Accident or Crime?: Thoughts on criminalization of medical accidents[*1]

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Pronouncement of a Judgment

On August 20, 2008, seven outside broadcast vans and many press photographers waited in front of Fukushima District Court on a usually quiet street of Fukushima City, Fukushima Prefecture, Japan. With feverish excitement, 788 people lined up to get 27 public admission tickets. The judgment on the case of Prefectural Oono Hospital was to be pronounced in Court Room No. 1 of Fukushima District Court on this day. The case that started with the arrest and indictment of a physician on February 18, 2006 was concluded after 6 pretrial conference procedures and 14 trial procedures, and the judgment was going to be given, watched by the whole medical community. The court opened at 10 a.m.

"The Accused is declared innocent!!"

At the first words of the Chief Judge, press reporters in the public gallery rushed out of Court Room No. 1. The crowd in front of the Court buzzed with the news, broadcasters made a quick report of the acquittal of the physician, and extra editions of newspapers were handed out at Fukushima Station.

What Is the Fukushima Prefectural Oono Hospital Case?

A woman with an extremely rare condition of placenta previa and placenta accreta underwent cesarean section and died at the Oono Hospital. The physician who performed the operation was arrested for professional negligence resulting in death and violation of Article 21 of the Medical Practitioners Law.

Two Faces of the Accident Investigation Commission

Cause for investigation

In every criminal case, there is a cause to start investigation.

The Law of Criminal Procedure provides that investigation be initiated by (1) the discovery of an offender during the committing of a crime, (2) the postmortem inspection of an unnatural death, (3) accusation, (4) complaint, and (5) the surrender of a criminal. In addition, (1) reporting from a crime victim or a third person (complaint report), (2) police questioning, (3) newspaper and magazine articles, a letter from a citizen, an informer's report, a rumor, etc. may trigger investigation. In the Oono Hospital case, the prosecutor asserts that the report of the Prefectural Accident Investigation Commission released on March 30, 2005 triggered their action.

An accident investigation commission is summoned when a medical accident has occurred. The essential purpose of the commission, naturally, is to clarify the sequence of events leading to the occurrence of the accident in detail with an eye to prevent the recurrence of medical accidents. However, except for grossly evident cases such as leaving surgical instruments in the abdominal cavity and mistakenly excising a healthy organ, it is an extremely difficult task to find demonstrable negligence in the act of medical practice when the process of performing medical procedures has ended with an unexpected result.

Accident investigation report

On the other hand, it is also necessary to consider

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compensation for accident victims as soon as possible. A problem here is that an accident investigation report may conclude differently depending on whether the main focus is on analysis of the cause of accident or compensation for the accident victim. In the Oono Hospital Case, the purpose of the accident investigation that the Prefectural Hospital Bureau commissioned to the Accident Investigation Commission focused more on "compensation for the family of the deceased patient" than on "fact finding." According to a member of the Commission, the Bureau commissioned it, stating "We expect investigation considering the application of liability insurance to the family of the patient assuming the presence of negligence."

This fact was articulated in the defense's opening statement following the reading of indictment at the 1st trial session as follows:

"The said report was prepared envisioning prevention of future accidents and considering the application of liability insurance assuming the presence of negligence, and should not be considered to admit the presence of negligence that might result in a charge of criminal liability against the accused."

The Bureau was not unique in taking this reaction to a medical accident. Considering the cost effectiveness of lengthy contention in civil and criminal proceedings, managers of national, public, and private hospitals share the common view that a better approach in terms of cost performance is to apologize to the victims and seek settlement out of court.

The accident investigation report assuming the presence of negligence pointed out the potential involvement of malpractice in the patient's death, stating that "the physician might opt to halt placental removal before using Cooper scissors and immediately switch to hysterectomy," "placental removal should have been performed after the arrival of adequate blood," and "it was necessary to ask for assistance of physicians in other departments and to increase infusion flow rate by establishing an infusion route."

Press conference

On the basis of this report, a press conference was held by the head of the Prefectural Hospital Bureau, the director of Oono Hospital, and the chairperson of the Accident Investigation Commission at Fukushima Prefectural Office on March 30, 2005.

Stereotypical headlines made the front page of newspapers the next day, March 31: "Malpractice Caused Maternal Death, Prefecture Admits Negligence and Apologizes" and "Prefecture Admits Malpractice." From this point, the situation started to develop in a direction contrary to the expectations of the Bureau and physicians.

