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Special Feature
Should medical accidents be judged in criminal court?—Establishing a new patient safety system in Japan

Should Medical Errors Be Judged by the Criminal Court?
—Towards the creation of a new system for patient safety in Japan—

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Introduction

Article 21 of the Medical Practitioners Act (hereinafter referred to as MPA) in Japan requires a physician to report to a police station within 24 hours when he/she recognizes any abnormality during a post-mortem examination of a body. After multiple cases of medical accidents that occurred at major hospitals in 1999, medical institutions have been required to report any cases of medical malpractice to the police, too, and since then, the number of medical accident cases being tried at criminal court has rapidly increased. In this paper, I point out problems that occur when the criminal justice system intervenes in medical accidents, and would argue that such interventions do not necessarily contribute to medical and/or patient safety.

In more recent years, there have been not a few cases of medical accidents in which the defendants have been found not guilty of professional negligence by criminal court, and, as a result, the prosecution appears to be holding back to a certain degree. Nonetheless, the system still allows criminal justice to intervene any time. We need to urgently establish a system for medical safety as it should be.

The Issues in Medical Safety

The issues in medical safety are namely: 1) How can medical accidents be prevented or decreased, and 2) If and when an accident occurs, how the physicians, other medical staff, and medical institutions involved should respond to it. The issues of medical safety boil down to how to prevent medical accidents in advance and how to respond afterward.

My interest lies in what roles the law should play regarding the two aspects above. In either case, it is indispensable to have foresight and perspective as to what contributions the law can make for the future of medical safety. Both in the past and present, however, the role played by the law in Japan only goes as far as giving sanction or penalty for the previous acts or awarding compensation damages to victims.

These responses are what I call the *sanctioning* type. But can intensifying such tendency really lead to medical safety? I am in search of other possible legal approaches to contribute to medical safety.

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The Number of Criminal Cases Involving Medicine—The number of medical accidents being tried by criminal court has been rapidly increasing since 1999

Professor Hideo Iida, a former prosecutor, examined as many cases of medical accidents as possible that were tried by criminal court and wrote *Medical Malpractice That Were Tried by Criminal Court* and *Medical Malpractice That Were Tried by Criminal Court II*. According to these books, the number of criminal cases involving medicine clearly shows an increasing trend.

More specifically, he found out 137 criminal cases that involved medical practice in the 50 years after World War II. However, in the only 5-year period of 1999 to 2004, there were 79 cases, which clearly show the rapid increase. Furthermore, the mass media began to cover medical accidents more actively and sensationally as well.

The turning point of the increase goes back to the two cases of medical accidents in 1999. In January of 1999 at Yokohama City University Hospital, a male patient who was to undergo lung operation and another male patient who was to undergo heart operation were mixed up and each received the wrong operation. Also in February of the same year at Tokyo Metropolitan Hiroo Hospital, nurses mistakenly injected antiseptic solution in an intravenous drip, and the patient died. These medical accidents that occurred in major hospitals caused a sensation and became a social problem.

Especially in the Hiroo Hospital case, not only those two nurses who made the mistake faced the charge of professional negligence resulting in death, but also the physician in charge, the hospital director, and the Tokyo Metropolitan Public Health Bureau staff, who were all involved in the handling of the accident after it happened, were all indicted under MPA Article 21.

After the cases of Yokohama City University Hospital and Tokyo Metropolitan Hiroo Hospital, there was a trend in society requiring physicians to report any medical accidents to the police under MPA Article 21. Since then, many more medical accidents have been tried by criminal court. According to the statistical data of National Police Agency and other sources, the annual number of reported cases to the police in 1997, 1998, and 1999 were 12, 19, and 20, respectively. However, since 2000, the annual number has been rapidly increasing from 80 in 2000 to 80 (2001), 118 (2002), 195 (2003), 199 (2004), 177 (2005), 163 (2006), 194 (2007), and 186 (2008).

The Intent and Applicability of Article 21 of the Medical Practitioners Act (MPA)

The intent of MPA Article 21

Let us review what this Article 21 of MPA states.

To begin with, MPA primarily defines the qualification, duties and other aspects of physicians who practice medicine in Japan. And its Article 21 states that "if a physician recognizes any abnormality in a corpse or stillborn infant that is 4 months of gestational age or older through a post-mortem examination, the physician must report it to the police station of the jurisdiction within 24 hours." The penalty for violation is a fine of up to 500,000 yen (5,882 USD; 1 USD = 85 yen) under MPA (Article 33, Paragraph 2, Item 1).

