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Introduction

Inadequate measures taken following the collapse of “bubble economy” deteriorated the Japanese economic basis and created enormous financial deficits in the beginning years of the 21st century. On the other hand, the Japanese society suffers from a sense of obstruction as it is faced with a myriad of problems ranging from fewer numbers of children and ageing society to those in education, environment conservation, and international coordination.

While the Japanese government is currently promoting “structural reform without sanctuary” to solve these problems by introducing the mechanism of market economy and focusing on efficiency, our concern is that the reform might lead to the decline of our social security system that we are so proud of. The government should not value speed above quality, but should proceed with caution so as to achieve the consensus of the society.

Structural reform is needed also in the field of medical care. The basis for reform lies in information disclosure and the manner with which we make the disclosure.

I would like to discuss the relationship between information disclosure and adverse events occurring in medical practice.

Adverse events are unfortunate for both the patient and the physician, and every effort should be taken to prevent it. However, there are regrettably a large number of adverse events in medical practice today. For those physicians who take the utmost care in securing the patient safety and dispensing quality medical care, this is quite infuriating and most deplorable. This situation erodes people’s confidence in medical care and amplifies their anxiety.

Many things are unforeseeable in the world of natural sciences and still more are yet to be elucidated. As medicine is practiced by applying highly developed sciences, there may occur incidents that could not have been anticipated. However, recent adverse events appear to occur as a result of most rudimentary error rather than that of using highly advanced scientific technology. Those of us engaged in medical care cannot help feeling anxiety.

If an adverse event did occur and if a party was proven responsible for the accident, that party should pay for consequences. For this
purpose, relevant parties should take out the medical malpractice liability insurance.

Current Status of Medical Malpractice Litigation in Japan

According to the Japanese Supreme Court, the number of new malpractice suits filed at the courts of the first instance in Japan was in the order of 300 a year in 1992, 400 to 500 in 1993 onward, and radically increased to 767 in 2000. This is an increase of 215% in 10 years (Fig. 1).

This radical increase reflects the serious degree of damage to the confidential doctor-patient relationship, and may serve as an indicator of people’s distrust in physicians.

Naturally, the medical side is not necessarily responsible for all the accidents over which malpractice suits have been brought. The court rendered unfavorable decisions for the medical sides in 37% of the cases during the past decade. This may appear that the medical side won a majority of cases, but one must not overlook that settlement was reached before the decision in 49% of all cases. A considerable number of cases were concluded by thus recognizing the fault of the medical side.

The author acutely feels that the medical profession should face this situation seriously and structure a system under which the patient may receive treatment with a sense of security.

Risk Management in Medical Care

I would like to consider the risk management in medical care.

1. Concept of risk management

The concept and practice of risk management developed in manufacturing and transportation industries for “self-defense of companies.” This aims at snipping buds of risk before factors that inhibit perpetual development of business surface, and maximally preventing disadvantage such as the lowered corporate image, labor management problems, and economical losses, to thereby secure healthy corporate management.

For instance, risks and their countermeasures include (1) minimizing damage to facilities caused by natural disasters such as earthquakes, typhoons, fires, and explosions, (2) taking thorough accident prevention measures in aviation, automobile, and transportation where the passenger safety is of the utmost importance, (3) hedging risks in foreign exchange and asset management, and (4) others. Risk management focuses on precisely identifying the mechanism under which a risk occurs, and structuring and implementing the system to avoid risks.

2. Risk management in medical care

Physicians offer daily medical care with respect for human life and appreciation of patient’s confidence in them. Since enormous risks are involved in their work and a great damage may be inflicted once an accident occurs, introduction of the risk management was considered necessary.

It was in the middle of 1970s that risk management techniques were introduced to the medical field in the United States to address the so-called “medical malpractice crisis.” As is well known, it was the time when laws related to “the patient right” were legislated and attorneys for the patient played active parts. Against such a background, medical malpractice litiga-
tions rapidly increased. The number of cases lost by the medical side jumped and the amount of damages soared causing many physicians and medical institutions to go bankrupt.

