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

The Case of Tokyo Women's Medical University *From the standpoint of the person concerned*

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In March of 2001, in the radical operation for atrial septal defect and pulmonary stenosis of a 12-year-old girl at Tokyo Women's Medical University (TWMU), I was the physician in charge of the heart-lung machine operation. In 2002, I was arrested on suspicion of professional negligence resulting in death, and in 2009, I was found not guilty of professional negligence by Tokyo High Court.

Malicious Arrest and Illegal Investigation

When arrested, where is a physician taken to? When I was arrested, I thought I would be taken to Tokyo Prison or Tokyo Metropolitan Police Department. But no, I was taken to Ushigome Police Station, which I had often visited during the voluntary interrogation stage. When I was arrested, I was taken to the police cell of the same place, a so-called substitute prison. There, the interrogation by a prosecutor starts, and it often goes on until 2 AM. At the same time, I was also interrogated by the police—namely, Investigation Division 1 and Special Investigation Section 3, which are mainly specialized in cases of professional negligence in medicine resulting in death.

In the police investigation in those days, my e-mails were read without my consent even during the voluntary investigation state. I have no doubt about it. Also, my phone calls were being tapped. In addition, they applied tremendous pressure to the medical staff who criticized TWMU's internal report and supported me.

In substitute prison, there are problems of human rights violations and injustice. Being forced to sign the record of interrogation—a so-called letters of confession—that they prepared creates false charges, as everyone knows. Sometimes, an interrogation lasts 20 hours while being handcuffed and tied by a rope around the waist. They also use starvation tactics, and meals are very poor. Besides these problems of a substitute prison, there is another issue that is not often recognized—that is, you cannot take any notes. Mr. Kitamura who is here today was able to take notes at the Supreme Court when he observed the proceedings from the public seat, but he fought to win that right for us. Being able to take notes seems like a fundamental right, but in substitute prison, the arrested suspect cannot make any notes.

Prosecutors and police officers have an interrogation manual. In this manual, it states that "for a big case with social influence, like a case that the media is covering extensively, the authorities should build a case and investigate even if the proof to sustain the case is insufficient." These are the words of Mr. Hideo Iida, who worked as a prosecutor for years and dealt with criminal cases in medicine. And, the police manual says that officers "need to have determined drive with persistency and tenacity to get a confession," and "once in the interrogation room, never let the suspect leave the room until he/she makes confession."

Only lawyers can confront such police and prosecutors. By mere coincidence, my best friend during the junior year of my high school, Mr. Tatsuo Ninoseki, is a lawyer, and fortunately I

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was able to have him as my lawyer immediately after the case was covered by the media. And later, he and Mr. Kitamura, who is his senior and mentor, became my defense counsel as a team.

In his speech, Mr. Kitamura talked about things to keep in mind when one becomes a suspect. In a magazine *Jamic Journa*l [in Japanese], I wrote a piece titled "Fighting Against the Leviathan" in a series (6 installments), and explained how to deal with investigators who conduct what seems to be an illegal investigation (from the Oct-2008 to Mar-2009 issues). I also wrote an article in *Medical Care Research* [in Japanese], published by Tokyo Medical Practitioners Association, about general issues in the medical judicial system including investigators as well as judges (the May-2009 issue), and I very much hope you will have the opportunity to read it.

We Need a System to Save Patients Involved in Medical Accidents and Minimize Recurrence

So, let's consider medical accidents in general. What should a physician do when a medical accident happens?

We physicians practice medicine to save patients. Therefore our first priority is to relieve the damage suffered by patients. Secondly, we need to investigate the cause and work to prevent the same accident from happening again. And thirdly, if someone is accountable, then his/her responsibility must be reviewed—and if necessary, an investigation may be in order to determine accountability. I believe this kind of concept is behind the bill of establishing the medical safety investigation committee.

But, when you think about it, of these three priorities, the second and third ones are contradictory. Is it really the right thing to entrust all of them to just one agency?