A similar regulation existed even in the Meiji period (1868–1912), which objective was to "mandate the reporting of any corpse with abnormality in order to facilitate the discovery of crime since such body is likely to involve a crime." For example, a physician who lost an emergency patient despite his/her best effort may suspect poisoning as the cause of death and report to the police, thinking that a crime is possibly involved. Hypothetically speaking, when a life is lost because of a crime, the culprit or culprits are out there, and therefore, there is a risk of escape and/or committing another crime. The physician's duty to report to the police within the time limit of 24 hours was therefore mandated in order to start an investigation as early as possible, and moreover, a criminal sanction was also defined against violation. This criminal sanction goes no further than a fine, because, in nature, cooperating with the investigation is supposed to be voluntary and not obligatory. However, in case of physicians, the duty to report was probably mandated because physicians are more likely to encounter an abnormal body that was involved in crime. If so, the interpretation of "abnormality" naturally expands. The daishin-in, the former Supreme Court in Japan (existed until 1947), clearly states that, "here, abnormality refers to a case in which any condition not caused by pure illness but leading to death can be recognized in a body," and scholars have supported it.

Applicability of the Duty to Report under MPA Article 21

For example, let's say Physician X mistakenly damaged an artery other than the affected site, and as a result the patient died of massive bleeding. If X admits the error, explains what happened to the patient's family, and apologizes to them, then, would X have the duty to report under MPA Article 21?

If this case is to be indicted as a criminal case, the charge will be professional negligence resulting in death. However, under the current Constitution of Japan, imposing the duty on Physician X to make a report would raise a serious problem under Article 38 of the Constitution, which clearly protects the right against self-incrimination. Furthermore, it brings up a question of whether MPA Article 21 ever anticipated such case.

At least, the administrative agency that governs MPA clearly did not anticipate it in their perspective. In 1981, the then Ministry of Health and Welfare (MHW)*2 published *Interpreting Medical Affairs Act and the Medical Practitioners Act (Including Dental Practitioners Act)* under the name of the section manager of Medical Affairs Bureau General Affairs Section. In it, there is no mention of physicians facing a charge of professional negligence resulting in death by his/her own mistake in medical practice with regard to the applicable cases under Article 21.

The current Article 21 of MPA inherited Article 9 of the Medical Practitioners Act Enforcement Regulations, which were established before World War II. Back then, the police agency was a branch of Ministry of Home Affairs, which governed a wide range of welfare functions, so it would have felt natural that not only crimes but also cases of unnatural death and death by plague were reported to the police.

After World War II, however, Ministry of Home Affairs was dissolved, and the safety of the people in terms of health and medical aspects was entrusted to the then Ministry of Health and Welfare, which is currently Ministry of Health, Labour and Welfare (MHLW). It goes without saying that typical crimes should be reported to the police. But when this change took place, the duty to report involving medicine such as unnatural death or death by illness should have been changed to public healthcare centers or other MHLW-related bodies back then. However, Article 21 of MPA was not revised and remained as it was—probably because, as shown in the aforementioned interpretation by MHLW, everyone naturally assumed that this article applies only to clearly criminal cases (i.e., murders), and no one thought Article 21 had to be modified.

Actually, until someone thought of reporting a case of death due to a mistake made in an operation, the problem did not become evident. Apart from the cases in which a victim (as in the family member of the deceased) of a medical accident reported to the police, no one—perhaps not even the police themselves—anticipated that MPA Article 21 would serve as the starting point for an investigation, requiring the physicians to report on their own mistakes.

*2 In 2001, Ministry of Health and Welfare and Ministry of Labour of Japan were merged and became Ministry of Health, Labour and Welfare.

MPA Article 21 at a Loss

There were two turning points that led to MPA Article 21 "going astray." The first one was *Guidelines for Notification of Unnatural Death* (also known as Abnormal Death Guidelines) announced by Japanese Society of Legal Medicine (JSLM) (which is an academic society of forensic medicine experts) in 1994. The second one was the two medical accidents that occurred in succession in 1999; Yokohama City University Hospital's case in which patients were mistakenly switched, and Tokyo Metropolitan Hiroo Hospital in which the wrong solution was injected in the intravenous drip.