Insurance companies could not bear increases in the cases lost and the amount of damages, and were forced to back out from this type of insurance or to raise the insurance premium radically.

Under the situation such as the above, the risk management was introduced so that medical institutions might maintain the quality of medical care and bear out the malpractice litigations. Initially, the risk management was a measure taken to solidify the financial basis and to secure the fund for damage payment, but the emphasis gradually shifted to prevention of medical injury themselves. Therefore, the risk management may be described as 1) the safety measure in medical care by preventing medical injury themselves, and 2) the means to pay damage to the patient in the event of medical injury.

Safety Measures in Medical Care

Japan Medical Association has taken the following measures for safety in medical care.

In order to offer safe medical care, JMA has taken various measures and presented proposals including establishing the Committee for Safety Measures in Medical Care in 1997. They consisted, among others, of (1) proposing “Risk management in medical care,” (2) proposing “Research on medical safety and needs for training personnel,” (3) establishing “the Department for Securing Patient Safety,” and (4) offering “Training courses for personnel in charge of medical safety.” JMA is determined to pursue safety in medical care as its most important challenge.

Safety measures in medical care should be based on a mature confidential relationship between the physician and the patient. The means to achieve such a relationship are discussed below.

1. Training in medical technology

First of all, physicians and medical care personnel should constantly pursue training in medical technology. Progress and development in medical care and medicine are remarkable today. Physicians should therefore pursue lifelong studies constantly, should not lag behind the progress in medicine, should acquire expertise knowledge for diagnosis and treatment, and should train themselves in applying the knowledge to clinical medicine. Not only the physicians but also those persons engaged in nursing, etc. should daily endeavor to improve their knowledge and continue studies in order to offer quality medical care.

The administration system of the medical facility as a whole should not be ignored. Constant reviews are needed of the systems of responsibility taking by physicians and of work assignment by nurses. Hardware such as buildings, facilities, machinery, and apparatuses should naturally be kept in optimum conditions by appropriate maintenance.

Court decisions in medical malpractice proceedings are based on evaluation of “the medical standard” prevailing at the time. The physician should always keep abreast with the current medical standards and continue research in order to respond to expectations of the patient.

2. Good communication

The next point concerns communication with the patient. In the past, treatment tended to be uniform as diseases were usually acute diseases, mainly infectious diseases. Therefore, the patient tended to entrust everything to the doctor, and the doctor used to take the paternalistic attitude. Medical care was offered and received based on tacit understandings without verbal information or explanation. Today, however, diseases are mainly chronic, and the means employed to treat chronic diseases are diverse. Often a disease is to be controlled rather than cured, and the patient should live with the disease. Thus, the patient often
consults the physician about the ways of co-
existing with the disease. Thus, the doctor-
patient communication becomes most impor-
tant in order to have the patient understand
that he/she should take the initiative to over-
come the disease.

If the physician or nurse were to treat the
patient perfunctorily without appreciating the
latter’s suffering or without giving adequate
information about the disease, problems are
bound to occur, and offering of complete med-
cal care is impossible. The physician should be
aware of his/her own role, and know that
medical care begins by first establishing the
confidential doctor-patient relationship based
on good communication.

According to a research, there are four rea-
sons why the patient brings medical malprac-
tice suit against the physician.

One concerns communication. The patient
complains that “information offered by the
doctor was insufficient,” “the doctor did not
appreciate his/her feelings and ignored them,”
“the doctor and nurse were not courteous to
the patient in attitude or language,” “they
lacked understanding or care of the patient’s
suffering,” and “they did not apologize for the
damage suffered by me.” The second reason is
that “they should try to prevent recurrence of
accident,” the third reason “they should pay for
damage,” and the fourth reason “they should
be punished severely.”

The paper reported that an overwhelming
number of litigations were started because of
inadequate communication. Communication is
thus critical, and patients usually do want to
improve communication.

3. Informed consent

The third point concerns informed consent.
The physician has the duty to inform and also
the right to use discretion in treating the
patient. On the other hand, the patient has
the right to learn the truth and that of self-
determination. Maintaining a balance between
the two is the difficulty in clinical medicine.

