who gives the consent should be competent, 18 years old or more and married, physically and mentally healthy, capable to understand, analyze, and use the information to make decision.

Fourth, the informed consent should be independently provided without any pressure from anyone, including the medical staff, siblings, friends, police, insurance company, and etc.

Fifth, the competent patient has the right to refuse any medical treatment although the decision seems unreasonable. Therefore, it needs to check whether the patient sees his/her medical condition, the medical treatment and therapy that he/she should get along with any possible risks and side effects.

Sixth, the informed consent for implementing a medical treatment can be postponed by the patient or the legal relative due to various reasons. For instance, there are still some members of the family that do not agree, it deals with financial condition or the schedule of implementation.

Seventh, the informed consent for medical treatment remains legal until it is taken off by the provider of the consent. Patients may abrogate their consent whenever they want by making a written statement of abrogation of the agreement for medical treatment. The statement should be filed before the treatment begins to conduct, and the patient should be informed that he/she should be responsible to any consequence of the abrogation.

Eighth, the informed consent for medical treatment is provided in a form of informed consent and it should be signed by the patient or his/her family or legal relative and the doctor who gives the treatment and takes a set of medical conduct, and also other witnesses if necessary.

Ninth, in a condition of medical emergency and it is impossible to ask for the patient's consent, and none of the family or relatives are available, the doctor may do a set of medical treatment for the patient's interest without having any consent before, given that the information will be provided later.

The following figure briefly presents the procedures of informed consent, as follow:

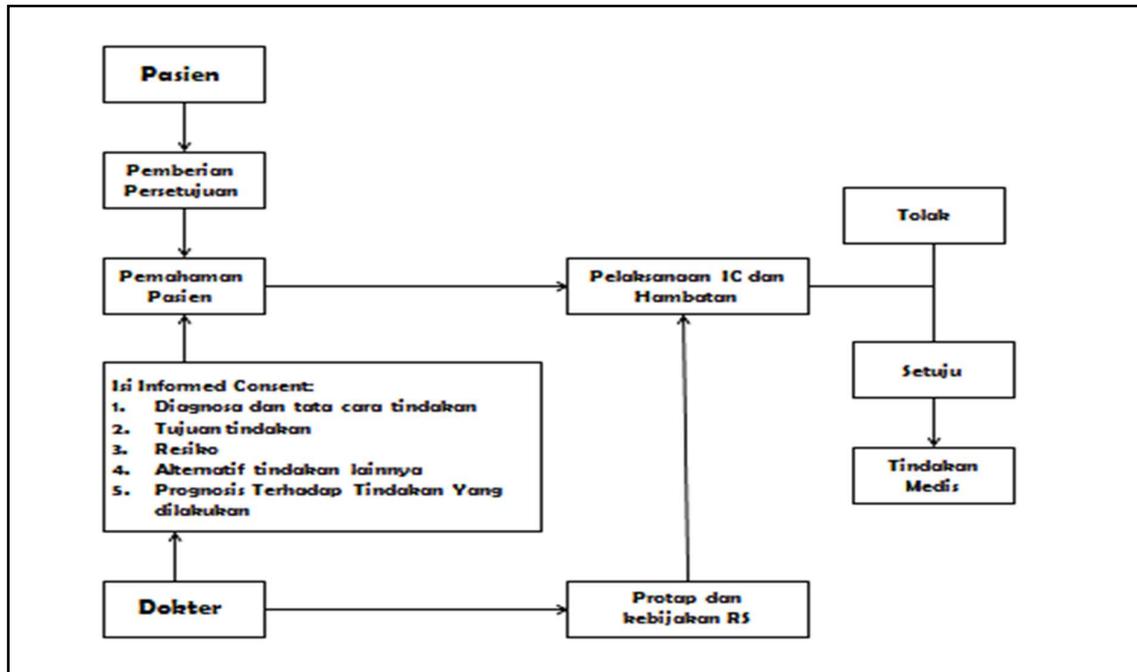


Fig. 1. The Procedures of Informed Consent in Bahasa

IV. CONCLUSION

Informed consent can be defined as the recognition on the principle of equality between doctor and patient. This recognition of equality does not merely deal with private (individual) relationship, but also reaching a broader context that emphasizes the government's participation in the implementation of health programs to reach higher level of health. Hence, *informed consent* does not only put the responsibility of medical professionalism in individual manner, but also in relation to the consistency of government's responsibility that corresponds to the constitutional mandate which is attempting to reach the assurance of equality in healthcare as the basic right of every people of Indonesia.

The procedures of providing informed consent begins since the doctor provides information to the patient or another legal relative that represent the patient about a set of medical treatment he is going to conduct including: diagnosis, the basis of diagnosis, medical treatment, the indication of the treatment, the goal, procedures, the risk of complication, prognosis, and another alternative risk. After having information from the doctor, patients and/or the family may approve or, otherwise, refuse the medical treatment. This is not apart from the basic principle of an agreement that puts the principle of proportionality in front as the basis of making an agreement, and both pertinent parties may have an equal position within.

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