Japanese Society of Legal Medicine's *Guidelines for Notification of Unnatural Death*

In 1994, JSLM released *Guidelines for Notification of Unnatural Death*. It starts with the following statement:

The original purposes of [Article 21 of the Medical Practitioners Act] were probably to detect crime and secure public safety. However, as social life among people became diversified and complex, issues such as human rights protection, public health, health administration, social security, worker's compensation insurance, and life insurance, must be considered more and more important, and accordingly, the interpretation of unnatural death must be defined broadly.

As a basic rule, if a person falls ill, receives diagnosis and treatment, and dies from the same illness, then, it will be considered "normal death." But any other death will be considered as unnatural death.

Additionally, the guidelines also state "any unexpected death related to the medical treatment as well as those with doubt of relation with medical treatment" all count as unnatural death. Accordingly, the cases listed below are all considered as unnatural death.

- Unexpected death during or relatively soon after any kind of treatment including injection, anesthesia, surgery, tests, or delivery.
- Death to which the medical treatment itself may have contributed.
- Sudden death during or relatively soon after treatment for unknown cause of death.
- Whether it was medical malpractice or negligence is not a question.

It is really an unbelievable declaration, but accepting these guidelines, Health Policy Bureau of MHW also issued a statement in 1995, clearly advising that reference be made to these guidelines. So, in terms of how things proceeded, first, forensic scientists who apparently took the intension of MHW boldly embarked upon the new and novel definition of unnatural death as the MHW's study group, then, JSLM produced the guidelines as the fruit of their labor, and lastly, Medical Professions Division of Health Policy Bureau supported the guidelines.

But what were the real purpose and intentions of MHW and JSLM? I do not believe they were hoping to perform a forensic autopsy on every single case of death that occurred during treatment regardless of negligence. Of all the cases of death, a little over 3% of them undergo pathological anatomy in Japan. According to WHO, this figure is the lowest among the 22 nations that collect such statistics. The low proportion of autopsy directly leads to the possibility that there are many cases of death that do not receive sufficient investigation regarding their cause of death. I would presume both MHW and forensic scientists probably became concerned over that situation, and they simple-mindedly tried to open up more ways to investigate causes of death through autopsy to the extent possible. At least, back in 1994 when JSLM released the guidelines, I suppose they did not foresee the current situation of medical accidents turning into criminal cases.

"Risk Management Standard Manual Committee Report" by National Hospital Department of Ministry of Health and Labour of Japan

In August of 2000, the "risk management standard manual committee report" of National Hospital Department of Ministry of Health and Labour stipulated that "in the event of death or injury due to medical malpractice or when such doubt exists, the head of an institution must promptly report to the police station of the jurisdiction." All national hospitals were instructed to follow this rule immediately, and later, private university hospitals and major hospitals including special function hospitals were instructed to do the same.

In this report, the cases to be reported were limited to those of "medical malpractice," unlike the JSLM's guidelines, which had clearly said that they should include all cases regardless of malpractice or not. The hospitals, however, were here instructed to report not only cases of death but also cases of injury short of death. Also, as for the cases of medical malpractice, hospitals were instructed to report any case of medical malpractice—not just for deaths but also for injuries—to the police, even when malpractice is not evident.

Japan Surgical Society's Guidelines

In July of 2002, Japan Surgical Society announced a statement "about death or injury of a patient related to medical treatment." The characteristics of their guidelines are summarized below.

(1) It questions the allegedly new meaning of MPA Article 21. More specifically, it doubts that Article 21 may apply to medical accidents. It is highly questionable that the reporting to the police is a wise policy. Ideally, a third-party agency of medical experts should accept and analyze such reports of medical accidents in order to secure the transparency of medicine and take preventive measures for the future patient safety. Under the current situation in Japan, however, the statement admits that there is no other choice but to report to the police station of the jurisdiction.

(2) It also allows the very physician engaged in treatment, not the head of the hospital, to

notify the police under the title of "report," which I believe is innovative but in a negative manner. Naturally, it brings up the issue of Article 38 of the Constitution, the fundamental right against self-incrimination, but the surgical society states that it is desirable that a physician "voluntarily" report to the police out of "the high ethics required of a physician."

(3) It limits the applicability of Article 21 to certain cases, such as when "major" medical malpractice or "strong" suspicion is involved. At the same time, however, the applicability is expanded to include cases of major injuries in addition to deaths that MPA Article 21 specifies.