It is important that the physician gives suffi-
cient information in easy-to-understand words
about symptoms, diagnosis, treatment regimen,
prognosis, etc., so that the patient understands
and accepts the proposed treatment before
starting the treatment. This way, therapeutic
effects are said to improve.

With advance and progress in medical care,
the patient sometimes has excessive expecta-
tions. The patient tends to think that all dis-
ees are curable by the physician. If the out-
come is not what he/she had expected, the
patient incurs distrust toward the physician,
and this may lead to a dispute. Sufficient expla-
nation about prognosis should be attempted,
understood, and accepted. Adequate history
taking regarding past drug allergy episodes is
also important, and the patient should be
explained fully that unforeseeable or unavoid-
able accidents could occur in medical care.

For instance, the discovery of antibiotics, a
major research achievement of the last century,
has drastically improved therapeutic effects
for infectious diseases, but the patient should
be made to understand that there might be
unforeseeable side effects.

At any rate, medical care based on informed
consent given as a result of smooth communi-
cation between the patient and the doctor is
essential, and the conventional paternalism
may cause problems.

JMA Professional Medical Liability
Insurance Program

1. Creation and purposes

The second point concerning the risk man-
gement is how to address the adverse event if
it does occur. In order to compensate the patient
adequately, sufficient financial resources or
funds for damage payment should be secured.
The best answer to this is to take out the med-
cal liability insurance.

Japan Medical Association created the cur-
rent JMA Professional Medical Liability Insur-
ance in 1973 as a system for adequately address-
ing disputes over adverse event that involve its Class A Members.

The insurance system is participated by all of its Class A Members under the spirit of mutual aid, and the Investigation Committee, Japan Medical Association, local medical associations coordinate together in dealing with examinations by the Medical Liability Review Board, a fair third party organ, and in resolving disputes with cooperation from the members.

Since its start, this Insurance Program has greatly contributed to fair and proper settlement of medical disputes, and has always advocated the ideal ways of resolving disputes.

Despite the recent increase in the number of malpractice litigations in Japan, “medical malpractice crisis” faced by our American colleagues has not emerged in Japan. I am confident that the system has greatly contributed to development of Japan’s national medical care.

2. Outline of JMA Professional Medical Liability Insurance Program

JMA Professional Medical Liability Insurance is outlined below.

(1) JMA’s Category A Members (A1 or A2) or physicians who subscribe to JMA by paying the membership fee can be insured.

The insurance contract is entered between JMA and a non-life insurance company (such as the Tokio Marine & Fire Insurance [the managing company], the Yasuda Fire & Marine Insurance, Nihon Koa Fire & Marine Insurance, Mitsui Marine & Fire Insurance, and Sumitomo Marine & Fire Insurance (the last two companies having merged as of October 1, 2001 is now called Mitsui Sumitomo Marine & Fire Insurance), and the JMA members do not need to take any procedure for insurance.

By payment of the prescribed membership fees, JMA Category A Members automatically become insured.

If a person becomes a Category A Member during the year, he/she will qualify as the insured party under the JMA Professional Medical Liability Insurance, but will disqualify if he/she loses the Category A Membership.

(2) If the demand for damage exceeds ¥1,000,000 for physical disorder attributable to a medical act, the accident is covered by the insurance. Accidents attributable to the ownership, use, or administration of building/equipment of medical facilities are not covered.

(3) Insurance money paid by JMA Professional Medical Liability Insurance covers the damage paid to the patient and the legal fees. The damage paid by the insurance (maximum amount) is ¥100 million per year per insured party (with the legal fees paid separately).

(4) The exemption amount (or the amount to be borne by the insured) is ¥1,000,000 per medical act. In other words, only the portion of damage in excess of ¥1,000,000 will be paid by the JMA Professional Medical Liability Insurance. There is no exemption for the legal fees.

(5) When a medical accident occurs and the patient demands damage payment, details from the time the accident occurred leading to the dispute should be reported to the local medical association to which the physician belongs. The latter Association will guide the member based on the instruction of the local medical associations. Pending on the investigation result, the local medical associations will decide whether or not the incident will be entrusted to the JMA Professional Medical Liability Insurance processing.

