

Special Feature

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

Japan Medical Association's Basic Proposal toward the Establishment of a Medical Accident Investigation System

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Introduction

In recent decades medicine has considerably advanced, and accordingly it allowed people to enjoy many benefits of medical progress. However, it is inevitable that not all people can be saved by physicians, no matter how advanced medicine becomes. Uncertainty in medicine, even if fully explained to patients by the physician, may not be a concept for them to easily understand. Unfortunate outcomes often cause frustration in the patient or people on the patient side, and in many cases the accountability of physician becomes a focus of the problem. Because almost all the medical fees in Japan are an officially fixed price under the universal health insurance system, health care is actually provided by the minimal resources in terms of manpower and finance. If a medical accident under this environment goes into litigation, especially criminal action, it truly places a tremendous burden on the physician side.

Criminal cases for medical accidents are not always a means to make a fundamental solution to reveal the truth, which often leaves the patients unfulfilled with the results. Lawsuits only leave them with feelings of hate. If health care services with the aim of saving the patient's life transform into criminal penalty, it is really unfortunate for both the patient and physician.

Japan Medical Association's (JMA) Basic Proposal

Investigating the true cause of medical accidents, communicating the investigation results to patients and their families, and making use of the investigation results to prevent recurrences are extremely important. At present, however, there are no third-party agencies in Japan in which medical professionals seriously investigate the causes of medical accidents.

In June 2008, the Ministry of Health, Labour and Welfare of Japan revealed "outline draft of the bill to establish (tentatively called) medical safety investigation committees," the purposes of which were the establishment of a medical accident investigation organization and the amendment of Article 21 of the Medical Practitioners Act. Many people, including the medical community, legal circles, and patients, debated the outline draft, but it reached a deadlock after political power was transferred from the Liberal Democratic Party to the Democratic Party of Japan in August 2009. That is why the situation in which a part of the resolution of medical accidents in Japan is dependent on criminal justice is not largely changed.

It is at such a time as this that there is a need for the JMA to mobilize the strength of the medical community, maintain professional autonomy,

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This article is based on a report compiled by the JMA exploratory committee on medical accident investigations in June 2011.

propose acceptable medical care system that can protect the public, and set it into action.

On December 24, 2010, the JMA established an exploratory committee on medical accident investigations. The committee, which was chaired by Dr. Akira Teraoka and consisted of 13 members who were physicians, lawyers, and journalists, engaged in substantial discussions. In June 2011, the committee compiled a report on the JMA Basic Proposal toward the Establishment of a Medical Accident Investigation System (hereinafter the proposal). The JMA is making policy recommendations in line with the report received from Chairman Teraoka.

Specific Contents of the JMA Basic Proposal

The objective of the proposal is for medical professionals to establish their own medical accident investigation system that enables them to strive to identify the causes and prevent recurrences of medical accidents while at the same time engaging faithfully and actively in medical care without medical staff shriveling. Physicians must independently establish and operate a system for investigating the causes of accidents and preventing recurrences within the physician's professional regulation and self-discipline as well as their social responsibility. That system must be guaranteed by a third party and acceptable to society. The JMA made the following proposals with the hope that they would lead to a stable medical environment in which a relationship of mutual trust can be built between medical professionals and patients.

Establish an in-hospital medical accident investigation committee in all medical institutions

Thus far when a medical accident has occurred in Japan, in-hospital medical accident investigations have been carried out only at large-scale medical institutions such as university hospitals, national and municipal hospitals and public medical institutions. Accordingly, the proposal recommended that all medical institutions establish at their own responsibility a committee that promptly investigates medical accidents and report the facts without hiding the truth.

The proposal called for the establishment of a standing medical safety committee in the first

stage with the aim of improving the quality of medical care including patient satisfaction and preparing for emergency situations. It also called for the establishment of an emergency medical accident investigation committee in the advanced stage—that is, a committee that goes into action immediately upon the occurrence of a medical accident.

However, it is difficult for small-scale hospitals and clinics to investigate in-hospital medical accident because of constraints in human and financial resources. Therefore, the proposal also suggested the establishment of a system in which their facilities can request support from larger organizations such as a medical association, regional medical care support hospital, core hospital, or university.

Investigate medical accidents by a third-party agency that is organized and run by the medical circles and the medical societies

The proposal recommended the creation of a third-party agency that can be requested to perform specialized investigations in cases where in-hospital medical accident investigations have found the “need for a determination of the cause of a death related to medical care” (cases in which the medical institutions in question conducted an investigation and analysis to the extent possible but that exceeded their analytical capabilities). This third-party agency must be an organization that is capable of making impartial and neutral judgments based on medical expertise. Patients and their families will also be able to request investigations by the third-party agency.

At present, although small, the Japan Council for Medical Safety Investigation, which was established by societies such as the Japanese Society of Internal Medicine, investigates the causes of deaths related to medical cares. The proposal specifically recommended the restructuring of an organization, based on this Council, in which concerned bodies from the medical community such as the JMA and the Japanese Association of Medical Sciences participate. It also suggested the establishment of one or more local secretariats in each prefecture under the active involvement of prefectural medical associations. This third-party agency needs augmentation of investigative and analytical capabilities including autopsies, personnel, and financial re-

sources, since it accepts reports from in-hospital medical accident investigation committees.

Investigation results are released with consideration taken for privacy, but they are not reported to the police or judiciary.

Amend Article 21 of the Medical Practitioners Act

Article 21 of the Medical Practitioners Act stipulates that “if a physician recognizes any abnormality in a corpse or stillborn baby that is 4 months of gestational age or older thought a post-mortem examination, the physician must report it to the police station of jurisdiction within 24 hours.” The penalty of violation is a fine of or less 500,000 yen (US\$ 6,494).^{*3}

Notifying the authorities about unnatural deaths has been a practice in Japan for over a century. However, ever since a physician who did not notify the police of a death related to medical care was convicted under Article 21 of the Medical Practitioners Act in the Tokyo Metropolitan Hiroo Hospital case in 1999, physicians have been urged to notify the police if there are any “abnormalities” in deaths related to medical intervention. However, notifying the police is the gateway to a medical accident being turned into a criminal case coupled with the ambiguous definition of “abnormality,” it has resulted in confusion in medical settings.

That is why the proposal recommended having no obligation to notify the police of deaths related to medical intervention except in cases that are intentional or should be treated as intentional. It also proposed the abolition of penal regulations under Article 21 due to concern over

infringement of the right to remain silent, which is guaranteed under the Constitution of Japan.

Note that while the outline draft calls for the third-party agency to notify the police in cases of gross negligence, the proposal does not have the third-party agency notify the police.

Promote the use of alternative dispute resolution (ADR)

Pursuing dialogue between patients and medical professionals is important as a premise in initiatives to investigate and analyze medical accidents and take measures to prevent recurrences. Accordingly, the proposal recommended not only court trials but also promoting the use of ADR.

Establish a patient relief system

The proposal recommended considering the establishment of a patient relief system for adverse events caused by medical care, regardless of whether there was negligence or not.

Conclusion

In the medical accident investigation system recommended by the proposal, the basic concept is for medical professionals to investigate medical accidents themselves, the purpose of which is to investigate the true causes of medical accidents and to prevent their recurrence. All of us sincerely hope that the proposal will enable the establishment of a system under which the public can receive medical care with peace of mind and trust.

*3 Yen/US dollar exchange rate: 1 US\$=77 yen.