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Special Feature Article

Difficulty in Obtaining Consent in a Case Report or Research: Lawyer's Viewpoint

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Abstract

To examine a specific disease in a case report or study for publication in an academic conference or specialized journal, sincere consent, as a rule, should be received from subjects. According to the revised Personal Information Protection Law, medical information should be specially protected as sensitive personal information. However, in reality there exist cases where consent cannot be easily obtained, from those with mental illness for instance. In the past, presumed, fictitious, or proxy consent was obtained to circumvent the consent principle. However, these methods are only for the sake of legal technicality, leading to speculation of the patient's intention. Therefore, I propose that we need to develop a model that circumvents the consent principle from different viewpoints in order to appropriately pave the way for necessary and meaningful academic research, while respecting the human rights of patients. In this paper, I would like to present a draft proposal.

Keywords: Personal Information Protection Law, special care-required personal information, consent principle, de-identification, biomedical ethics

Introduction

The theme of the symposium, which was the basis for this paper, was "Difficulty in Obtaining Consent in a Case Report or Research," and here we consider cases involving patients who have limitations in understanding the content of case reports and research and in making decisions about consent, mainly due to mental illness.

I. Personal Information Protection Law

1. Patient Consent for Provision of Personal Information to Third Parties

The most problematic issue in obtaining consent for case reports and research on psychiatric disorders is the issue of patient consent for the provision of personal information to third parties, and the application of the Personal Information Protection Law is problematic 2).

2. Revised Personal Information Protection Law

The revised Personal Information Protection Law, which has been in effect since 2009, clarifies several definitions. In terms of medical care, "medical history" is considered "personal information requiring special consideration" and is positioned as personal information that should be given special protection. According to Article 2, Item 1 of the Order for Enforcement of the Personal Information Protection Law and respective items of Article 5 of the Ordinance for Enforcement of the Personal Information Protection Law, "physical disability, intellectual disability", and "has a mental disorder or other impairment of physical or mental functions, including developmental disabilities" are typical examples of medical history, and "information that identifies mental disorder as defined in the Mental Health and Welfare Law" is applicable to mental disorder. For mental disorders, "information that identifies a person as having a mental disorder as referred to in the Mental Health Welfare Law" is considered to fall under this category.

3. Basics of Personal Information Handling

Article 23 of the Personal Information Protection Law stipulates the "Principle of Consent," which states that, with certain exceptions, the prior consent of the individual is required for the provision of personal information to a third party. Paradoxically, the law assumes in advance the cases in which the provision of personal information to a third party without prior consent of the individual is permitted. Among the methods of obtaining consent, the so-called opt-out method of obtaining consent is not permitted for special care-required personal information.

4. "Exemptions" Provision

As described above, the Personal Information Protection Law stipulates that "the principle of consent is the basis" for the provision of personal information to third parties, but Article 76 provides for uniform "exemptions" from the provisions including the principle of consent in situations where personal information is handled for certain purposes. Closely related to this theme is Article 76, Paragraph 1, Item 3. In other words, this provision states that the consent principle does not apply when "universities and other institutions or organizations for academic research, or persons belonging to them" handle personal information for "the purpose of using it for academic research."

Since this "exemption" provision states that the consent of the individual is not required for the use of personal information in case reports and research, much discussion has been devoted to the question of what falls under this exemption. The idea is to find a way of interpreting the law in such a way that they will not be sued by the patients later, assuming as many cases of "exemptions" as possible. However, it should be noted that such an attempt to develop an interpretation of "exemptions" is based on a misunderstanding of the Personal Information Protection Law.

(Exemptions)

Article 76.

1. The provisions of Chapter IV shall not apply to any of the following Business Operators Handling Personal Information, etc., when the purpose of handling Personal Information, etc., is wholly or partially for the purposes prescribed in the respective items.

