

## Letter to the Editor: The challenges of medical ethics educators at a research university

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As medical ethics educators at a research facility, we are in charge of ethics reviews and research misconduct prevention education and come in contact with many researchers. In this letter to the Editor, we would like to briefly discuss conflicts of interest and ethics education concerning research activities in present Japan. First, we are critical of the assumption that a researcher's conflicts of interest can be well managed through the current self-reporting system. Self-declaration of the researcher's conflict of interest to one's institution, academic society, and journal is expected to prevent one from both interpreting and presenting study results in a biased manner according to self-interest. However, we feel that undesirable influences of researchers' conflicts of interest are likely never going to be eliminated at the basic level. This is because self-advancement, self-actualization, self-preservation, and family life of researchers all depend on the amount of research funds they have obtained and the number of papers they publish. Regardless of self-declaration, substantial conflicts between fundamental self-interests and public and professional interests never dissolve.

Second, ethics education for researchers is not likely to be effective enough to prevent research misconduct. In Japan, the Ethical Guidelines for Medical and Health Research Involving Human Subjects (December, 2014) state that the chief executive of the research implementing entity as well as investigators shall receive education and training on the ethics of research and on knowledge and skills necessary to carry out the research prior to its implementation and that they shall also receive education and training during the research period on a regular basis as necessary. At Japanese research institutions, one cannot receive an ethics review of a research proposal without undergoing research ethics education. A "certificate" of having received the education is necessary. Nowadays, many researchers do not participate in the education to learn about ethics, but rather to obtain proof that they attended the classes. There is a feeling that they are undergoing education merely to expedite the process of ethics review. In other words, they are akin to students who show up to class merely for attendance purposes.

Current research misconduct prevention policies in Japan could be summarized as "plowing the field and forgetting the seeds." Many researchers adopt the "shortest distance principle," making it their motto to achieve maximal results with the least amount of time

and effort. There is no room to consider ethics with such a mindset. We ourselves have no bright ideas for planting the seeds of ethics in people's minds, and welcome any suggestions from the readers.

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## Informed Consent: Substantive v. Formalistic Approach and the Law

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### Abstract

The rule of informed consent is universally regarded as a cornerstone in governing patient-physician relationships. The key element of "informed" stresses that only the consent given after consideration of sufficient information constitutes valid consent. However, various studies in many countries have shown inadequate information can often take place resulting in lack of understanding of medical procedures. What role does the legal system play in promoting substantive informing and respecting the will of the patients? And how does it realize the true idea of informed consent?

Taking Taiwan as an example, this paper reveals the dynamic and interactive relationships between law and practices on this issue. First, the law may incorporate the idea of informed consent into specific mandates to prompt its implementation. Second, however, the need of evidence in court may sustain or even reinforce undesirable formalistic practices that largely focus on written consent forms rather than substantive explanation. Third, to respond to these formalistic practices, courts could reconstruct the shape of the legal requirement and guide institutions and physicians to the new direction. The assertion of this paper is that formalistic practices are inconsistent with the legal nature of informed consent, regardless of whether they appear to have complied with the law or not. If courts can acknowledge the problem of formalism and are willing to actively investigate or request institutions for alternative evidence to determine whether a meaningful dialogue existed or not, the practices may be directed further towards fulfilling the spirit of informing.

### Introduction

The rule of informed consent is universally regarded as a cornerstone in governing patient-physician relationships. The key element of "informed" stresses that only the consent given after consideration of sufficient information constitutes valid consent. It follows that the purpose of requiring physicians to provide this information is so as to allow patients to gain sufficient enough understanding to

make a sound decision. Hence, imparting a large amount of medical or technical terminology onto a patient without reasonable explanation would be considered inadequate. In reality though, medical institutions may comply with the rule of informed consent formalistically by merely asking patients to sign consent forms that contain too much complex medical terminology for patients to digest and not giving the patients the necessary time to reflect on the situation based on their own values.

When the law absorbs the idea of informed consent into its system, does it intrinsically promote substantive informing and the respect of the patient's will? Legalizing the rule of informed consent does impel physicians and medical institutions to demonstrate compliance. However, when physicians and medical institutions do not sincerely embrace the core value of the rule, practices may be directed to solely avoid legal liability rather than to pursue true respect for patients' autonomy. Physicians and medical institutions may place much emphasis on signed forms of consent, as a means to be supporting evidence in case of litigation, rather than truly helping the patient to make a sound decision.