I believe the key note speech by Dr. Higuchi addressed something very important. Currently, Article 21 of the Medical Practitioners Act stipulates that a physician must report to the police, receive criminal punishment, receive administrative sanction, and pay a civil liability. Is this current system really helping the medical safety of patients? I say no, for sure. The current system is not helping medical safety at all. The legal system cannot guarantee the safety or future of patients.

It is good that legal experts discuss the system plan or where responsibility lies. But when it comes to addressing medical safety, medical accidents, or investigating the cause, they are all laymen. And, as for a medical safety investigation committee, I believe it should be created with the benefit of all citizens in mind. What I am trying to say is, it should aim to relieve all patient damage, and, take preventative measures scientifically without being preoccupied with finger pointing.

The importance of relieving patents impartially and equally

Regarding relieving all patient damage, I personally feel that, for any accident that occurs in medical practice under the universal national insurance system that Japan is so proud of, naturally, all patient damage should be remedied based on the very spirit of the universal national insurance system. And, it should be unbiased and equal, and not just for patients (or their family) who claim with persistence or cases that the media covers extensively. For this to happen, politicians, administrators, lawyers, physicians, and other specialists and experts need to collaborate.

The autopsy rate in Japan is down to 2%. The so-called "model project of medical accident investigation for death that involves medical practice," is implemented only to those autopsied cases, on the premise that only 2% are autopsied in the Japanese system. I believe this goes against the spirit of relieving impartially. The target for this model project was 1,000 cases in 5 years, but the project was implemented in only 105 cases—that's only 10% of the target. Wouldn't you say that this project was a major failure? I would think the project will be modified in various details as time goes—but so far, its outcome is questionable.

Review a medical accident that has already occurred under the guidance of medical specialists who regularly practice similar medical acts, and consider preventative measures

So, who should be entrusted with the task of taking preventative measures scientifically?

To discuss this point, I would like to briefly mention the case of mixing up patients that happened at Yokohama City University Hospital. In this case, the hospital mixed up a patient who needed cardiac surgery with another who needed

lung surgery, and conducted the wrong operation on each. One instructor who used to work at a nursing school saw this news and said, "the basic rule of nursing is to check three times, and this kind of mistake happens because the basic is no good." This "check three times" refers to the important idea for physicians and nurses when carrying out medical acts, to confirm at each stage of preparing, conducting, and finishing treatment. She died about a month later in a case of mistaken drugs—when she was hospitalized at Tokyo Metropolitan Hiroo Hospital, by mistake an antiseptic solution was injected to her arm vein. This case, which became known as Tokyo Metropolitan Hiroo Hospital Case, was covered by the media extensively.

As for the "check three times" rule involving drug administration, before the case of Hiroo Hospital, there was a case of injecting ethanol by mistake at Kyoto University Hospital. In this case, distilled water was supposed to be injected in a ventilator's humidifier but ethanol for disinfection was injected by mistake, and the patient died of acute ethanol poisoning. A nuclear power safety and control researcher at the time said "Everything depends on one act, conformation. This is just surprise. Medicine lacks in systematic ideas. It is obvious that medical system planning is designed incorrectly," in his written opinion. This person works in medical safety now, and has written books.

To scientifically take preventative or safety measures, medical staff who are actually engaged in clinical practice have to take part, as well as specialists and medical engineers who are currently actively involved in medicine. Surgeons who have not operated for years and are busy attending meetings cannot help. Specialists who are currently active must be involved. And to address human factors and safety measures, safety specialists must also participate.

As Mr. Higuchi already mentioned, I believe lawyers and scholars should play a supportive role when it comes to this issue, and criminal law experts and media have no part to play in this issue.

Seeking Criminal Accountability Can Be an Impeding Factor for Medical Safety

Regarding criminal accountability for physicians, physicians now strive to achieve professional autonomy. Among physicians, we have a fair concept called *peer review*, besides the so-called *top-down* concept. And, we try to have this professional autonomy. For this aspect, I would like to have opinions from lawyers and scholars.