(6) The matter entrusted to JMA will be investigated and discussed by “the Investigation Committee” working under the JMA Professional Medical Liability Insurance, and presented to the “Medical Liability Review Board,” a fair and neutral review organization. Based on the review result, JMA management policy is notified to the local medical associations. According to the policy, the member in question will try to settle the dispute under the guidance of the local medical associations to which he/she belongs.

(7) JMA Professional Medical Liability Insurance has a different scheme from those of physicians’ medical liability insurance taken
out by clinics and hospitals.

JMA Professional Medical Liability Insurance insures only its Category A Members, and the insurance money will be paid for damage attributable to the Category A Member as an individual. If the review finds a party other than JMA Category A Member responsible for an accident, the portion attributable to such other party shall not be covered by the insurance, and will be deducted from the insurance money.

JMA Professional Medical Liability Insurance is managed in a restricted way because the insurance premiums are paid from the membership fees of the Category A Members. Thus, it is different from general medical liability insurances under which the right to seek remedy from the responsible party for the accident is waived in advance.

JMA Professional Medical Liability Insurance with Special Clause

JMA Professional Medical Liability Insurance is managed in a restricted way because the insurance premiums are paid from the membership fees of the Category A Members. Thus, it is different from general medical liability insurances under which the right to seek remedy from the responsible party for the accident is waived in advance.

JMA Professional Medical Liability Insurance with Special Clauses (the Special Clause Insurance), which was created in 2001, is explained below.

1. Creation and purposes

As discussed above, the current JMA Professional Medical Liability Insurance basically insures its members against liability for their medical act. Therefore, if a Category A Member who is the founder or administrator of a hospital or a clinic employs a physician who is not a Category A member (non-A member), and the physician causes a medical accident and the Category A Member is demanded to pay damage as the responsible administrator, the insurance does not extend to the liability of the non-A member. The same applies to an entity such as a medical corporation.

Therefore, the insurance money is paid by deducting the amount for damage that is attributable to a non-A party member. This is called “the payment deduction.” The amount thus not covered by the insurance was often borne by the Category A Member as the founder or administrator of the clinic or hospital.

The recent trend is that the amount of insurance payment exceeds the maximum liability.

In view of such a situation, “JMA Special Clause Insurance” that the Category A Members may optionally take out was created as of September 1, 2001 to cover the Category A Member who is also an administrator or to enable the member to pay high damages.

2. Outline of the Special Clause Insurance

(Fig. 2)

The Special Clause Insurance covers the amount in excess of the maximum coverage of the current JMA Professional Medical Liability Insurance, and the Category A Members may choose to take out this insurance.

Applications for the insurance are accepted by the local medical association to which the Category A member belongs, and the Japan Medical Association enters the contract as the insurer with a non-life insurance company. Similar to the current JMA Professional Medical Liability Insurance, the contract is entered directly between JMA and the insurance company without an agent.

The premium is collected by the due date upon instruction of the local medical association. If the insurance premium is not collected by the due date, the insurance becomes invalid retrospectively.

The system of dispute settlement for medical accident is the same as the current JMA Professional Medical Liability Insurance.

(1) The insurer

Only the Category A Member is qualified to become the insurer. Non-A Members are not qualified. Those Category A Members whose fees are exempted by JMA may pay the prescribed fees and become the insured party.

(2) Taking out the insurance

This is a voluntary insurance for the Category A Members.

(3) The insured
The Category A Member (the registered member) and the corporation managing a medical facility for which the Category A Member serves as the director or administrator (the registered corporations) are insured; such medical facilities include (1) clinics, (2) hospitals established by individuals, and (3) hospitals with 99 or less beds established by corporations. The following two points should be noted.

* A non-A member physician working in such a medical facility is not insured. Therefore, if a non-A member physician is demanded payment of damage by a patient, this Special Clause Insurance is not applicable.
* Medical facilities that are managed by the government, social insurance schemes, companies or public medical facilities (including clinics and hospitals in both instances) are not applicable.

