Control and Prevention of Medical Malpractice
—Keynote Speech in the Seminar on Patient Safety—

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Abstract: There have been a number of medical cases of malpractice at the Musashino Red Cross Hospital. In 1995, we established a “Medical Practice Evaluation Committee” consisting of 11 doctors to review incident reports submitted by doctors describing their mistakes to resolve their own problems with reference to risk management systems in the field of aviation. I discuss the challenges faced by the Musashino Red Cross Hospital in preventing medical malpractice by referring to the principle that improvement of the institutional operating system should be based on the principle that even a minor incident can become a lesson to be shared by the whole hospital. Also, I address the establishment of risk management system in a hospital and what the medical field can learn from the risk management system in the field of aviation.

Key words: Risk management in healthcare; Medical risk management; Healthcare risk management introduced from aviation risk management

There had been a number of cases of medical malpractice at Musashino Red Cross Hospital, and since the autumn of 1994 the hospital has been engaged in activities to prevent such malpractice. Today, I will begin with the history of this situation.

Next, I will describe approaches to the establishment of risk management systems from the perspective of both a health care institution and as an individual concerned with patient safety.

Lastly, I will point out what the medical world can learn from the field of aviation, a matter I have been studying.

Traditional Approaches to Medical Malpractice

In response to medical malpractice the traditional form of investigation focuses on what happened, who was responsible for it, and who had previously been responsible. Then the incident is eventually settled by punishing the responsible person. Most medical malpractice has
been dealt with in this manner, in what is called the responsibility-oriented approach. It never improves the situation.

It is necessary to implement a cause-oriented approach, or to discuss causes and required measures in order to prevent such incidents.

**Approaches to Preventing Medical Malpractice**

Let me introduce a brief history of the situation at Musashino Red Cross Hospital. There have been a number of cases of medical malpractice at Musashino Red Cross Hospital. During the 5 years between 1988 and 1992 there were 5 major cases of medical malpractice. The hospital paid settlement packages of over 250 million yen, which involved payments of 7 to 20 times the insurance premium. The highest demand for compensation was 340 million yen, but it was finally reduced to 110 million yen.

I was appointed as a Vice-President of the hospital in 1992. In 1993, a manager of the insurance company through which the hospital was covered visited the president of the hospital. I met him in behalf of the president who was absent, and I became involved with the matter. Some of his comments impressed me greatly.

Let me illustrate an example. When a fire occurs in a factory, the company investigates its cause through various means. As a result, the company rarely repeats the same type of accident. In contrast, accidents of the same type repeatedly occur in the same hospital. He said, “Why does it happen? Is it impossible to learn from mistakes in medical care?” His words shook me and I thought I had to do something to improve the situation. In addition, the insurance company strongly requested the introduction of institutional preventive measures to prevent medical malpractice.

In the Musashino Red Cross Hospital, each department has its own way of medical practices. In a sense, however, an individual doctor starts a private practice in a hospital. As I thought that there was no institutional control system to establish the overall direction and level of health care in the hospital, I started to implement measures to prevent medical malpractice.

The first goal we set was to raise the awareness of medical malpractice among medical professionals.

We thought that the Quality Control (QC) activities, that have supported Japanese industries, were the most appropriate means for this purpose.

We asked a QC group in each work unit to select topics through a top-down approach, focusing on the prevention of medical malpractice. A total of 11 groups started QC activities. All QC group activities ceased after about 2 years because the top-down system was adopted instead of the preferable bottom-up system, and the majority of the topics covered by the QC activities concerned problems related to nurses alone. We are currently trying to resume QC activities with a bottom-up approach.

We learned a lot from the QC activities over these two years, and I believe that the experience established the basis for future activities to prevent medical malpractice in our institution.

The nursing section has traditionally been involved in efforts to prevent medical malpractice. In association with this new venture, they started to make various improvements including revision of their accident report forms. Within a period of 18 months, the nursing section developed a manual entitled “Accident Prevention.” On completion of the manual, doctors were pressed to take action. But I could not respond to their concern.

In response, the doctors themselves decided to introduce an incident reporting system. We organized a “Medical Practice Evaluation Committee,” that was later renamed the “Medical Risk Management Committee.” It is composed of 11 doctors. I will give you the details later.