The assertion of this paper is that the factor of legal liability may to some extent contribute to the occurrence or at least fail to address the continuing existence of the formalistic practices, which actually are inconsistent with the legal nature of informed consent; if courts can acknowledge the problem of formalism and are willing to actively investigate or request institutions for alternative evidence to determine whether a meaningful dialogue existed or not, the practices may be directed further towards fulfilling the spirit of informing. The argument is presented in three parts: Part I clarifies the legal foundation of informed consent and comments on the formalistic practices from a perspective based on the spirit of law. Part II explores the informed consent law in literature and its formalistic operation in action.<sup>2</sup> Lastly, Part III seeks to respond to the issue of formalistic practices through judicial actions, while also acknowledging the limits of this approach.

Since observations and analysis of laws and practices require the context of jurisdiction, Taiwan is used as an example.<sup>3</sup> Yet, the thesis in this paper can improve general understanding with respect to the interactions of the law and practices of informed consent anywhere. The insufficient or even formalistic informed consent process appears to be a problem worldwide. Many studies conducted in different countries similarly report doctors' inadequate informing and patients' poor understanding of certain medical

procedures.<sup>4</sup> Hence, it is the author's hope that this paper could provide valuable insight to people in many countries, especially in where the practices of informed consent remain in the developing stage.

### I. The Foundation of Informed Consent from a Legal Perspective

Although the idea of informed consent in the view of many doctors is originated from bioethics rather than law, this rule actually has strong legal background that precedes bioethics. The most influential approach of bioethics establishes its analysis through specific "principles," such as respect for persons, beneficence, and justice.<sup>5</sup> From this perspective, informed consent is primarily rooted in the principle of respect for persons/autonomy.<sup>6</sup> In comparison, law constructs its framework by "rights," which have surfaced in constitutions, civil codes, and other laws in most countries. Therefore, finding a foundation for informed consent in legal systems should begin with protection of the rights that are involved in medical intervention.

Medical intervention impacts patients' rights of bodily integrity and health, which are legally protected. Taiwan's Constitution does not explicitly list the rights of bodily integrity and health. However, recognizing them as constitutional rights has been supported by scholarly opinions and judicial decisions.<sup>7</sup> Taiwan's Constitution contains a provision of *unenumerated rights*,<sup>8</sup> and in one case the Constitutional Court has interpreted the Constitution to include the right of bodily integrity through that provision.<sup>9</sup> Additionally, in many other cases, the Constitutional Court has

<sup>2</sup> The law and society movement has provided an important insight that not only the written law but also the law functioning in reality deserves careful attention. See generally, e.g., Macaulay, Steward, *et al.*, *Law in Action*, pp. 15-141; Pound, Roscoe, "Law in Books and Law in Action," pp. 12-36.

<sup>3</sup> For a brief legal history of Taiwan, see Lo, Chang-Fa, *The Legal Culture and System of Taiwan*, pp. 1-4.

<sup>4</sup> E.g., Jawaid, M. *et al.*, "Preoperative Informed Consent: Is It Truly Informed?," pp. 25-30; Falagas, Matthew E. *et al.*, "Informed Consent: How Much and What Do Patients Understand?," pp. 420-435; Kušec, Sanja *et al.*, "Improving Comprehension of Informed Consent," pp. 294-300; Amir, Mohammed *et al.*, "Informed Consent in Elective Surgical Procedures: 'What Do the Patients Think?'," pp. 679-82.

<sup>5</sup> The National Commission for the Protection of Human Subjects of Biomedical Behavioral Research (1979). The Belmont Report, Part B. <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html> (Retrieved: December 21, 2016); Beauchamp, T.L. & J.F. Childress, *Principles of Biomedical Ethics*, pp. 12-13.

<sup>6</sup> The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *supra* note 5, at Part C.1.; Beauchamp & Childress, *supra* note 5, p. 117.

<sup>7</sup> For scholarly opinions supporting the recognition of the constitutional rights of bodily integrity and/or health, see e.g., Li, Chen-Shan, "On the Right to Be Free from Bodily Harm from the Perspective of Constitutional Law," In *Human Dignity and the Protection of Human Rights*, p. 159 (*in Chinese*); Li, Chen-Shan, *Plurality, Tolerance, and the Protection of Human Rights*, pp. 121-128 (*in Chinese*); Chen, Tsung-Fu, "The Realization of Patients' Medical Human Rights," p. 33 (*in Chinese*); Chen, Chung-Lin, "The Right to Bodily Integrity as a Constitutional Right," p. 113 (*in Chinese*).