The most unique characteristic of these guidelines is that it expresses the idea to act based on high ethics even at the cost of abandoning the fundamental privilege to refuse self-incrimination, and in doing so it tried to regain and maintain the public's trust in medicine. That was indeed a very well-intended expression of determination. But later, Supreme Court took advantage of this good will and made a judgment for the case of Tokyo Metropolitan Hiroo Hospital, that the requirement of reporting by the physicians themselves was not unconstitutional, which is very unfortunate and regrettable.

Cases of Yokohama City University Hospital and Tokyo Metropolitan Hiroo Hospital

Case of Yokohama City University Hospital

In January of 1999 at Yokohama City University Hospital, there was an accident of switching patients, in which a male patient who was to undergo a lung operation and another male patient who was to undergo a heart operation were mixed up and each received the wrong operation.

Six medical experts including the operating surgeon were accused of professional negligence resulting in injury. The district court found the five of six guilty, finding only one anesthesiologist not guilty. Four of the defendants were fined, and one nurse was sentenced to 1 year's imprisonment with suspension of execution for three years. The court of appeal, however, found all six defendants guilty, but all were sentenced to a fine only. Only the anesthesiologist made a final appeal, but it was dismissed according to the Supreme Court judgment (2007-3-26). (Also refer to: Yokohama District Court Decision 2001-9-20, *In* Hanrei Times, Vol. 1087, p. 296; Tokyo High Court Decision 2003-3-25, *In* Tokyo High Court Criminal Case Newsletter, Vol. 54, Issue 1–12, p. 15; *Medical Malpractice That Were Tried by Criminal Court II* written by H Iida & I Yamaguchi (2007), p. 242)

Case of Tokyo Metropolitan Hiroo Hospital

In February of 1999, a nurse mistakenly injected antiseptic solution in an intravenous drip instead of the intended infusion at Tokyo Metropolitan Hiroo Hospital, and the patient died. The important point to note is that in this Hiroo Hospital case, not only the two nurses who made the mistake faced the charge of professional negligence resulting in death, but also the physician in charge, the hospital director, and the Tokyo Metropolitan Public Health Bureau staff, who were all involved in the handling of the accident after it happened, were all indicted under MPA Article 21.

It did not take long before Tokyo District Court found the two nurses guilty of professional negligence resulting in death, and they each were sentenced to 1 year's imprisonment with suspension of execution (Tokyo District Court Decision 2000-12-27, *In* Tokyo District Court Criminal Case Newsletter, Issue 1771, p. 168). Also, Tokyo Prosecutor's Office brought a summary indictment on the physician in charge under MPA Article 21, and he was fined 20,000 JPY as the final decision. The Tokyo Metropolitan Public Health Bureau staff member, who was in charge of the case, was indicted under MPA Article 21 and was found not guilty by the district court, and it became the final decision. The hospital director was indicted under two accounts; one is the charge of counterfeiting of signed official documents for falsifying a death certificate, and the other as the accomplice for the violation of MPA Article 21 for not reporting the case to the police within 24 hours of confirming the patient's unnatural death. When the appeal court sentenced him to 1 year's imprisonment with 3 years' suspension of execution and a fine of 20,000 JPY, he made a final appeal, but Supreme Court reached a final judgment in April of 2004 to dismiss the appeal. Supreme Court made a judgment concerning the relationship between the duty to report under MPA Article 21 and Article 38 of the Constitution.

The duty to report in question can be interpreted as the means to allow the police to get a lead on

criminal investigation and also as the administrative duty to facilitate the social welfare so that the police can take urgent measures to prevent the spread of damage. In any unnatural death, there is a chance that a major crime that led to the loss of life is involved, and therefore, the necessity of fulfilling this duty to report is high in terms of public interest. On the other hand, the legal intention behind Article 38 Item 1 of the Constitution can be interpreted as the guarantee of a person's right of not being forced to confess for items that may incriminate himself or herself. The duty to report mandates a physician to report to the police if he/she examines the body and finds any abnormality with regard to the cause of death or other aspects, and this act itself does not force the physician to make statement on issues that constitute criminal acts. Also, a physician's license provides a person with the qualification to perform medical treatment that can directly influence someone's life, and he/she must also bear the social responsibility that accompanies this. Considering the nature, content, and degree of the duty to report and the unique characteristics required for having a physician's license, and in light of its importance in terms of public interest as mentioned above, the duty to report should be accepted as a reasonable burden that comes with a physician's license even if fulfilling this obligation consequently provides a clue for the police to detect his/her own crime. For the above reasons, a physician who realizes any abnormality during a post-mortem examination should bear the duty to report even if he/she may be accused of professional negligence resulting in death concerning the medical treatment that he/she provided, and it is not considered a violation of Article 38 Item 1 of the Constitution.

