Laws on Medicine

Lecture No.8 (in Classroom 22, on Wednesday, November 19, 2008, at 15:00-16:40)

Chapter 8: Article 21 of Medical Practitioners Law—Medical Mishap and Report to the Police/Criminal Justice

1）What is Article 21of Medical Practitioners Law for?

2）What is the criminal justice's role for medical mishaps?

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Supplement to Last Class
Split of Work among Medical Professions

①Doctor v. nurse

②Midwife v. nurse

But the structure does not apply to internal examination problems.

③Doctor v. emergency medical technician

5 Medical Mishap and Law

A. Until 10 years ago
  Limited interventions of criminal justice
    Article 21of Medical Practitioners Law had nothing to do with medical mishaps
  Administrative punishments came after criminal ones.
  Civil suits (malpractice suits) played a small role.
B. Recent trend
  Increased criminal cases; independent administrative punishments
  Doubling of civil suits
◎I.e., an increase in the sanctions-type course of actions

Medical Safety

Hunt for the truth (revelation of the truth, finding out the cause of death)

Recurrence prevention

If a retributive factor gets involved…

①To conceal the truth/remain silent in fear of sanctions

②Truth gets concealed in sanctions focused on individuals.

③To avoid high-risk medical treatment in fear of sanctions

But then, whether it's really all right without any sanctions: dilemma.

Reality Not in State of Rewarding Good and Punishing Evil

Thus it requires to figure out a good way to handle the situation.

Nonetheless, the current tone of society is just like that of *Toyama-no-Kinsan:* a simple viewpoint that things get solved in the manner of "rewarding good and punishing evil."

What's more, it's not "rewarding good," but only "punishing evil."

Can't we do something about it?

Can a legal intervention aim for medical safety?

Or, what kind of legal intervention is meaningful?

【Case of Fukushima Prefectural Ono Hospital】

Feb. 18, 2006: Fukushima Prefectural Police arrests a doctor with the hospital

Nov. 22, 2004: A woman into 32 weeks of pregnancy, in condition of threatened premature delivery, was hospitalized having been diagnosed with partial placenta previa.
Dec. 17, 2004: Cesarean operation in the 36th week of pregnancy (massive bleeding at the time of separation of the placenta, causing the pregnant woman to die)
Mar. 22, 2005: Announcement of the report of the accident investigation committee (acknowledged errors at 3 points); (1) forcible separation of the placenta accreta, (2)not enough doctors to handle, (3)delay in the treatment of blood transfusion
Feb. 18, 2006: Doctor K in charge was arrested , the premises such as the hospital were searched.
Feb. 24, 2006: "Announcement" was issued by Japan Society of Obstetrics and Gynecology / Japan Association of Obstetricians and Gynecologists , stating the arrest and custody were doubtful.
Mar. 10, 2006: The same associations criticized the state where the doctor was held criminally responsible.
Mar. 27, 2006: Ono Hospital's obstetrician/gynecologist continued to be closed, causing the town mayor to request the dispatch of a doctor.
Apr. 14, 2006: Fukushima Prefectural Police gave recognition to Tomioka Police Station regarding the case of arresting the doctor.
May 9, 2006: Fukushima medical society requested a revision of Article 21 of Medical Practitioners Law.
May 17, 2006: Both Japan Society of Obstetrics and Gynecology /Japan Association of Obstetricians and Gynecologists declared their strong apprehension.
Jan. 2007: The trial was held and closed.
Aug. 20, 2008: Judgment of acquittal
Sep. 2008: Fukushima district public prosecutors office did not appeal to a higher court, hence confirming the decision of "not guilty."

Charges against Doctor K

- Professional negligence resulting in death ＋ Violation of Article 21 of Medical Practitioners Law
- Article 21: “The doctor, upon finding abnormality by the examination of a corpse or a stillborn baby in the pregnancy more than 4 months, shall report to the competent police station within 24 hours.”

- Article 33, paragraph (2) of Medical Practitioners Law: the penalty of a fine not exceeding ¥500,000 against an offender.