<sup>8</sup> Article 22 of the Constitution ("All other freedoms and rights of the people that are not detrimental to social order or public welfare shall be guaranteed under the Constitution.")

<sup>9</sup> Interpretation No. 689.

stressed the importance of protecting the interests of people with respects to health and bodily integrity.<sup>10</sup>

In the level of statutory law, civil and criminal laws establish rules to embody the protection of the rights of bodily integrity and health. The Civil Code specifically mentions the interests of bodily integrity and health as protected personal interests.<sup>11</sup> Infringing those interests triggers delictual liability.<sup>12</sup> At the same time, intentionally or negligently harming the body or health of a person constitutes a crime under the Criminal Code.<sup>13</sup> Similarly to the delict, the purpose of the provisions of the Criminal Code is to realize the protection of the rights of bodily integrity and health. Here it is worth mentioning that this paper intentionally uses the term delict rather than tort. Although delict (a concept in the civil law) and tort (a concept in the common law) share many of the same ideas and characteristics, they do develop into different forms.<sup>14</sup> For example, delict manifests itself in a general fashion of expression, while tort constructs the whole picture through formulating particular causes of action.<sup>15</sup> Because of the high visibility of the U.S. development of informed consent, legal discussions in Taiwan often begin with the U.S. laws and proceeds under the notion of tort. However, because of the restriction from the statute language as well as established civil law principles in Taiwan, the informed consent laws developed through individual tort cases in the United States<sup>16</sup> might not necessarily fit squarely into the legal context in Taiwan. On the other hand, despite the emphasis above on the differences in name and substance between delict and tort, both systems are established and designed to protect rights.<sup>17</sup>

The very notion of the rights of bodily integrity and health entitles an individual the control over her/his body and health. An individual may authorize intervention or otherwise prevent it, depending on how she/he views her/his best interests. These two sides of power constitute complete control. It naturally follows that medical intervention must have the individual's authorization, that is, consent; otherwise, the patient's rights are violated. In addition, consent must be made fully voluntarily, and cannot be considered as such when an individual made it based on insufficient information. To illustrate, an *ill-informed* patient who consented to a certain medical intervention could have declined that intervention or have chosen an alternative treatment, consequently avoiding the harm resulting from the intervention. Therefore, valid

consent must be made after the individual has been adequately informed.

Based on this perspective of patients' rights, deeming informed consent as merely a legal obligation of physicians, with view to avoiding liability as its purpose, oversimplifies its legal meaning. Since legal liability constitutes an imminent threat to physicians, physicians may tend to focus attention on the obligation of informed consent. However, it is the person's rights that represent the ultimate purpose behind legal rules, and legal obligations are merely the means to advance rights. Similarly, non-liability does not necessarily mean full compliance with the rule of informed consent. Law, under adequate understanding, requires physicians to act under respect for patients' rights. Sincerely informing patients and helping them to make sound decisions fulfills that requirement whereas devoting effort to escape liability does not.

The discussion above demonstrates that the rule of informed consent has solid justification in legal systems and that the constitutive elements of the rule exist independently from bioethical theories on informed consent. Properly understanding patients' rights protected by law would naturally lead to acknowledging the rule. In turn, this right-based understanding grants us the adequate perception of informed consent, indicating that placing much emphasis on obtaining a signed consent form, rather than being committed to constructive dialogue with patients with view toward making sound medical decisions, does not truly satisfy the expectation of law.

## II. The Informed Consent Law and Formalistic Practices

After describing the legal nature of informed consent from a perspective of jurisprudence, the discussion in this section is turned to specific laws that provide the rule. In Taiwan, the rule of informed consent has clearly become a legal mandate. The legislature incorporates it into the Medical Care Act and the Patient Autonomy Rights Act, and scholars and courts include it into civil law and criminal law through interpretation. Still, it should be noted that although the informed consent law implicates medical practices, it does not necessarily ensure ideal or desired results.