In the court trial, prosecutors alleged that the prefectural police had first become aware of the medical accident through local newspaper coverage of the apology press conference of the head of the Bureau and the director of Oono Hospital, and filed front-page articles of local newspapers as evidence. However, strangely enough, the Prefectural Accident Investigation Report itself was not filed as evidence throughout the process of the trial. Despite this fact, the 2 prosecutor's expert witnesses, who were not specialists in perinatal care, wrote their expert opinion reports basically misled by this accident report. The prosecutors seem to have considered that having expert witnesses recapitulate the content of the report might be better than filing the report itself as evidence.

Review the events again

There were more strange facts. Let us look at the sequence of events again. First, the investigation report presupposing the presence of negligence was prepared at the request of the Prefectural Hospital Bureau. After the press conference of the head of the Bureau and the director of the Oono Hospital in the Prefectural Government office, the media made a great fuss about the prefectural hospital's malpractice, and the Prefectural Police Headquarters commenced investigation triggered by the media coverage. Then, why did the Bureau not explain to the Headquarters the "aim" of the report? Why did the Headquarters not gather information from the Bureau before initiating investigation? The Headquarters is the 4th floor of the Prefectural Government Building, and the press club is on the same floor. The Bureau is in a building sharing the same premises side by side with the Prefectural Government Building. In view of this relationship, the lack of information exchange to meet the minimal need in investigation is puzzling, even considering the fact that these 2 organizations are in different chains of command with the Hospital Bureau under the governor and the prefectural police under the

Chief of Headquarters.

Why Was the Physician Arrested?

Arrest in one year and two months

Police investigation started on April 1, 2005, and Dr. K who performed the operation was arrested and detained on February 18, 2006. One year and 2 months had already passed since the occurrence of the medical accident. February 18, 2006 was Saturday. The police station in charge searched the residence of Dr. K on this day from 7 a.m. to 9 p.m. After the search, Dr. K was told by the investigators that they had something they wanted to ask, and he went voluntarily with them to the police station. An arrest warrant was read in the investigation room, and the physician was confined in the detention room of the station, a substitute prison, for approximately 1 month until he was released on bail on March 14.

Article 199 (2) of the Code of Criminal Procedure provides that "in cases where a judge deems that there exists sufficient probable cause to suspect that the suspect has committed an offense, he/she shall issue the arrest warrant upon the request of a prosecutor or a judicial police officer except in cases where the judge deems that there is clearly no necessity to arrest the suspect." At the time of arrest, Dr. K was the head and the only physician of the department treating 10 inpatients at the Obstetrics and Gynecology Department of Oono Hospital and seeing nearly 30 outpatients every day, and the police had already gathered evidence. Considering these facts, it should have been possible to investigate the case without arrest.

In the first place, arrest and detention are legally allowed only when there is the possibility of flight of the suspect or the concealment or destruction of evidence, according to Article 60 of the Code of Criminal Procedure.

Dr. K obviously had a fixed residence, he was regularly employed as a physician, and he was going to have a child shortly. In this situation, it was evident that he would not flee because of a charge of negligence. (As it turned out, Dr. K's wife gave birth to their first child while her husband was detained.) As for the possibility of concealment or destruction of evidence, the material evidence including medical records had already been confiscated, and interrogation of related persons had largely been completed. Even if one suspected the possibility of concealment or destruction of evidence through conspiracy with associated persons, such possibility was very small at the time when 11 months had passed since the beginning of investigation. Nevertheless, the Court permitted detention and also rejected the defense appeal against the elongation of detention on March 2.

Considering these aspects of the situation, it seems natural to infer that the investigating organization resorted to the arrest and detention of Dr. K with the intention of interrogating the suspect in confinement and elicit a confession. This suggests how greatly the investigators were in need of a confession in this case.

Opinion letters

As soon as Dr. K was arrested and detained, a number of opinion letters were sent to the Court, objecting from a medical standpoint to the deduction of negligence of an individual from the process of this medical accident. (The author was one of those who submitted opinions.) However, on March 10, the Fukushima District Public Prosecutors Office brought in an indictment against Dr. K. Under the principle of discretionary prosecution stipulated in Article 248 of the Code of Criminal Procedure ("where prosecution is deemed unnecessary owing to the character, age, environment, gravity of the offense, and circumstances or situation after the offense, prosecution need not be instituted"), the decision regarding whether or not to prosecute was at the discretion of the prosecutors. It is not clear whether or not the prosecutors were working presupposing prosecution from the beginning, nor whether or not they were in a situation in which they had to prosecute. What the Office clearly failed to notice was the presence of extraordinary tension running throughout the whole medical community.