Two Serious Incidents in 1999

○Jan. 1999

- The case happened at Yokohama Municipal University Hospital where the surgeries were performed confusing a male patient for an operation of the lung with another male patient for one of the heart.

◎Feb. 1999

- Metropolitan Hiroo Hospital case in which a nurse mixed up intravenous infusions and injected the wrong one, leading the patient to death.
- Both the head of the hospital and the physician in attendance were found guilty of the breach of Article 21 of Medical Practitioners Law.

Succession of Guidelines and Supreme Court's Decision

- Aug. 2000: “Report prepared by the committee for the risk management standard manual,” hosted by Department of National Hospitals, Ministry of Health and Welfare, set up the rule for the head of hospital to report. The rule was directed to national and public hospitals throughout the country, and subsequently to such hospitals for specific functions as private university hospitals and large-scale hospitals.
- Jul. 2002: Japan Surgical Society’s guideline was announced, setting for attending physicians themselves to report,including serious injuries.
- Apr. 2004: Supreme Court's decision on the Hiroo Hospital case, ruling that forcing an attending doctor to report was constitutional.

Article 21 of Medical Practitioners Law on Forcible Reporting

Case in Fukushima

No concealment
Errors acknowledged in the accident investigation committee

And yet it became a criminal case,
and furthermore, with a breach of Article 21…
In a sense, a breach of Article 21 is a violation of adjective law.
All mishaps in medical practice to be reported to the police!!!

Cause Unfolding and Recurrence Prevention ⇔ Criminal Justice

1 Criminal justice = Outcome of judicial autopsy to be classified
2 To be closed if not linked to a crime
3 Medical mishap→Roles played by pathological dissection and clinicians
To find the truth by a medicolegal judgment alone?
4 Police alone = No more than an investigation, leaving an unpleasant aftertaste
5 In general, criminal investigation is cautious, too.
6 Even in case of a trial, the verdict is “not guilty,” or, “guilty” with probation.

Recurrence prevention functions at most as preventing a recurrence of concealment

Demerit of Criminal Justice

To the patient: Actually, it is not an activity for the sake of the patient, thus no notice about the outcome of judicial autopsy.

To society:

- Satisfaction with identifying the culprit is temporary and short-lived.
- It does not necessarily lead to medical safety.

To the police/criminal investigation:

- Activities in the area they're not good at, and restriction on other crime investigations

To the hospital:

- Fear to become a criminal, and cracks within the hospital
- Passivity and daunted medical service that rely on others as to transparency of medical care
- Unfair application in reality? The one who repots gets badly hit.

Third Draft Plan in Apr. 2008 by Ministry of Health, Labour and Welfare

Handling by the administration to date has not been adequate, and the current situation is that the solution is expected upon civil affairs proceedings and criminal proceedings, which, however, do not lead to unfolding of causes. From the standpoint of securing medical safety, it is necessary to establish an organization that technically conducts analysis and evaluation regarding fatal medical mishaps.

With the objectives to determine the cause of and prevent the recurrence of fatal medical mishaps, and to secure safety of medical service, an investigation commission for medical safety will be established.

It is not aimed at pinning the blame on those involved in medical service.

With the revision of Article 21 of Medical Practitioners Law, when the medical institution conducts the reporting, no report is necessary regarding unusual death based on the same statute.

Fukushima Local Court's Decision on Case of Ono Hospital

- Any medical standing rule that can become a criterion to have a doctor engaged in clinical medicine bear the duty of an act related to medical measure and to impose a punishment on the one who has acted against the said duty must be fully provided with generality or a common trait to the degree at which, faced with the situation under review, it can be said that a majority of doctors engaged in the clinical medicine of the subject takes the medical measure which is consistent to that criterion.

Local Court's Decision on Case of Ono Hospital

- In order to show that there is the duty to suspend a medical action, the public prosecutor must prove that not only there is a danger with the subject medical act, having clarified *specific risks* involved in the case the subject medical act is not suspended, but also there are alternative methods that are more pertinent. Stating in conformity with this case, the high probability of the patient's death must be proved based on the clarification with respect to the high degree of probability for the uterus not to contract, the one for bleeding not to stop when the uterus contracts, and an anticipated volume of bleeding in that situation, whether or not alternative actions exist that can be easily taken to stop bleeding, and their effectiveness. And it is maintained that, in order to concretely give proof to these, to say the lease, *it is imperative to present a considerable number of clinical cases to go on, or ones with the resemblance to compare against*.