According to the Medical Care Act, in principle, medical institutions are obliged to provide information to the patient and to obtain his/her consent in writing before commencing surgery, invasive examination or treatment.<sup>18</sup> The provisions specifically stipulate that institutions must obtain not only consent but also signed consent forms.<sup>19</sup> Violation of the law leads to a fine of between TWD50,000 and TWD250,000 (USD1,500 to USD7,500).<sup>20</sup> The competent agency can fine not only the medical institution but also the

<sup>10</sup> *E.g.*, Interpretations No. 414, 472, 476, 531, 547, 550, 551, 577, 612.

<sup>11</sup> Articles 195 of the Civil Code.

<sup>12</sup> Article 184 of the Civil Code.

<sup>13</sup> Articles 277, 284 of the Criminal Code.

<sup>14</sup> Lee, R. W., "Torts and Delicts," pp. 721-730.

<sup>15</sup> *Ibid.*, pp. 727-29.

<sup>16</sup> For an introduction to the evolution of the informed consent case law in the United States, see King, J. S. & B. W. Moulton, "Rethinking Informed Consent: The Case for Shared Medical Decision-making," pp. 429-501.

<sup>17</sup> *Ibid.*, pp. 727-729.

<sup>18</sup> Articles 63, 64 of the Medical Care Act.

<sup>19</sup> *Ibid.*

<sup>20</sup> Article 103 of the Medical Care Act.

acting persons.<sup>21</sup> Moreover, if the acting persons are medical professionals, they could be subject to professional sanctions.<sup>22</sup>

To stress the idea of patient autonomy and further embody the rule of informed consent, the Legislative Yuan enacted the Patient Autonomy Rights Act in December, 2015. The Act, repealing the Medical Care Act, mandates medical institutions to obtain signed consent forms from patients before commencing surgery, invasive examination or treatment.<sup>23</sup> More importantly, it clearly establishes that “a patient has the right to be informed about his/her condition, treatment options and their potential effects, and prognosis and has the right to choose from treatment options provided by physicians and make related decisions.”<sup>24</sup> Nevertheless, it is worth noting that the Act does not contain any sanction provision. It should also be noted that this new law provides a three-year grace period and will not come into effect until January 6, 2019.<sup>25</sup>

In addition to administrative fines and professional sanctions mentioned previously, civil liability and criminal penalty may be triggered by a violation of informed consent. The Civil Code establishes that a person is liable for wrongfully infringing, with intent or negligence, the rights of another person.<sup>26</sup> Medical institutions or professionals that implement invasive procedures without obtaining legally valid consent may be held liable for the harm that they cause. By the same token, these medical professionals may also violate criminal law, which imposes the penalty of imprisonment or a fine for intentionally or negligently harming the body or health of a person.<sup>27</sup> These potential liabilities place significant pressure on institutions and physicians, and impels them to adhere to the rule of informed consent.

The meaning of informed consent under contract law is also worth noting. Although the implication of informed consent in contract law draws much less attention, some have indicated that the informing that a physician delivers and the consent that the patient gives may well constitute an offer and an acceptance and together form a contract.<sup>28</sup> To illustrate, imagine someone buying food from a night market stand, or looking for a massage from a massage parlor. In both cases, it is easy to assume that in order to make a practical decision, this person would require certain information about the food he is buying or the service he is soliciting. Otherwise there would not be a valid contract. Making such choices based on sufficient information is an everyday activity. This also applies in

the patient-physician relationship. Undergoing medical intervention at a medical institution naturally involves a contract, which provides the subject matter, quality, quantity and so on of the service. It follows that when the physician does not fulfill the promises outlined in the contract, the patient may rescind the contract or sue for enforcement or damages, depending on what kind of obligations had been violated.<sup>29</sup>

Despite the clear mandate of informed consent empowered by administrative fines, professional sanctions, civil liability, and criminal penalty, some have indicated that medical institutions and professionals often carry out informed consent by formalistically asking patients to sign consent forms and do not pay sufficient attention on offering reasonable explanations.<sup>30</sup> When the liability is a weighty concern for medical communities, preparing evidence that can later be presented in court if required becomes an important task. Naturally, a written consent form with required information and the patient's signature on it constitutes a convenient piece of evidence of informed consent. Moreover, in order to avoid a stalemate of one person's word against another, the Medical Care Act has explicitly required written consent forms and patients' signatures. With this clear mandate, the focus becomes even further directed towards the formalistical implementation of informed consent. In one study a doctor reported that this requirement leads to a misguided focus of clinical practices, placing more emphasis on written consent forms than on providing adequate information.<sup>31</sup>

Such observation indicates that the law does not necessarily bring the sound embodiment of the idea of informed consent and that the overhanging threat of legal liability may misguide physicians. Obviously, this is not the intention behind the legislation, nor is it consistent with the spirit of law. Some have indeed criticized this situation and have argued in favor of establishing the patient-physician relationship on more positive and firmer ground than that of the fear of litigation.<sup>32</sup> In that light, guiding practices toward the realization of the ideal, recognizing the true legal meaning of informed consent is a key step.