The additional critical issue in the appeal to the Supreme Court was whether the hospital director, who did not conduct the post-mortem examination, has violated MPA Article 21 for not instructing to make a police report. On this issue, the court decision made clear two points.

Firstly, the court substantially expanded the interpretation of the conditions stated under Article 21 of MPA, which states "when a physician recognizes any abnormality during a post-mortem examination of a corpse or stillborn infant with a gestational age of 4 months or older." It interpreted that the word "physician" should include a hospital director who is notified of the case. Legally speaking, the court regarded the hospital director as an accomplice to the physician who conducted the post-mortem. In essence, the hospital director himself was held responsible for the duty to report stipulated under MPA Article 21. In future, a hospital director will have no choice but to report to the police to avoid his or her own indictment. More importantly, a hospital director now faces the risk of criminal punishment on one side and the mission to secure medical safety as a hospital organization on the other. It raises a serious question if it is a wise policy for a hospital director to entrust the investigation to the police before responding to a medical accident as a head of a hospital.

Secondly, as I wrote before, Japan Surgical Society had proposed a high ideal in light of the "high ethics required of physicians" at the expense of the constitutional human rights for physicians. The Supreme Court judgment taught a valuable lesson that things have a way of developing unexpectedly. Physicians reached an agreement that they should "report" to the police "voluntarily" when a major medical accident occurs. It is an ethical judgment as medical professionals, never intending that it is a legal duty. But within years, reporting to the police was no longer the ethical or ideal option but became a legal obligation under this Supreme Court judgment. The ideal has been secularized and lost its dignity. From now on, physicians will file a "report" with the police, not voluntarily but out of the fear of criminal sanction. I cannot help but wonder if the Supreme Court judges really believe that the nation governed by law and police in this manner can actually improve medical practice. The current situation is in serious doubt of what roles criminal proceedings can and should play for the safety of medicine.

Case of Fukushima Prefectural Ono Hospital

In December of 2004 at Fukushima Prefectural Ono Hospital (Ohkuma-cho, Fukushima), a woman (then age 29) received a caesarean section during delivery and died due to massive bleeding. Fukushima Prefectural Police arrested the obstetrician on the suspicion of professional negligence resulting in death and violation of Article 21 of MPA on February 18, 2006.

Later, the prosecutor indicted the obstetrician

on two accounts: 1) when pulling the umbilical cord did not detach the placenta from the uterus, the obstetrician should have immediately stopped the placental detachment and switched to hysterectomy or other procedure, and yet by casually detaching the adhered placenta using Cooper scissors the obstetrician invited massive bleeding that led to her death from loss of blood, and this constituted professional negligence resulting in death, and 2) during the post-mortem of the said female the obstetrician recognized an abnormality in the body and yet failed to report to the police accordingly within 24 hours, which constituted a violation of MPA Article 21.

In this Ono Hospital case, the arrest and indictment itself was questioned by many medical experts. The medical circle raised strong objections against the arrest, saying that it was like holding a physician accountable for the outcome of treatment. The media were also rather sympathetic to the defendant in this case, which was unusual. In August of 2006, Fukushima District Court found the obstetrician not guilty. The prosecution did not appeal, and the acquittal judgment became final.

Since 2009, the annual number of medical accidents reported to the police by medical institutions showed a decreasing tendency, to 116 in 2009 and 105 in 2010. The annual number of indicted cases also dropped.

Medical Safety and Criminal Justice

Observations by Professor Robert Leflar

Professor Robert Leflar, an American professor of law who has been conducting a comparative study of medicine and law between the USA and Japan for several decades now, claims that an important difference between the two countries in terms of the legal regulations regarding medical safety lies in the difference of the role played by the criminal justice system. According to Professor Leflar, cases such as those of Fukushima Prefectural Ono Hospital or Tokyo Metropolitan Hiroo Hospital, or even Yokohama City University Hospital, would not have become criminal cases in the US—at least, such chance is extremely small. They would be tried by civil court, not criminal matters. The nurses and physicians involved may face some sort of administrative sanctions, however, and medical or healthcare professionals in the US rarely have to be concerned about the risk of criminal proceedings. If a medical accident is to become a criminal case, it would be limited to a case such as murder or when a drunken or drug-addicted physician was involved in an operation.