But some criminal law experts and media still strongly insist on seeking criminal accountability against medical personnel. But seeking criminal accountability of medical personnel does not help with the investigation of the cause, and in fact, it could become a factor that impedes medical safety. This is not just my idea. In "Various problems involving accidents and negligences" in *Criminal Law Journal* (Vol. 28, 2011) [in Japanese], which discusses not just medical accidents but various accidents, an expert expresses the same idea. Also, *Responsibility of Medical Accidents* (2007) [in Japanese] written mainly by a lawyer Keiko Kamiya clearly says the same thing, too.

Consider the Scientific Investigation of the Cause and Improvement of Safety by Studying the Operation Methods Used in This Case

In this TWMU case, the death was caused by brain disorder while the patient was on the heart-lung machine. Regarding the cause of death, Tokyo High Court stated that the poor positioning of a blood withdrawing cannula inserted in the superior vena cava caused cerebral circulatory insufficiency. As Mr. Kitamura said, this is what the defense counsel had been claiming since the beginning. But most people were not aware of it—because it was not covered by the media and no medical society made an announcement.

There is a saying, "Big Surgeon, Big Knife." In the old days, a skillful surgeon made large incisions. Even a famous surgeon who was decorated twice by the president of the United States made large incisions. But in the 1990's, laparoscopic surgery, which uses small incisions, was employed in gastrointestinal surgery, urology, gynecology and obstetrics. So, less invasive cardiac surgery and small incisions became popular in pediatric cardiac surgery as well. Today's audience are mainly physicians, but if I show a picture of the operation site in small-incision cardiac surgery,[1] many of you would probably not be able to tell where the surgery is taking place.

Laparoscopic surgery is supposed to be less invasive—and yet, too much technical difficulty led to a fatal operation. This also applies to the cases of Showa University Fujiigaoka Hospital and the then Jikei University Aoto Hospital. Cardiac surgery as supposed to be minimally invasive, but technical difficulty led to the death of the patient—that is the case of TWMU.

MICS (Minimally Invasive Cardiac Surgery)

In the "Big Knife" procedure, meaning large skin incision, a large incision is made along the median—this is common cardiac surgery with a skin incision. On the other hand, in minimally invasive cardiac surgery (MICS), the cosmetic effect is most valued rather than the degree of invasion to the patient's body and the effect of pain relief. Because the scar is minimal, female patients and the parents of child patients favor this procedure.[1,2]

In the 1990's, those "Big Surgeon" physicians started to encourage MICS. As I have explained, in the "Big Knife" procedure, the sternum underneath is cut apart after cutting the skin. That is typical cardiac surgery, and the operating surgeon can visually see the entire heart in the operation site.[3]

In this particular case, a surgeon was supposed to open the right atrium and the pulmonary artery to perform the operation. But when using MICS, which employs a small skin incision, the site of incision is very small—about 5 to 8 cm in length, about the size of a credit card. And, the only partial sternotomy underneath is made. In this way, the operating surgeon can see only portions of the right atrium and right ventricle, and can barely see the right ventricle.[1]

So, how does the operation proceed? First, the surgeon pulls out the heart to perform the operation. The surgeon will pull the heart at various locations, but first the right appendage at the tip of the right atrium is being pulled out to start the operation.[4] Then, the heart-lung machine start extracorporeal circulation, by draining blood from the superior or inferior vena cava, sending to the artificial lung to oxygenate the blood, and pumping the blood back to the ascending aorta. And in this MICS, the blood drainage cannula of the superior vena cava should be an extremely flexible, supple, and straight tube. However, in this TWMU case, an extremely rigid right-angled tube made for direct cannulation was used, instead of the one that is designed to go to the right appendage.

Now, allow me to explain how the insertion of the blood drainage cannula to the hidden superior vena cava is properly performed. When inserting a cannula to the superior vena cava, it will go smoothly if the cannula is inserted through the right appendage and kept at a certain angle. This is the basic rule in MICS. In some cases the blood drainage cannula is positioned outside, but in the end, it is all the same.[4]

Then, why does a right-angled blood drainage cannula exist in the first place? This is because, in the "Big Knife" method, there are cases that require direct cannulation to the superior vena cava.[3,4] In such case, it is logical that it is right-angled.