### III. The Judicial Response to the Formalism and Its Limits

<sup>29</sup> See Hung, *supra* note 28, pp. 69-70; Chen, *supra* note 28, pp. 500.

<sup>30</sup> Yang, Hsiu-I, “Warm Paternalism vs. Empty Autonomy: Exactly What Physician-Patient Relationships Does Law Want?,” p. 23 (*in Chinese*); Wang, Huang-Yu, “The Obligations of Physicians for Informing and Examining: Comments on the Court Decision No. 2005-Taishang-2676,” p. 267 (*in Chinese*); Yang, Hsiao-Yu *et al.*, “Clinical Ethics Case Discussion (7): Informed Consent,” p. 30 (*in Chinese*); Guo, Suh-Er *et al.*, “Informed Consent: What Patients Want to Know Before the Surgical Operation,” p. 146 (*in Chinese*).

<sup>31</sup> Wang, Chih-Chia, *Patient Autonomy and Related Criminal Issues: Case Study*, p. 212 (*in Chinese*).

<sup>32</sup> Sprumont, Dominique, “Informed Consent: Do Not Be afraid,” published on line on 28 September 2015, <http://dx.doi.org/10.1016/j.jfma.2015.08.013> (Retrieved: December 21, 2016).

<sup>21</sup> Article 107, Section 1 of the Medical Care Act.

<sup>22</sup> Article 107, Section 2 of the Medical Care Act.

<sup>23</sup> Article 6 of the Patient Autonomy Rights Act.

<sup>24</sup> Article 4 of the Patient Autonomy Rights Act.

<sup>25</sup> Article 19 of the Patient Autonomy Rights Act.

<sup>26</sup> Article 184 of the Civil Code.

<sup>27</sup> Articles 277, 284 of the Criminal Code.

<sup>28</sup> Chen, Chung-Lin, “The Legal Meaning of Informed Consent in Human Tissue Research and the Application of the Biobank Act,” pp. 499-500 (*in Chinese*); Hung, Min-Yu, “The Legal Meaning of Informed Consent in Medical Research,” pp. 65-67 (*in Chinese*).

In reality, the situation largely depends on the action of institutional forces. The judiciary, the final authority regarding law interpretation, has the potential to change how the law is viewed. Since the analysis in the previous chapter demonstrates that practices do not completely realize the true legal nature of informed consent, is it possible that courts could take the true legal nature into account, reconstruct the application of law, thereby guiding institutions and physicians to a new direction? The discussion below addresses this inquiry by taking into account observations of current opinions of the courts.

In some cases, written consent forms heavily influenced the judicial determinations regarding the existence of informed consent. The courts in those cases based their findings on signed consent forms to find that institutions or physicians have fulfilled their obligations of informing the patients.<sup>33</sup> This way of fact finding is not without legal grounds. As certain declarations of the Supreme Court have previously explained, institutions or physicians carry the burden of proof to show that they have satisfied the rule of informed consent; however, when they submit the signed consent forms as evidence, the burden of proof may shift to the patient to show that adequate informing did not exist.<sup>34</sup>

In comparison, in several cases, the Supreme Court has declared that merely relying on signed consent forms is not sufficient enough to determine the satisfaction of informed consent.<sup>35</sup> After elaborating on the spirit of informed consent and identifying the protection of patient body autonomy as the purpose, the court made it clear that the obligation of informing requires substantive explanation and merely asking patients to sign a consent form with related information does not fulfill the obligation.<sup>36</sup> Accordingly, the court criticized the lower court in its failure to sufficiently investigate whether the physician really fulfilled the obligation of informing and whether the patient understood the content of the consent form.<sup>37</sup> In a more recent case, although the court did not elaborate as clearly, it seemed to follow the same train of thought. The court questioned the sufficiency of the consent form before the court as proof that the physician had explained and helped the patient understand the risk and alternatives of the surgery, in light of the fact that the consent form did not contain