To explain this difference, he raised two factors in which American and Japanese law and society are in variance. One is that the Penal Code of Japan includes a crime called professional negligence resulting in injury or death, in which "negligence" as in mere error is sufficient to constitute. In the US, a case of death due to an error can be considered a crime, but it would have to be a major, gross or reckless one. In other words, more increased level of criminal intention has to exist behind the error in question as the subjective prerequisite. The second factor involves the special situation in Japan, in that there was no other means of addressing and sanctioning medical mistakes, and in the end, criminal justice was the last resort for patients. Specifically for the latter, Professor Leflar argues:

Historically speaking, self-discipline by specialist or a peer-review system was never popular in the medical circle of Japan. Hospital receiving a qualification or accreditation was not mandatory but just a voluntary option. Physicians who committed major malpractice hardly ever faced an administrative sanction, either. Until recently, civil lawsuits were also small in number at a level that did not draw attention or serious concern to many physicians in general. Several years ago when Japanese people suddenly became aware that medical mistakes are occurring very frequently, or more frequently than expected, professional organizations for medical experts were still very slow in responding to it. The administrative agency in charge of public health issue was not ready to action, and furthermore, the civil lawsuit system in Japan was inefficient to respond. Because there was no other means to pursue proper public accountability, the police and the prosecution stepped in as a substitute using the laws that are at their disposal. No matter how serious problems went unnoticed by entrusting the role of a regulator for medical procedures to the criminal justice system—and, the problems were indeed serious—pursuing criminal responsibility in some of the major cases that drew public attention in the first few years of this century clearly and effectively acted as a wake-up call to the Ministry of Health,

Labour and Welfare and medical experts in Japan. The criminal justice system of Japan and its activities on which the media at first widely supported produced an effect of filling in the empty space that had been created by the lack of a responsible system of public accountability.*3

As Professor Leflar pointed out, the Japanese medical profession did not practice self-discipline or a peer-review system sufficiently. Moreover, the administrative sanction of a physician is carried out by the MHLW under the name of its minister in Japan (MPA Article 7), but previous records show that almost all cases that received any sanction as a result of their own medical practice were those that were found guilty in criminal court. That means, administrative sanction is only a follow-up after the guilty judgment in the criminal proceedings. Professional or academic organizations such as Japan Medical Association or various fields of medical academic societies have the authority to dispel or penalize their own members, but it is still a sanction by a voluntary organization only with little practical effect.

*3 See the articles written by Professor Leflar listed in the end of this paper, especially No. 7.

Interventions by criminal justice: pros and cons

In a situation such as this, intervention by the criminal justice system has been believed to have at least a few benefits.

Firstly, for patients, being able to rely on the police in cases of medical accidents may have the effect of redressing the imbalance of power. When patients try to confront physicians and hospitals on their own, it is often described as strong physicians on one hand and weak patients on the other. Here, the concept of power includes not only economic power but also gaps in knowledge and access to information between professionals and nonprofessionals. Relying on the police may remedy this unfair relationship and equalize the balance of power.

Secondly, police assistance may contribute to securing transparency. If the police investigation revealed a falsification of medical records, then it would be a crime itself. The threat of criminal punishment can reduce the risk of cover-ups, and consequently, we can expect the truth behind a medical accident to be better revealed. For patients who want to know the truth, that is the hope.

However, increasing reliance on the police or frequent interventions by the criminal justice system clearly comes with disadvantages, namely the following three points.

Firstly, in some cases intervention by criminal justice can rather hide the "truth." Criminal accountability is unique in the way that an individual person becomes the target. Sometimes the corporate accountability of a company becomes an issue, but those cases are exceptional. In criminal procedures, the responsibility of an individual as the principal of a crime is pursued. In other words, a perpetrator or perpetrators directly involved in a given medical accident will be picked and punished, but it goes no further. So, the whole picture of a medical accident is not necessarily revealed in criminal procedures.