(i) Broadcasting organizations, newspapers, news agencies, and other news organizations (including individuals who engage in news reporting as a business): for the purpose of reporting.

(ii) Persons engaged in writing as a profession: for the purpose of writing.

(iii) Universities and other institutions or organizations for the purpose of academic research, or persons belonging to such institutions or organizations: for the purpose of academic research.

(iv) Religious organizations: for the purpose of religious activities (including activities related thereto).

(v) Political organization: for the purpose of political activities (including activities incidental thereto).

(Omitted)

3. The Business Operators Handling Personal Information, etc., listed in each item of paragraph 1 shall take necessary and appropriate measures to secure the management of personal data or anonymized processed information, handle complaints concerning the handling of Personal

Information, etc., take other necessary measures to ensure the proper handling of Personal Information, etc., and shall endeavor to make public the details of such measures.

5. Legislative intent of the "Exemption" provision

The purpose of the "exemptions" provision is to balance the "protection of personal information" with the guarantee of human rights such as freedom of the press, freedom of speech, freedom of religion, freedom of study, and freedom of political activity, and to provide "brakes" so that the state does not interfere with the spiritual freedom of individuals in the name of personal information protection. In other words, it is essentially a code for administrative authorities to deter excessive regulation and imposition of penalties on personal information handlers by administrative agencies. As a result, it effectively balances the usefulness of personal information with the protection of individual rights and interests.

Therefore, it cannot be said that "personal information does not need to be protected when it is used for academic research, so it is exempt from application of the Act. Even if the information falls under the "exemptions" of the Personal Information Protection Law, the existence or non-existence and degree of infringement of the right to privacy are actually issues that should be examined and discussed separately. Even if the information falls under the "exemptions" of the Personal Information Protection Law, there is a possibility that the use of information without consent may be considered an infringement of rights.

II. Article 76, Paragraph 3 of the Personal Information Protection Law and Consent Requirements

1. Ethical Guidelines and Other Guidelines

The "exemption" provision of Article 76, Paragraph 1 of the Act on the Protection of Personal Information obliges business operators handling personal information to make efforts to take necessary measures for the safe management of information in Paragraph 3 of the same article. However, in the field of medical research, several ethical guidelines and other guidelines have already been published as autonomous efforts on the part of the medical community 3). These ethical guidelines require that, in principle, consent be obtained after sufficient explanation to the individual when conducting various types of clinical research and case reports. In other words, this is a positive action on the part of the medical community to protect patients by maintaining the

principle of consent for special care-required personal information, without being satisfied with the "exemptions" of the Personal Information Protection Law. If this is from the viewpoint of the protection of private rights, beyond the direct purpose of the Personal Information Protection Law, it can be said that the intention is commendable.

However, the fact that the guideline seeks to go back to the "principle of obtaining consent" makes it very difficult to handle, and it is hard to shake off the impression that the medical community may have tied themselves up.

2. Legal function of patient consent

Considering the legal function of patient consent regarding the use of personal information (e.g., provision to a third party), first, it functions as a legality requirement under the Personal Information Protection Law (to avoid regulation by the government). More broadly, it also functions as prior consent against infringement of privacy rights (to avoid the obligation to compensate for damages). However, there is no clear provision in the law regarding the ability to give such consent.

In order to be able to say that legal "consent" has been given, it must be provided by a person who understands the explanation as a premise for consent and has the ability to accurately understand the meaning of consent, but in order to judge this point in a concrete situation, substantive interpretation theory is necessary. Here, it is helpful to note that under the Civil Code, the age of consent for the ownership of property is 20 years old (Civil Code Article 4), and the age of testamentary capacity is 15 years old (Civil Code Article 961). It is generally understood that the age of testamentary capacity is 15 years old, and that the capacity to consent to medical treatment also requires the judgmental capacity of about 15 years old.