the signature of the physician as the form itself required.<sup>38</sup>

These two views lead to different realities. Following the traditional rule of burden of proof, the first view protects institutions and physicians from the accusation without a factual basis. However, it may reinforce the practices that place a great deal of focus on the written consent form. As the previous chapter shows, the formalistic practice is actually not the desired result of the law. To pursue a clearer realization of the spirit of law, courts need to consider changing the interpretation of law. The second view has indicated a possibility of this changing, although the first view appears to remain more common. Considering the severity of criminal sanctions, the traditional view of assigning burden of proof could be sustained in determining criminal liability. On the other hand, in the context of civil liability, this paper argues for a change to the second view. Courts should actively investigate or request institutions for evidence other than consent forms to determine whether any meaningful dialogue existed. This should not be deemed as particularly harsh, considering that institutions are in a better position to find potential witnesses – nurses, anesthetists, and other medical professionals, and so on. This interpretation of law, if it becomes a mainstream judicial view, would help urge institutions and physicians to pay attention to not only written information but also adequate informing.

That is not to say that this proposed judicial response would fundamentally eliminate formalism. Relying on judicial judgments on civil liability still confines physicians to a perspective of legal obligation and liability. Only when physicians sincerely respect patients' rights, will they sincerely practice informed consent and formalism will no longer be an issue. The achievement of this ideal depends on to what extent physicians absorb genuine understanding of informed consent, rather than the threat of legal liability. To promote a more appropriate practice of informed consent, the proposed judicial response could be a key step. But seeking a fundamental change may need to appeal to a scheme that plants the idea of respect for patients' rights deep into every physician's heart when they inquire what the law is truly concerned with.

## Conclusion

This paper has revealed the dynamics and the interactive relationship between law and practices. First, the law may incorporate the idea of informed consent into specific mandates and prompt the implementation in reality. Second, however, the need of evidence in court may sustain or even reinforce the undesirable formalistic practices, which largely focus on written consent forms rather than substantive explanation. Third, to respond to formalistic practices, courts may reconstruct the shape of the legal requirement and guide institutions and physicians toward the practices that further fulfill the spirit of informing. This observation clearly shows the

<sup>33</sup> *E.g.*, Supreme Court judgment No. 2013-Tai Shang-192; Supreme Court judgment No. 2010-Tai Shang-588; Supreme Court ruling No. 2009-Tai Shang-1877; Taiwan High Court judgment No. 2011-Yi Shang Geng Er-1; Taiwan High Court judgment No. 2012-Yi Shang-5.

<sup>34</sup> Supreme Court judgment No. 2010-Tai Shang-2428; Supreme Court judgment No. 2013-Tai Shang-192.

<sup>35</sup> Supreme Court judgment No. 2005-Tai Shang-2676; Supreme Court judgment No. 2006-Tai Shang-3476.

<sup>36</sup> Supreme Court judgment No. 2005-Tai Shang-2676; Supreme Court judgment No. 2006-Tai Shang-3476.

<sup>37</sup> Supreme Court judgment No. 2005-Tai Shang-2676; Supreme Court judgment No. 2006-Tai Shang-3476.

<sup>38</sup> Supreme Court judgment No. 2014-Tai Shang-774.



importance of attending to *law in action*<sup>39</sup> and provides valuable insights on the relationship between law and practices regarding informed consent.

In terms of theoretical understanding, this paper clarifies the legal foundation of informed consent and indicates the failure of the formalistic practices in complying with the spirit of informed consent. The legal requirements of informed consent is rooted in patients' rights, and only approaching the requirement through this right-based perspective provides adequate understanding. Deeming informed consent as merely a legal obligation of physicians, with view to avoiding liability as its purpose, is an oversimplification. After acknowledging that the expectation of law is actually sincere respect for patients' rights, physicians should implement the rule of informed consent by promoting substantive and meaningful dialogue with patients. In that light, providing information only through written forms fails the expectation of law.