No.6 Re: Violation of Medical Practitioners Law

1 In the light of the fact that Article 21 of Medical Practitioners Law is the regulation intended for the police officer to easily find a clue for a crime investigation, and to enable the planning of social safeguard by urgently taking measures for preventing the damage from spreading, abnormality said in the same article is interpreted to mean, from a medicolegal standpoint, the state where one is recognized to be dead in a condition different from being ordinary. Therefore, a case where a patient under medical care dies from the relevant disease for receiving care lacks the requisite for abnormality maintained in the same article, it should be stated.

In this case in question, the patient of this case had a Cesarean section operated by the accused as the one of placenta praevia, and died when receiving a measure to separate the placenta adhered to an inner wall of the uterus. While the accused without an error provided a measure, as a medical care for the placenta accreta, the placenta did not separate easily , and due to bleeding from the stripped plane, the patient of this case was led to hemorrhagic shock, and bled to death, all of which are in accordance with the recognition stated above. Then, the result of the death of the patient of this case has no option but to be mentioned as the one that, caused by a disease called the placenta accreta, could not be avoided even with a medical care without an error, thus this case does not come under the condition of abnormality said in Article 21 of Medical Practitioners Law.

2 Based on the above, there is no need to examine the remaining, and regarding the accused, the crime of the violation of Article 21 of Medical Practitioners Law has not been established, and the charge No.2 has not been proved.

Significance of Local Court's Decision

Despite the local court's decision, the prosecution did not appeal to a higher court.

The decision put an extremely high hurdle against the prosecution as to a case with options in therapeutic method, and the fact that the prosecution accepted it has an influence for the future.

This is a proof that the medical mishap does not lend itself well to a criminal trial.

- Mutually exclusive setup
- Both hunt for the truth and recurrence prevention are difficult.

From Standpoint of Bereaved family

Desire for the hunt for the truth

Criminal trial

①To be shown a mutually exclusive setup

Defense side to insist on no error

②Satisfied if guilty?

Irrevocable life

No self-examination if not guilty?

Wish for a route that is not either guilty (〇) or innocent (×)

Bill for Establishing Investigation Commission for Medical Safety (Tentative Name)

Proposal of General Principles (Jun. 2008)

◆No.1 Purpose

◆No.3 ○○Ministry ◆ No.5 Independence ◆ No.7 Those in the position to receive medical care ◆ No.12_Not aimed at pinning the blame ◆No.15 Request from bereaved families ◆No.21 Listening to opinions

◆No.22 Report, disclosure, minority voice

◆No.25 Relation with the police

◆No.32 Revision of Medical Practitioners Law

◆No.33 Revision of Article 21 of Medical Practitioners Law

Two Difficult Problems

1) How do you respond to a certain doctor's opinion as follows?

It is improper that, as compared to the jurist, the crime of professional negligence resulting in injury and/or death is applied only to the doctor. Suppose the accused in a certain case gets executed, and subsequently a real criminal appears. In here, the public prosecutor, attorney and judge involved in this case are suspicious of the crime of professional negligence resulting in injury and/or death, and ought to be investigated and prosecuted.

2）Crime of Professional Negligence Resulting in Injury and/or Death

(Professional Negligence Resulting in Injury and/or Death, etc.)

Article 211: A person who has neglected necessary business-related care, thereby has someone killed and/or injured shall be punished by imprisonment with hard labor or detention for not more than 5years, or a fine for not more than ¥1 million. The same shall apply to a person who has someone killed and/or injured with a grave error.

- Exclusion of its application to the doctor, or a reduction
- Is this justifiable?

- Story of a bus driver:
- Sole transportation means in an underpopulated region
- Job to be given responsibility for safety and life
- 2 dead and 3 seriously wounded in an accidental fall