However, there is a limit to the conventional argument, i.e., "What age of discretion is required for the ability to consent to ____?" In the first place, the delimitation of "the capacity to consent at the age of about ____" itself is unclear. In addition, depending on the subject of consent, it may be difficult to determine the capacity to consent uniformly according to age. This is especially true when the subject of consent is specialized and complex. In such cases, it is difficult to uniformly determine the ability to consent because the level of understanding of the subject of consent depends not on age but solely on personal ability. In the case of medical research, it is not possible to determine the ability to understand research in a uniform manner.

Even if a judgmental capacity of about 15 years of age were necessary, the model forms for explanation and consent documents that are currently published in the guidelines are very voluminous. For example, the "Model Forms for Informed Consent Explanation and Consent Documents" 4) published by the Ministry of Education, Culture, Sports, Science and Technology (MEXT) show evidence of efforts to use plain language, but even so, the contents are not easy to understand, even for the average adult.

Furthermore, when we try to overcome the consent requirement in the field of psychiatry, we are caught in the dilemma of having to consider the operation based on unrealistic factors such as "presumptive consent" and "constructive consent."

III. Breaking free from the consent requirement

From the above, it seems that it is necessary to find a way to overcome the "consent requirement" by breaking away from it. The legal function of patient consent for the use of personal information (e.g., provision to a third party) was discussed above, but it is based on the idea that "the use of personal information is an inherently bad act." If we examine the question "What is wrong with this?" in detail, we come to the conclusion that it is an "infringement of the individual's right to privacy. Then, why not find a way to dilute the degree of violation of the individual's right to privacy, so that the use of information, with or without consent, is not a bad thing?

In fact, the case of "not illegal even though the right holder does not give consent" is provided in Article 23 of the Personal Information Protection Law, and is also found in other laws. The most famous examples are self-defense and emergency evacuation under criminal law. Among these, the legal requirements for emergency evacuation, such as the "requirement of urgency," the "requirement of non-substitutability," also known as the "supplemental principle," and the "requirement of a reasonable balance of interests," also known as the "principle of balance of legal interests," are helpful. With reference to these requirements, we should consider whether there is a level of use of patient information that does not require consent, and whether it would be possible to have guidelines for the use of patient information at a level where there is no need for consent.

The discussion of the "Hepatitis Study at Willowbrook," as introduced by Beauchamp, T. L. et al. in "Principles of Biomedical Ethics" published in 1979, will be a useful reference 1). This study is not a case of handling patient information, but a case of clinical

experimentation on patients. To briefly introduce the case, in the 1970s, at Willowbrook State School, an institution for mentally retarded children in New York State, about 800 children were exposed to the hepatitis virus with their parents' consent and tested to see if they could become asymptomatic by acquiring antibodies, and the researchers published their findings. The study was criticized on the grounds that it was conducted on mentally retarded children with or without parental consent, that there was no benefit to the children, and that there were other methods (such as gamma-globulin administration) available to control hepatitis in the facility. On the other hand, the fact that there were some in favor of the study on the grounds that the children were not exposed to any greater risk than if they were in a normal, non-experimental state, that they would receive better medical care than if they were naturally infected, and that they could make an important contribution to the future well-being of similar children.

IV. Consent Requirements Not Required

Therefore, I have come up with my own idea of a requirement that does not require consent in order to break away from the consent requirement. Please note that this is only a tentative proposal.

The following "six requirements" would make it possible to report cases and conduct research without the need for patient consent:

First is the requirement of "dilution of violation of individual privacy rights" by "de-identification and anonymization."

Second is the "urgency" requirement. Traditionally, the general view has been that there is no urgency in medical research and case reports, but I believe that there may be situations where urgency can be affirmed, such as research for vaccine development, and that such research should be allowed. So I have included this requirement. However, if this requirement is the same as that of "emergency evacuation" as a justifiable reason for noncompliance with the Penal Code, then research and case reports can almost invariably be denied urgency, so it should be positioned as a more moderate urgency requirement.