Many Voices from the Medical Community

Strong shock to the medical professions

The arrest and detention of Dr. K gave a great shock to not only obstetricians/gynecologists working in the same field as he but also many medical professions who are faced with frequent occasions requiring emergency responses in daily clinical practice. There had been previous cases in which physicians performing operation and

Table 1 Number of hospital-based physicians at medical institutions handling childbirth

	Number of institutions	Ratio of medical institutions handling childbirth	Number of hospital-based physicians					
			1	2	3	4	5–9	10–
Hospitals	1,273	52%	187 15%	299 23%	285	159	235	93
Clinics	1,783	47%	1,214	452		99		
Total	3,056	99%	1,401 46%	751 25%		871 29%		

(JSOG Survey in 2005)

other physicians were arrested and detained for charges related to medical practice (the case of medical record tampering at the Heart Institute of Japan attached to Tokyo Women's Medical University, March 2001 and the case of a laparoscopy accident at Jikei University Aoto Hospital, December 2002). However, medical professions strongly protested against the arrest and detention of Dr. K in the Oono Hospital case, which was unrelated to obvious violation of rules, such as tampering with medical records and performing advanced medical procedures at a medical institute without authorization. As the details of the practice of Dr. K in this case became known, some expected that the prosecutors would drop the case due to a lack of reasonable suspicion.

However, on March 10, the prosecutors office mentioned above indicted Dr. K, and an increasing number of voices of disappointment and objection against the office were raised from the medical community of Japan's nearly 100 medical organizations, including the Japan Society of Obstetrics and Gynecology (JSOG). Other specialized academic organizations, medical associations, and associations of specialist physicians submitted statements of protests, opinions, and requests. It was unprecedented in the history of criminal trials in Japan that so much criticism was raised regarding the charge against a physician of professional negligence resulting in death.

Furthermore, when Dr. K was released on bail on March 14, he was forbidden to meet, correspond with, or contact any persons related to this case, including the staff of Oono Hospital and his colleagues at Fukushima Medical University, by telephone, mail, or any other means, in addition to the bail of 6 million yen (60,000 USD, 1 USD = 100 yen). The medical community also frowned on this strict condition of release. To the utmost astonishment of medical profession, the police station received official commendation from the Chief of Police Headquarters for the merit of arresting Dr. K.

In addition to accusation against the prosecutors, many expressed a sense of crisis: "A medical accident in a single-physician department may turn out to be a criminal case."

Withdrawal of experienced physicians

According to a national survey conducted by JSOG in 2005, the year before the arrest of the physician, single-physician departments existed in 15% of major hospitals handling childbirth. Of the 3,056 institutions handling childbirth in Japan, including small clinics, as many as 1,401 (46%) were operated as single-physician practices. The mean number of regularly employed physicians at major hospitals was 1 or fewer than 2 in 8 prefectures. The percentage of hospitals with 2 or fewer physicians among all hospitals was 71% in Fukushima Prefecture and 60% in other six prefectures. In one of these prefectures, 40% were single-physician practices. More and more experienced physicians left core hospitals, where community medicine had scarcely been supported by the hard work of these solitary physicians.

The domino-effect degradation of the sphere of obstetric medicine, which later created the term "obstetric refugee," was triggered in the first place by the arrest and prosecution of the solitary physician in the Oono Hospital case.

How Should We Evaluate the Process of Medical Practice?

Nothing is absolutely perfect

In any field of medicine, not limited to obstetrics, there is nothing that is absolutely perfect. This fact was well acknowledged in society at large in the past. However highly medical science and technology may develop, this fact never changes. In the case of driving a car or piloting an airplane, accidents should basically not happen as long as operation is performed according to the manual. This does not apply to medicine, where the subjects of action are not healthy human bodies but those with some disease. The condition of the disease changes from moment to moment, and there are also individual variations. Therefore, it is natural that physicians are required to treat patients making quick decisions according to circumstances. It is not appropriate to discuss responsibility for the result by skipping the process leading to the result.

Acts of medical professions are accompanied by the risk of death in many patients. A slight difference in the procedure performed may be directly connected to death in a number of cases. As this fact implies the foreseeability of death, it is not reasonable to interpret it as the duty to foresee in the Penal Code. Let me emphasize again that medicine is not almighty. There are many areas that are not fully understood by medicine, and there naturally are limitations.

With the diversification and specialization of medicine, we need to adhere to the general principle of medical information disclosure, and address cases of unexpected results by evaluating the processes leading to the occurrence of incidents making use of specialist analysis or peer review.