Fulfilling the expectation of law largely depends on institutional responses though. The judiciary, as an actor that possesses the final authority over law interpretation, plays a key role. If courts are willing to actively investigate or request institutions for not only consent forms but also more effective evidence to determine whether a meaningful dialogue existed, institutions would be encouraged to focus more on the essence of substantive informing. However, the schemes that seek to transform physicians' understanding of informed consent, other than threatening physicians with legal liability and judicial enforcement, are more important. As this paper has clarified, the true expectation of law is to act out of respect for patients' rights. This sincere respect is the fundamental solution.

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<sup>39</sup> See *supra* note 2.

Yang, Hsiu-I (2002). Warm Paternalism vs. Empty Autonomy: Exactly What Physician-Patient Relationships Does Law Want? *Newsletter for Research of Applied Ethics* (21): 23 (in Chinese).

# Nurses' Awareness of Biomedical Ethics and Their Attitudes Toward Withdrawal of Life-Sustaining Treatment

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## I. Introduction

### 1. The need for research

The development of technologies in life science and medicine have enriched our lives by extending life expectancy through the cure of various diseases. As such, changes bring about abortions, euthanasia, organ transplants, the criteria of death, and stem cells, and they are creating new ethical situation, which make the ethical judgments and practices for them inevitable.

Especially, the development of life science targeting human life and natural environment requires careful ethical judgments and the right institutional responses because of its influences on human lives today and in the future. Accordingly, biomedical ethics began coming to the fore in the sense of new ethical choices for humans in the age of life science since 1960s (1,2).

Since biomedical ethics is a field that concerns human life and is an important issue for health care providers working in areas related to life, a consensus on the ethical standards of bioethics are needed (3). While the development of modern medical technology made a large contribution to curing human diseases and saving lives, it also brought about the meaningless extension of the painful lives of critically ill terminal patients due to limitations of treatment (4).

Such a situation creates many conflicts and ethical issues for health care providers between continuing life-sustaining treatment to prolong the life of the patient and stopping it to relieve the pain and protect the patient's right to die with dignity (5).

Especially, nurses who do not have clearly established opinions on death or withdrawal of life-sustaining treatment face ethical conflicts and tend to be passive in nursing (6). Therefore, nurses' firm awareness of biomedical ethics can be an important factor when they face ethical issues, such as withdrawal of life-sustaining treatment in health care facilities.

Despite such importance, there is very limited research on nursing related to biomedical ethics and

withdrawal of life-sustaining treatment. The majority of nursing research related to biomedical ethics are on the ethics of nurses (7), ethical values of nurses (8), health care professionals or nurses (3, 9,10), or medical or nursing students (11-14). Previous studies on the withdrawal of life-sustaining treatment are mostly focused on the institutional, ethical, and religious aspects (15) attitude of the general public toward life-sustaining treatment; and medical staff and families on euthanasia (5,16).

Accordingly, the present study was conducted to create the foundation of educational data on the establishment of the desirable bioethical viewpoint of nurses by identifying the level of consciousness of bioethics among nurses and investigating their attitudes toward the corresponding withdrawal of life-sustaining treatment.

## 2. Research purpose

The purpose of the present study was to identify the level of consciousness of biomedical ethics and attitudes toward withdrawal of life-sustaining treatment among nurses, and the objectives are as follows:

- 1) To identify the general characteristics of the subjects.
- 2) To identify the consciousness of biomedical ethics among nurses.
- 3) To identify nurses' attitude toward withdrawal of life-sustaining treatment.
- 4) To identify nurses' consciousness of biomedical ethics and the attitude toward withdrawal of life-sustaining treatment based on their general characteristics.
- 5) To analyze the correlation between nurses' consciousness of biomedical ethics and the attitude toward withdrawal of life-sustaining treatment.

## II. Research methods and procedures

### 1. Research design

The present study is a descriptive research to identify the nurses' consciousness of biomedical ethics and the attitude toward withdrawal of life-sustaining treatment, and the relationship between these two variables.

### 2. Subjects

The subjects were nurses working at Y hospital in W city who understood the purpose of the present study and consented to participate. The minimum number of subjects needed to maintain the significance level of .05, effect size of 0.5, and power of .95 was 210, based on the G\*power program, and with the consideration given to the dropout rate, 250 subjects were randomly sampled, and the data from 230 subjects excluding insincere responses were used in the final analysis.

### 3. Research instruments

#### 1) Consciousness of biomedical ethics

The Biomedical Ethics Scale by Gwon (2003), a modified and supplemented version of the ethical value scale developed by Lee (1990), was used for

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