THE LEGAL RIGHTS IN INFORMED CONSENT FORM FOR TREATMENT

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Abstract: **This dissertation focused on the legal rights in the informed consent form for treatment and its application in China. The purpose was to find out the way to modify the contents of the informed consent form for treatment in China according to the current written laws.**

Informed consent for treatment has become a legal requirement in China more recently than in the West, in 1994 when the Regulation of Administering Medical Institution went into effect. China has a long history in using written law instead of common law or case law as the base of the legal system. But to date, no statutory laws or regulations can provide detailed answers to the question of what should be included in the consent form for treatment. Conflicts between patients and doctors occur inevitably from time to time. In this study, 80 samples of the consent forms were collected from five hospitals in Guangzhou, the capital of Guangdong Province in South China. After analyzing the items of the 80 informed consent forms according to the statutes, we found that there were many problems in the consent forms, such as the absence of record of age, mental status, and time. The practice of informed consent needs more attention by scholars and administrative officials. The usage status of the consent form in the whole country needs to be investigated in further studies.

Keywords: **Informed consent, Legal rights, Chinese legal system**

The informed consent for treatment has been required in western countries for about several decades. But in China it has become a legal requirement more recently in September 1994 when the Regulation of Administering Medical Institution, promulgated by the State Council, has been implemented. It requires that the medical institute should gain the consent from the patient who should sign the document before surgery, special treatment and examination. This is the first statute about informed consent pronounced by the legislative authority. In 2002, the Regulation of Dealing with Medical Malpractice and the Basic Criteria of Writing Case History (For Trial Implementation), distributed by the Ministry of Health and the State Administration of Traditional Chinese Medicine, establish the rules about the using of the written informed consent form in medical treatment. But to date, no statute laws or regulations can provide detailed answers to the question of what should be included

in the consent form for treatment. In general practice, doctors may write down what they think they are supposed to do according to their medical experience. Because of lack of legal education background, some contents of the consent form cannot be accepted for judicial judgment. Patients may try to argue with their doctors for their deserving legal rights based on the laws. Conflicts between patients and doctors occur inevitably from time to time.

Although the informed consent form for treatment is an important legal document in the procedure of health care service, there are few articles or books about informed consent for treatment in mainland China. Among the articles, some are about the ethical principles, and some are Chinese versions of the foreign articles. Only several articles are about the contents of the consent form for treatment from the judiciary viewpoint. One of them wrote by Deyan Wang (2004) combined the relevant statutes about the principle of informed consent in China. He tried to "point out the problems and difficulties of carrying it out" in China. At the end of the article he pushed to enhance the education of informed consent in public.

In order to find out the current status of the informed consent form for treatment in use in China, I collected the informed consent forms for treatment from five hospitals in Guangzhou, the capital of Guangdong Province in South China. They included two general hospitals and three specialty hospitals, one women and children's hospital, one psychiatric hospital, and one dental hospital. The consent forms were provided by the administrative department of each hospital. The only one criterion for the collection was as many consent forms were collected as possible. However, it was difficult to ensure that all the consent forms for treatment used in these five hospitals were collected. A total of 84 consent forms were collected. There were only two inclusion criteria. One was that all the consent forms were used in the procedure of the treatment, including diagnosis, therapy and admission. The other was that they were about the patient's opinion of the choice of medical treatment. After considering the inclusion criteria, 4 consent forms were excluded, in the remaining 80 consent forms, 62 (77.5%) were used in the procedure of therapy. Consent forms for diagnosis and admission are less common, with 10 (12.5%) and 8 (10%) respectively.

For the sake of satisfying the legal requirement for the protection of patient's and doctor's rights, the informed consent form for treatment must meet all legal criteria to gain the valid effect from the judicial judgment. Otherwise, it could lead to a lawsuit for battery or negligence. Several aspects need to be included into the consent form, such as patient, provider, information, and time. From the samples of the consent forms collected, I tried to find out whether there are any problems in the current consent forms.

The name is the most common identification to distinguish one person. It is not surprising to find out that all the samples of the consent forms require the patient's name to be recorded. However, in China, a person's name is very short. Law of the PRC on Identification Card

establishes the number in the Identification Card is the exclusive and lifelong identification code of each citizen. In the 80 collected samples, there were only 6 (7.5%) require the Identification Card number.

Legal capacity may be defined as an individual's ability to fully comprehend all of the implications, weigh up the information, and predict the consequences of his actions. Under the law, we need to consider two elements to decide on patient's legal capacity, age and mental status. In the General Principles of the Civil Law (1986), a citizen aged 18 or older shall have full capacity for civil conduct, and may independently engage in civil activities. In the 80 samples, there are 70 samples (87.5%) which register this item. All the 10 consent forms without age record came from the Psychiatric Hospital which accepted mental patients only.