A textbook I once read in the original language when I was young, *Cardiac Surgery: Safeguards and Pitfalls in Operative Technique*, was recently published in Japanese. It says that the safe technique of the superior vena cava cannulation is to enter from the right appendage and reach the superior vena cava. In addition, it warns of the danger of entering the azygos vein by mistake, which is also located nearby.

Another textbook, written 40 years ago by Dr. Sakakibara who is known as the father of cardiac surgery in Japan, also cautions about entering the azygos vein by mistake in superior vena cava cannulation.

The cause of death in the TWMU accident and preventative measures

The cause of death in this TWMU case, in essence, was that the rigid blood drainage cannula with a right angle was forcibly entered directly to the hidden superior vena cava. This led to poor venous drainage, and this condition continued for a long time. Then, when and if such situation happens, how should it managed? The tube that was actually used in the surgery (**Fig. 1**) was not really at a right angle, it was much more angled than that. So, when such tube is being used by mistake, how does one mange the heart-lung machine?

The operation of the heart-lung machine requires many devices, and there are various monitors to watch. The one that requires special attention is called the central venous pressure (CVP). It is imperative for the operator to carefully monitor this CVP and observe the condition

of blood drainage.

So, what does this CVP mean? As you know, the superior vena cava and the inferior vena cava are both central veins. During the extracorporeal circulation, or cardiopulmonary bypass with the heart-lung machine, their values differ because of cannulation. A narrow tube is entered to monitor sequentially. If the patient is a baby, then, the cannulation to the superior vena cava is performed from the neck.

However, in this TWMU case, only the inferior vena cava was being monitored. In MICS, I believe the superior vena cava pressure should have been monitored. In my own blog site, I introduce preventative measures to avoid an accident like the TWMU case. In MICS, the cannulation to the superior vena cava is to be performed through the right appendage as a basic rule and never performed as direct cannulation. Also in MICS, the superior vena cava must be monitored without any exceptions. These cautions are essential in preventing recurrence.

The Internal Report of Accident Investigation, Which Served As a "Letter of Accusation" As Well As "Written Expert Opinion"

I mentioned about the human factor engineering. *To Err Is Human* [written by Linda T. Kohn and Janet M. Corrigan, translated in Japanese] and *Human Error in Medicine* [written by R. Kawano, in Japanese] are very popular reading, but there are many other books on human error and medicine. Of those books I have read, I think *Just Culture: Balancing Safety and Accountability* written by a Swedish professor Sydney Decker,[6] also translated in Japanese, is most important.

After reading the work of Sydney Decker,[6] I became keenly aware that the organization of TWMU really lacks a "just culture." And, the in-hospital report of the accident investigation that TWMU prepared was turned into a "letter of accusation" as well as a "written expert opinion" to the investigative authority.

Reportage: Medical Accidents [in Japanese], written by Masahiko Idekawa who won Japanese Association of Science & Technology Journalists (JASTJ) award in 2009, discusses this TWMU case in it, with the subtitle "The refused internal report." In that chapter, there is a section called "Not Science," which includes comments by the chair of the accident investigation committee, Dr. Tohma. "The conclusion of the internal report is groundless." "If someone says 'it is not science,' then I would have to agree." So, the internal report was not prepared scientifically.

In the article I wrote for the March 2011 issue of *Medical Care Research*, I also discussed the problems with this internal report prepared by the accident investigation committee.

The In-hospital Accident Investigation Report That Was Prepared without Any Specialists

Now, regarding this in-hospital accident investigation committee, the chair was a urology professor, and naturally, he has never seen cardiac surgery. An anesthesiology professor was in the committee, but he was no expert in pediatric cardiac anesthesiology—actually, he had been avoiding cardiac surgery, if anything. There was a professor of cardiology, but since she was an internist she had never seen any surgery. In fact, cardiac surgery specialists were excluded from this committee. No cardiac surgeon was elected to serve in the committee, not from the Heart Institute of Japan (HIJ) to which I belonged, not from the first surgery department of TWMU, which had cardiac surgeons, and not from the East Medical Center (then Second Hospital), which had many cardiac surgeons—they were all ignored.