Recently, there have been new efforts to prevent medical accidents in Japan, which is drawing attention in society. In this new approach, an accident is not perceived as a problem caused by an individual, but rather, an entire system in which human errors are repeated is recognized as a central problem. It considers comprehensive management of the quality of medicine, including non-human factors.

A similar movement happens in the United States. Institute of Medicine, one of the most authoritative agencies in that country, published a report titled *To Err is Human: Building a Safer Health System* in 1999, which is being translated in many countries. The Japanese edition is popular reading in Japan, too. Its main theme is to bring the information of failed cases including accidents out in the open, learn from those errors, and attempt to create a system that will not repeat the same mistakes. In short, it is the transition from the punishment model, which is preoccupied with penalizing the individual who made a mistake, to the learning model, to think what should be done to prevent further accidents. Medical professionals in Japan are also starting to establish a mechanism to learn from mistakes. Considering such movement currently taking place in society, reliance on the police and criminal procedures could bring back the old ways, in which only one bad guy for one crime gets caught. Or worse, it could possibly result in counteracting the effort to prevent medical accidents or reversing the trend of decrease in

the number of medical accidents.

The second disadvantage from the reliance on the criminal justice system is that it can increase mutual distrust among staff members within a medical institution. Medical practice through team work is now emphasized and praised. Asking only the operating physician who actually performed the procedure and/or the nurses who made a mistake to bear heavy criminal responsibility would split the internal bonds shared among medical and healthcare professionals. The physicians and nurses being targeted would be so isolated that they may not be able to cooperate with future in-hospital efforts such as peer-reviews to prevent recurrence. That could become a major obstacle when trying to reveal how an accident happened.

The third disadvantage I raise concerns the attitude behind the dependency on the police. After all, a medical accident is still within the range of medical arts or expertise. I cannot help but wonder if entrusting the investigation to the police, who are not expert in medicine, is truly considering professional accountability. In people's mind, a proactive police report under MPA Article 21 could appear as if the innate nature of the medical circle is so predisposed to cover-ups that medical professionals have no choice but to actively report to the police. Out of such skepticism, people may think that medical professionals have irresponsibly abandoned the disclosure of truth by entrusting it to the police, that is, medical lay persons.

Needless to say, criminal procedures do have certain roles and significance. The violation of the duty to report itself is, however, not considered a major offense—its violation is only fined. In contrast, an act of covering up, like falsifying medical records, is considered a major problem. Maybe active interventions by the criminal justice system can scare physicians, making them think that trying to cover up would cost highly. Then, active intervention has some significance. But at the same time, many physicians would probably feel ashamed at such notion. What people really want is trustworthy medicine and a patient-physician relationship in which there are no cover-ups even without any interventions by the law enforcement, I believe. Criminal sanction is like a strong poison that requires utmost care in the administration, and prolonged dependency to it can weaken the "patient"—in this case the medical practice in Japan—as a whole.

Efforts within the Medical Circle to Investigate and Analyze Medical Accidents

As I have stated above, the medical circle itself must strive to analyze the cause of medical accidents and prevent recurrence in order to put an end to the criminal justice system's interventions. Described below are some of the efforts that have been made since 1999 in Japan.

Duty to report medical accidents to a public health agency

Since October of 2004, the amendment of Medical Institutions Act and its regulations have required the 272 major hospitals including those called as specific function hospitals to report any medical accidents to Japan Council for Quality Health Care, a public-interest association, which examines and analyzes the reports and considers preventative measures.

Model project to investigate and analyze deaths that are related to medical treatment (by Japanese Society of Internal Medicine)

In September of 2005, Japanese Society of Internal Medicine initiated independent efforts to conduct post-mortem examinations for the deaths related to medical treatment, with the support of 38 medical and dental professional societies. In this project, called the "model project to investigate and analyze deaths that are related to medical treatment," physicians whose expertise are autopsy and a post-mortem examination and other physicians of a variety of expertise together conduct a medical evaluation of the clinical progress of the deceased. This project, funded by MHWL, investigated a total of 105 cases in 4 years and 6 months. Since April of 2010, Japan Council for Medical Safety Investigation, another public-interest association, took over the project. This model project has been an independent, voluntary effort for the medical safety of the entire medical circle and societies. Its activity is highly esteemed, but it has many obstacles, including the insufficiency of financial support and the lack of mandatory investigation power, since it is supported only by the voluntary efforts on the part of medical professions without any statutory basis.