Besides the person aged below 10, the psychiatric patient is also defined as "a person with no capacity for civil conduct", which is prescribed in Article 13 of the General Principle of the Civil Law (1986). Therefore, when the medical staff pays attention to the age of the patient, the patient's mental status should also be noted and recorded in the consent form. Even when the patient shows no signs of mental illness, this still needs to be recorded by the doctor, because it is an essential element to ensure the validity of the consent form. Not expectedly, in all the 80 consent forms, none requires to record the patient's mental status.

The agency mechanism frequently appears in the procedure of informed consent, because when the patient is without capacity or with limited capacity for civil conduct, he needs a statutory agent or appointed agent to stand for him to communicate with the doctor and make the decision about the treatment. The opinion of the patient's representative about the treatment should be formally documented. Therefore, in order to ensure the validity of the agency, it is important to clarify the relationship between the patient and the agent in the consent form. In the 80 collected consent forms, 73 (91.3%) require the agent to sign the name. But in these 73 consent forms, only 64 (87.7%) require the agent to clarify his relationship with the patient.

In the procedure of informed consent, it is an important question to make clear who the legitimate provider is. In the Regulation of Administering Medical Institution (1994), Article 33 requires the medical institute to fulfill the duty of informed consent. In the Law on Licensed Doctors (1999), Article 26 requires the doctor to explain the information to the patient and the relatives. The Regulation of Administering Medical Institution is promulgated by the State Council. And the Law on Licensed Doctors is promulgated by the command of the Standing Committee of the National People's Congress, which is at a higher political power level than the State Council. So the Law on Licensed Doctors has more judicial power than the Regulation of Administering Medical Institution. When the statutes have conflicts, we shall obey the statute with higher judicial power, and this rule is set up in the Legislative Law (2000). Therefore, in all instances, the information that is given to the patient must come from doctor

who is more qualified by education and experience than the nurse or other medical staff. A few years later, the Administrative Measure of Prenatal Diagnosis (2002) also specifies that the doctor is the information provider in Article 23. Because the provider may affect the legal validity of informed consent, it should be recorded as another element in the consent form. In the 80 consent forms, 69 (86.3%) require the doctor to sign his name in the form.

Informing is the fundamental procedure in informed consent. In the statutes of China, only the Basic Criteria of Writing Case History (For Trial Implementation) and the Administrative Measure of Prenatal Diagnosis have set up the rules about the scope of disclosure. Article 25 of the Basic Criteria of Writing Case History (For Trial Implementation) (2002) requires that the content of the consent form shall include the purpose of the treatment, the complication and the risk. Article 23 of the Administrative Measure of Prenatal Diagnosis (2003) requires that doctors shall tell the pregnant women or their relatives the safety, validity and risk of the diagnosis technology, and help them to understand the possibility of the danger and the uncertainty of the result. In the 80 consent forms, 8 consent forms for admission were all focused on both patient and hospital's rights and liability during the duration of admission. And 2 of them described the possibility of complication during the admission. In the 10 consent forms for diagnosis, they all just provided the information of complications and side effects. No other information, such as objective, result or procedure, can be found. More information was shown in the consent forms for therapy. In the 62 consent forms for therapy, 60 (96.8%) referred to complications showing that complications are still the main content in the consent forms for therapy. 8 forms mention the result of the treatment. The procedure of the treatment and the recovery after the treatment were shown in 4 forms. And 3 forms mentioned the objective of the treatment. However, no consent form mentioned the alternatives of the therapy.

Time is also an important element in the consent form, because Article 54 of the General Principle of the Civil Law (1986) allows people to change their activities in accordance with their personal will. Patients have rights to change their mind after signing the form. In the procedure of informed consent, if the patient wants to change his mind after he has made the decision and signed the consent form, the doctor should give another form to the patient to sign again. The recorded time may show the sequence of the two forms. Between there are two consent forms, the latter one will be the final decision of the patient. In the 80 consent forms, they all require the record of the date of the signature, but only 6 (7.5%) of them required to sign the time of the signature.

From the discussion above, we can find that there are many faulty aspects in informed consent in China. More work is needed to improve the implementation of the civil rights of informed consent. Even though the 80 samples of the consent forms were collected from medical institutes of Guangzhou, it might not represent the whole usage status of consent form in China. Because the patient's legal rights are equal everywhere in the country, we examined the current status of the contents of the consent forms in these five hospitals, which could reflect at least partial usage status in China.

In sum, all these phenomena of usage status are worthy to be studied in the future to find out the proper ways to develop and promote the informed consent form for treatment. It should be noted that the present thesis only focuses on consent forms in the inpatient treatments. In the outpatient treatments, informed consent is assumed. Increasing disputes are arising. Some of these problems could be due to the lack of a completed informed consent form to prove that informed consent has been obtained. Further studies on the informed consent for outpatient treatments are also urgently needed.

REFERENCES

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