The TWMU knew that a brain disorder had occurred, but no physicians who deal with the central nervous system, such as neurosurgeon or neurology specialists, were selected to serve in the committee. There were many anesthesiology specialists. But, anesthesiologists like the chair of the board of directors of Japanese Society of Cardiovascular Anesthesiology, or a specialist of pediatric anesthesiology which is rare in Japan, were ignored.

In the statement, this committee chair explains that the reason for excluding any physicians who belong to HIJ was "Interviewing the physicians who have been in charge of the surgery regarding the propriety of the operation or procedure could result in various disagreements among them, which would make it difficult to seek the truth, and that could prolong the investigation by the committee and make it difficult for the committee to come to a conclusion." But I have to

question the logic in trying to seek the truth by ignoring the opinions of medical practitioners who are currently involved in actual cardiac surgery.

As one of my mentors, Dr. Hideki Komatsu, often says, "The original purpose of an in-hospital accident investigation committee in principle is to firmly understand the progress of events from the medical point of view and to fully analyze the cause, and the issue of safety can be addressed by a safety committee separately." To this end, the voice of medical practitioners who are currently active in clinical medicine would be most valuable, I believe.

It is necessary to seek the cause of an accident; however, this can be difficult. It is easy to say the word "truth," but as Dr. Kitamura also often says, the truth can be quite subtle and complex. The idea of improving the medical quality and safety is out there—as seen in Dr. Komatsu's concept of an in-hospital accident investigation committee, or by improving the scientific awareness toward medical accidents, establishing professional autonomy of physicians, and improving hospital functions as an integrated organization. But there is a huge gap between the reality and the ideal.

Hospitals Prepare In-hospital Accident Investigation Reports at Their Own Convenience

An in-hospital accident investigation committee has hidden objectives—for example, to prepare for conflict or avoid attack from patients or society. And, one major reason is to win compensation money from insurance companies. But, these are all for the convenience of hospitals.

The primary purpose of preparing an accident report includes explaining the accident to patients. Patients ask for a convincing explanation, rather than truth. For medical professionals it is important to analyze the cause from the medical point of view. But for patients, a convincing explanation often means more than being told the truth. When involved in a medical accident, the patient may have various hopes and wishes. But when a medical accident results in death, most likely the patient's family hope for sincere handling of the matter and an apology.

Now, let's put ourselves in the shoes of the hospital's side. When executive members of a hospital or an in-hospital accident investigation committee makes excuses without acknowledging responsibility as the hospital organization, or when they try to protect the medical practitioners involved, the patient's side become very offended. What's more, if the media exposes them, social sanctions are imminent.

So, in order to protect themselves, it is logical for those who are accountable to admit moral responsibility, acknowledge that management in practice was insufficient, review the event, and apologize. In other words, substantial responsibility is being transferred to the medical practitioners who were actually involved in treating patients. It also has an additional benefit of being recognized as a progressive hospital director who is proactive in information disclosure. This is exactly what TWMU did.

False In-hospital Accident Investigation Report

The TWMU's internal report concluded that the cause of death was cerebral circulatory failure due to poor venous drainage, and that the poor venous drainage was caused primarily by the increased suction pump speed. The report recognizes that the filter was occluded, but it is regarded as a facilitating factor that did not directly contribute to the death. So, the report is saying that the increased speed of suction pump turned the reservoir pressure positive, reversed the air flow, and caused the brain disorder.

First, I would like to examine the issue of the occluded filter. The filter used was actually meant to be used for a different purpose, to which the Pharmaceutical Affairs Act does not apply. This filter was not supposed to be re-used, and yet, it was used repeatedly. The document attached to the filter specifically states that it is meant for single use only and cannot be re-used. Here, the hospital is clearly at fault. In the site inspection conducted when the investigative authority has not decided who to suspect, my investigator was saying, "How could anyone think of doing things like this for a medical item?" For many, this is probably the true impression.