Evaluation by expert witnesses

In the case of civil trials of medical cases in Japan, there is a system of recommending expert witnesses. In this system, the Medical Suit Board of the Supreme Court asks specialist academic societies to recommend expert witnesses that are the most appropriate for trials of medical cases. The recommended expert witnesses evaluate the process of medical practice from an independent position. In principle, the basis for evaluation is which of the following categories applies to the acts conducted by medical professions:

1. Intentional act: This is a crime conducted through medical care, corresponding to homicide or bodily injury.
2. Careless accident: This is an accident caused by a casual mistake, such as mistakenly substituting one drug for another or a simple error in performing a procedure. This occurs when a person acts in an unintended way due to simple carelessness or mistake.
3. Accident due to inexperience: This is an accident resulting from a lack of sufficient knowledge or technical experience. This applies to a case where the person responsible is evidently below the professional standard.
4. Professional case: This is a case where the judgment and acts of a profession conducted at his or her discretion resulted in a bad outcome.
5. High-risk case: The occurrence of a bad outcome that inevitably takes place with a certain probability.
6. No association: This is a case where the alleged fact is not causally associated with the act of medical practice or where the alleged fact is nonexistent.

Intentional acts (1 above) are naturally culpable. Such cases are very rare in Japan. Careless accidents (2) and accidents due to inexperience (3) are usually recognized as negligence in expert opinion. (Needless to say, (2) and (3) may sometimes be traced back to accumulation of systematic errors in the medical practice system as a whole, such as overworking of physicians and nurses.) The acts (4) and (5) are on the border line and judged non-culpable in most cases, but in other cases judged no-fault.

Placenta previa is medically considered as high risk, irrespective of the presence or absence of placenta accreta, and is a frequent cause of maternal death. Of the 230 cases of maternal deaths that occurred in the 2 years from 1991 to 1992 in Japan, detailed investigation into the cause of death was completed in 197 cases (Study on the Prevention of Maternal Death, Ministry of Health and Welfare Studies of Physical and Mental Disorders, Fiscal Year 1996 Research Report) and identified 7 cases of death from placenta previa (3.6%, including 4 cases accompanied by placenta accreta). In all these cases, death is considered to have resulted from hemorrhagic shock due to poor uterine contraction after child delivery accompanied by DIC.

Therefore, the process of medical practice taken by Dr. K in the Oono Hospital case is considered to fall under 4 or 5 among the 6 categories which is a rough classification of civil liability.

How the Accident Investigation Commission Should Be and Work

Importance of the accident investigation commission

The accident investigation commission set up in-house or attended by outside members is an important instrument to evaluate the quality of medical care, particularly outcomes. How the accident investigation commission should be and the work is a subject of active discussion not only in the medical community but also in industrial circles. Naturally, the purpose of the accident investigation commission is "the prevention of similar accidents in the future," and the content of an accident investigation report is organized into the gathering and understanding of factual information, analysis, results, and conclusions and recommendations. However, as the case of Oono Hospital exemplifies, an accident investigation report may often trigger criminal investigation.

Discussion is also taking place around the concept of the "Medical Safety Investigation Commission," which the Ministry of Health, Labour and Welfare proposed after the Oono Hospital case as a medical version of the "independent accident investigation commission." There is an unprecedentedly strong movement towards reform to combine accident investigation and criminal investigation procedures as an integrated whole. In such reform, it is always necessary to consider (1) assurance of the procedural right of the persons under investigation (the right of silence) and (2) restriction on the use of material obtained through accident investigation.

Regarding the accident investigation report of an airplane accident, some countries legally prohibit the out-of-purpose use of information other than "factual information." In Japan, a certain extent of mutual cooperation was provided in the Memorandum regarding the Act for Establishment of the Aircraft Accident Investigation Commission signed between the National Police Agency and the Ministry of Transport at the time in 1972 and in the Details regarding the Implementation of Criminal Investigation and Accident Investigation signed between the National Police Agency and the Aircraft Accident Investigation Commission at the time in 1975. In the US, the National Transportation Safety Board (NTSB), which is the organization conducting accident investigation, takes precedence over the Federal Bureau of Investigation (FBI) unless an intentional crime is reasonably inferred.

In contrast to the US, where an act of simple negligence is not punished as a rule, Japanese citizens share a general consensus that an act of simple negligence resulting in personal death or injury is punishable. Although there may be a need to consider this difference, it is certain that the intervention of criminal and judicial authorities should not interfere with information acquisition during accident investigation, as such interference would have only negative effects on the management of the quality of medical practice.

True relief of the victims

On the other hand, as seen from the standpoint of the general public, some consider that an accident investigation ending in stereotyped "prevention of similar accidents" may not be effective in realizing a true remedy for the victims, even if the purpose of accident investigation is shifted from accusation of individuals with liability in negligence to identification of system errors.

The same applies to medical disputes. We should promote a shift from accusation of neglect of individuals to identification of system errors, and redefine the way that the investigation commission works so that the end point of investigation should be the improvement of the survival rate in the event of a medical crisis. In other words, we should set our sights on the increasingly diversified and multilayered medical care in the future, keeping up with the development and popularization of advanced medical technologies, and study the conceptual change taking a step ahead from "risk management" to "crisis management."