Steps toward legislation

MHLW announced the "draft plan concerning the pursuit of causes of death related to medical treatment: the second draft" in October of 2007, then, "draft plan concerning the pursuit of causes of death and preventative measures in medical accidents to secure medical safety: the third draft" in April of 2008, and finally, "outline draft of the bill to establish (tentatively called) medical safety investigation committees" in June of the same year.

The outline draft aims to establish what they tentatively call medical safety investigation local committees, which will appropriately conduct investigation to pursue the cause of death in medical accidents and other unnatural deaths, whereas a medical safety investigation central committee (also a tentative name), which will provide recommendations and other statements with regard to the measures to employ in order to improve medical safety. This proposed system has the following three points to note.

(1) In order to cut the flow of MPA Article 21 linking to the police, local committees for medical safety investigation consisting of medical professionals and other experts will investigate medical accidents.
(2) Gross negligence is required to apply the charge of professional negligence resulting in death for medical accidents. The current Article 211 of the Japan's Penal Code just states "negligence," just as the equivalent law in New Zealand once did. But when this term was revised to "gross negligence" in New Zealand, it brought considerable change in the nation. So, maybe we could expect the same result here in Japan, too.
(3) A local committee will examine whether a given medical accident constitutes a crime, and if and when it was found to be: a) suspicious of intended murder or stillbirth, b) suspicious that the death or stillbirth is caused by medical treatment that is far below the standard one, c) suspicious that evidence has been destroyed, falsified, or modified with the purpose of hiding the facts concerning the said medical accident or unnatural death, a similar accident was repeated due to negligence, or any other major equivalent unethical act is involved; only then, will it be reported to the police. The third point, filing a police report, would require the advance decision by a third-party agency, in which medical practitioners will professionally check before the police and prosecutor's office become involved, will serve as a procedural safeguard for not leading to the intervention by the criminal justice system.

Ministry of Justice and National Police Agency both supported this outline draft, which is a very important aspect. However, some members of the medical circle raised a voice of opposition, and the bill has not been legislated yet. The reasons for their opposition are as follows.

(1) The term "gross negligence" is ambiguous, and it does not clarify the range of punishment.
(2) A third-party agency will be reporting to the police under certain conditions, so it will serve as a channel that links a medical accident to the police. But the truth is that the purpose of the establishment of a third-party agency is to narrow the way to the police, so it seems more like paranoia.
(3) A medical institution will be required to report any medical accidents to a third-party agency if "a patient is lost due to clearly inappropriate medical treatment" or "a patient is lost due to medical treatment provided, although it is not clear if the treatment was inappropriate or not." The coverage of report appears to be broad so that the new system might be more burdensome than the current situation.

Concluding Remarks

Accidents will happen is an English expression I learned when I was in junior high school. Here, the word "will" does not refer to a future in tense, but implies a likely or inevitable event. In Japan, we have a proverb *Getting hurt on tatami*, which means people can get hurt in places that are presumably safe. It is almost equivalent to the English expression *Accidents will happen*. In both expressions, the message is that you can never know when or where accidents or the unexpected will happen. Although such expressions are commonly used in everyday life, Japanese people are more stringent with mistake than the people of other cultures, and it would certainly provoke antipathy if a physician were to use it to a patient.

However, we need to have the wisdom not to let the accidents that have already happened

become a negative contribution—but instead, we must think hard and use our brains to turn the negative into positive. The people who suffered medical accidents are victims, of course. But at the same time, the physicians involved also suffer from accidents, in a sense. We cannot just say "okay, your life is over now" to those physicians and stigmatize them as criminals. For as long as they are alive, they should be allowed to fulfill their lives for the better (and in the way that they can help others). There must be something the legal system can do toward such goal, not through sanctioning them but by supporting them—and for those physicians, having such lives will truly be a way of taking responsibility as physicians, I believe.

At present, MPA Article 21 still exists, with solemn authority. If a major accident occurs, the police will investigate under the suspicion of professional negligence resulting in death, and the police will not reveal any information obtained to maintain the secrecy of the investigation. Even if an investigated physician wants to somehow make use of his/her experience for the good of other physicians in similar positions as early as possible, the investigation system will not allow that until the investigation is completely over.

I sincerely hope this paper would serve as a small but important step to re-evaluate the need to rectify the current situation in Japan.

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