Increasing the suction pump speed to 100 revolutions was my act, and mine alone. The proper examination of the suction pump used in the actual operation would show that the maximum speed is 250 revolutions. In fact, the device

would operate without any problems even if the speed is raised to 250. In the vacuum-assisted venous drainage method used in this TWMU case, the heart-lung machine was manufactured by a company called Baxter. And, for years before the accident, the presentation they have under their Q&A has been saying that increasing the speed of the suction pump will not cause any problems.

Tokyo District Court carried out a verification experiment using the same devices as those used in this case. So, what happened when the speed of the suction pump was raised? No change at all. Therefore, the court proved that the in-hospital accident investigation report prepared by TWMU was wrong through their experiment.

In-hospital Accident Report Was Prepared without Any Consideration to the Human Rights of the Person Concerned

The fundamental problem of the in-hospital accident investigation report was that it ignored the person concerned. I, the person concerned, thought that the act of increasing the pump speed itself would not cause any problem. TWMU questioned this, but they never told me.

When this report was prepared, it was given to the family of the patient, and I did not even know that such report existed. Naturally, I was never given any opportunity to state my opinions in the report.

Let me return to the basic policy of the committee head, Dr. Tohma. "Interviewing the physicians who have been in charge of the surgery regarding the propriety of the operation or the procedures could result in various disagreements among them, which would make it difficult to seek the truth," so the committee ignored the persons concerned and cardiac surgeons. This is the same as ignoring human rights or judgment by default.

In *Just Culture*[6] I mentioned earlier, it says that a single explanation cannot fairly address a complex event. An explanation requires multiple layers to get close to the truth, and some views will be overlapping and some will be contradictory, but it this is to be expected. It also says, in culture of fairness, the viewpoints from the bottom-up within a multi-layered explanation deserve attention. I believe this is an important point.

Last month, Japan Medical Association published a brochure "Basic proposal toward establishing a system to investigate medical accidents." On the third page of this brochure, it mentions about establishing an in-hospital medical accident investigation committee in all medical facilities. If this vision is realized, enormous number of accident investigation report will be released in future. To release an in-hospital medical accident investigation report, there are 2 absolute conditions, I believe. This is a topic I frequently discuss in my recent lectures, but now I would like to describe these 2 conditions. One is to guarantee the right of the persons concerned to dissent or refuse, and the other is to secure the right to make statement in the report of dissenting reasons.

The Ministry of Health, Labour and Welfare of Japan includes these ideas in their third tentative plan of establishing the so-called medical accident investigation committee, which is currently at a standstill. I am absolutely against this tentative plan as well as the general outline plan; however, they include some good ideas. Namely, the parts that say, "before completing the investigation of an individual case, the opportunity to hear the opinions of the medical professionals and the family members of the deceased involved in the said case should be arranged," and "when the committee's opinions disagree with the medical professionals and/or the family members of the deceased involved in the said individual case, their main points can be attached as a separate document."

To the medical accident investigation study committee of the Japan Medical Association, I would like to remind, yet again, to value the standpoint of culture of fairness stated in *Just Culture*[6] and the bottom-up viewpoints from the medical practitioners who are actively engaged in clinical practice. The committee probably has very highly regarded and famous physicians, but probably not many of them are actively engaged in clinical practice or have so-called bottom-up viewpoints. Some members are probably lawyers, too. So I am afraid that some committee members do not have such awareness. At least, I believe it is very likely that one of those committee members 9 years ago had no viewpoint of a "culture of fairness."

Once again, I would like to announce my proposal regarding the absolute conditions of releas-

ing medical accident investigation reports.

1. Guarantee the right of the persons concerned to dissent or refuse. Meaning, before completing an investigation, the opportunity to hear the opinions of the medical professionals involved in the case must be arranged.
2. Secure the right to make a statement in the report of dissenting reasons. When the opinion of the committee disagrees with that of the medical professionals involved in the case, their main points should be attached as a separate document.

I would like to declare that any accident investigation report that does not observe these conditions cannot be called a product of a culture of fairness.

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