Third is the "legitimacy" requirement that "the purpose of the research is legitimate. "

The fourth is the requirement of "impartiality." It means that the research must not discriminate against the subjects of the research. This requirement is particularly important in the field of mental illness because of the stigma associated with it.

Fifth is the requirement of "non-substitutability (the replenishment principle). This is limited to cases where there is no other way to obtain the results of the research in question.

The sixth requirement is the "balance of interests" requirement, which means that there must be a balance of interests between conflicting interests in the relevant research. It is necessary to comprehensively evaluate the merits of obtaining the research results, such as whose merits, when, what merits, and to what extent, and the demerits of the research subjects, such as whether there is harm due to the research method, and to what extent.

I am of the opinion that such a requirement should be under consideration and that there should be guidelines to facilitate the consent requirement.

V. Consent Not Required and Biomedical Ethics

Here, I would like to mention the biomedical ethics of Beauchamp et al., which you may already be familiar with 1). In order to break away from the consent requirement in this theme and overcome such a requirement, I believe that it is necessary to understand and apply these biomedical ethics.

Autonomy: Principle of promoting autonomous patient decision-making.

Non-maleficence=Do no harm: Principle that requires the patient to remain unharmed.

Beneficence=Do some good: the principle of doing good to the patient.

Justice: Principle of fair treatment of patients.

These biomedical ethics are also behind the aforementioned "consent requirements not required " (Table).

Conclusion

Thus, starting from the principle of autonomy, we should take a step in the direction of actively allowing medical research and case reports that are necessary and useful for all humankind, including research subjects, while balancing interests and protecting personal medical information, etc., based on the principles of good conduct, justice, and safety. There must be a legal framework and method for this. I would like to conclude this paper by expressing my hope that biomedical ethics will be fully discussed and stating that guidelines are necessary to overcome the need for consent; such guidelines can be developed.

There are no conflicts of interest to disclose in connection with this paper.

References

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表　自律原則を出発点とする研究・症例報告の同意不要要件

①個人のプライバシー権侵害の希釈化：非識別化，匿名加工化
②緊急性：研究・症例報告には緊急性がないというのが従来の一般的見方だったが果たして本当にそうであるか再検討する必要がある.
現在のコロナ禍の経験➡ワクチン開発のための研究など，緊急性を肯定できる場面がある.
③正当性（➡善行原則，正義原則）：研究目的が正当である.
④公平性（➡正義原則）：研究対象者に対する差別ではない.
⑤非代替性（補充原則）（➡善行原則，正義原則）：当該研究の成果獲得のために他の方法がない.
⑥利益衡量（法益権衡原則）（➡無危害原則，善行原則，正義原則）：対立する利益間の権衡がとれている.
研究成果獲得のメリット（誰の，いつの，いかなるメリットか，その程度は？）
研究対象となる人のデメリット（研究方法上の危害の有無・程度は？）

Table Consent Not Required for Research and Case Reports Starting from the Principle of Autonomy
(1) Dilution of violation of individual privacy rights: De-identification, anonymization.
(2) Urgency: The conventional view is that there is no urgency in research and case reports, but it is necessary to reconsider whether this is really the case.
The current experience of the coronary disaster → There are situations in which urgency can be affirmed, such as research for the development of a vaccine.

(3) Legitimacy (→principle of good conduct, principle of justice): The purpose of the research is legitimate.
(4) Impartiality (→principle of justice): There is no discrimination against the research subjects.
(5) Non-substitutability (principle of supplementation) (→principle of good conduct, principle of justice): There is no other way to obtain the results of the research.
(6) Balance of interests (principle of equity of legal interests) (→principle of safety, principle of good conduct, principle of justice): There is a balance of rights between conflicting interests.
(7) Merits of obtaining research results (whose, when, what benefits, and to what extent?)
Disadvantages for the research subjects (whether and to what extent there is harm due to the research method?)