(4) **Payment of insurance money**

Under the “Special Clause Insurance,” the Category A Member who is the insured party is paid the full amount of the insurance money for the damage for which a non-A member is specifically liable.

Provided, however, if the non-A member is insured by the general medical liability insurance, payment is shared by the JMA Professional Medical Liability Insurance and JMA Special Clause Insurance. In other words, if the non-A member is insured by other medical liability insurance such as by his/her affiliated specialized medical society, the portion that is attributable to the non-A member is paid by the said insurance.

(5) **Insurance money and maximum compensation amount**

The insurance money consists of the payment for damage and the legal fees. The total maximum compensation per year is ¥200 million per accident (of the same medical act) and
the total amount for the entire insurance period (per year) is ¥600 million. The maximum compensation amount is applied to the sum of damage of the registered member and the registered corporation.

(6) **Exemption Amount**

The amount exempted per medical act is ¥1 million per accident. Provided, however, this amount is not applicable when the insurance money is paid from JMA Professional Medical Liability Insurance.

(7) **Insurance period and procedure**

Since the Special Clause Insurance is the special policy condition of JMA Professional Medical Liability Insurance, and their insurance periods coincide or it is one year from July 1 every year, the insurance can be taken out once a year, as a rule.

Provided, however, the exceptional measure was taken for the year 2001; ten months from September 1, 2001 to July 1, 2002, and six months from January 1, 2002 to July 1, 2002.

The Category A Members wishing to take out the insurance should submit the application at least two and a half months prior to the start date to the local medical association.

When a hospital established by a corporation and having 99 or less beds wishes to switch to this insurance from the general medical liability insurance, the period may be shorter and monthly installments may be made, i.e. from the first day of the month in which the former insurance expires until July 1. In this case, the hospital should apply to the local medical association at least two and a half months prior to the start of insurance.

(8) **Insurance premium and payment method**

The premiums are classified for clinics, the Category A Members, and hospitals, and collected through the local medical associations.

(9) **Exercise of the right to claim for damage**

Any exercise of the right to claim for damage will be examined by the Medical Liability Review Board. The current JMA Professional Medical Liability Insurance reserves the right to claim for damage and the present Special Clause Insurance does the same.

The Special Clause Insurance shall pay the insurance money in full to the Category A Member for the portion attributable to the non-A member if the Category A Member is so demanded. Provided, however, a non-A member may be asked to pay for the damage after the Category A Member is paid the insurance money in full.

Exercise of this right to claim for damage shall be subject to examination by the Medical Liability Review Board.

(10) **Accident at medical facilities**

Both the Special Clause Insurance and the current JMA Professional Medical Liability Insurance do not cover accidents attributable to the ownership, use, or administration of medical facilities. We recommend taking out “facility damage insurance” aside from insurances discussed in this paper. Special care should be taken by facilities such as hospitals where patients are admitted.

(11) **Others**

The insurance for the Category A Member will be automatically renewed in the ensuing years unless the conditions change.

The Special Clause Insurance was outlined and discussed. The Special Clause Insurance is managed along with the JMA Professional Medical Liability Insurance in order to deal with disputes involving serious medical accidents, and will therefore function to improve the financial basis.

For details of these two insurances, reference should be made to the commentary attached to the JMA Journal dated June 1, 2001 (Vol. 125, No. 11).

**Conclusion**

The society’s interests in the matters of medical care, particularly those of medical accidents, are mounting. As people’s awareness of their rights changes and medical sciences advance further, disputes involving medical accidents are expected to become more com-
plex and increase in quality and quantity.

Medical care givers and patients alike desire quality medical care and the environment where patients can receive secure and safe care. Physicians should, therefore, strive to promote and implement measures for securing the patient safety.

JMA Professional Medical Liability Insurance and the Special Clause Insurance are characterized by uniquely excellent features and sound management. However, these systems need to be optimally balanced. The best measure to prevent the medical liability insurances from becoming bankrupt is to offer safe medical care and secure the patient safety.

To secure the patient safety and to manage the JMA Professional Medical Liability Insurance as the hedge against accidents, JMA is resolved to continue its serious endeavors. We welcome proposals and suggestions from our members and thank for their continued support.