Then we tried to establish a risk prediction system. All of the department heads were asked to prepare a list of accidents that were most likely to occur in medical care in their departments and to formulate and submit measures.
to prevent them. These reports have been incorporated into appropriate chapters of the “Manual to Prevent Medical Accidents.”

Risk Management Technology in the Field of Aviation

At the beginning of our attempt to deal with medical malpractice, Dr. Isao Kuroda, then a professor at the School of Human Sciences of Waseda University, suggested the introduction of risk management technology developed in the field of aviation because malpractice in health care resembles the accidents that occur in aviation.

There is a well-known saying of “chain of events” in aviation accidents. Meaning that three or more minor incidents always occur in a row before a larger, more serious accident. This is called a chain of events. Every pilot is instructed to faithfully report every incident that occurs during a flight regardless of its seriousness (including near-miss incidents). They are assured that filing such reports will in no way affect their chances of promotion or future pay increases. This encourages honest reporting. Safety in aviation is ensured by compiling and analyzing these incident reports to cut the chain of events at an early stage.

Incident Reporting

We still use a registered incident/accident report form. It requires completion of the following sections: Diagnosis; place, date and time, type and conditions of the accident; subsequent reaction to the accident; evaluation of the degree of risk; mental and physical health status of the medical personnel involved; views on the cause of the accident; and thoughts on the steps to be taken in future. These are submitted to the general affairs section, and transferred to me.

However, there are some problems in the incident reporting system. One problem is whether a report will be registered or not. Because a registered report requires strict control, some specialists say that it should not be registered. However, because of three consecutive incidents caused by the same doctor in the hospital, we do not discuss the registered system.

Another major problem is that the incident reporting system is not legally enforceable, which is closely related to the matter of registration. If it is expected that information will become available by some other route for other purposes, including legal affairs, reporting cannot be effectively implemented.

Therefore, I consider it necessary for the government to urgently provide legal protection for the incident reporting system. In Japan, it has been regarded as a kind of taboo to review the medical practices of doctors in investigating medical accidents. Accordingly, medical incidents that come into a gray zone of malpractice remain unresolved. This situation will decrease confidence of doctors as leaders of the team in medical practices. I believe that the objective evaluation of various problems in medical malpractice, even if they are minor, will be of benefit to the entire hospital.

Establishment and Responsibility of the Medical Practice Evaluation Committee

A properly functioning system with self-appraisal by doctors to resolve their own problems will reduce medical malpractice in a hospital. The Management Conference approved my proposal to organize a Medical Practice Evaluation Committee based on this concept. In order to obtain the consensus of the hospital staff, I explained the purpose at department head meetings and wrote an article for the internal hospital newsletter.

Later it was renamed the “Medical Risk Management Committee,” and consists of 11 doctors from 11 departments, including 6 department heads and 5 assistant heads. The standard for selection was based on the capacity to provide experienced and balanced judgement. The committee meets once a month. Based on
the incident reports, this committee investigates various factors such as problems related to medical technology, appropriateness of clinical judgements, the working backgrounds, and the psychological condition of the medical staff.

It is most important to note that an incident seemingly caused by an individual mistake is sometimes the result of the hospital system itself. In this case, the system should be changed or revised. Also the monitoring functions within the hospital need to be reviewed.

Such a review sometimes discloses problems on the part of the patients.

It was also hoped that the committee would play the role of a medical audit system. At first the committee was going to hold CPC (clinico-pathological conference) or inquiries related to deaths, but they have been restricted to prior hospital incidents due to various internal conditions. I think that as a result the committee has strengthened its function as a medical audit system.

Learning from Actual Cases

Let me introduce two malpractice incidents.

A 49-year-old patient with a pacemaker was carried into the emergency department after a tachycardia attack. The doctor in attendance ordered 50 mg of Xylocaine. Intravenous injection of the fluid in the provided syringe relieved the tachycardia, but made the patient unconscious with muscle cramps. The doctor did not realize what had happened, and moved the patient to the ICU where the patient was satisfactorily treated. The doctor found that the injection he had administered was an ampule containing 1,000 mg of Xylocaine, not 100 mg. His prescription had been for 50 mg of Xylocaine, but he actually administered 500 mg. This caused an acute Xylocaine adverse reaction in the patient.

Based on this experience, the Committee re-organized medicines in the emergency department. The committee discussed the necessity of providing 1,000 mg ampules of Xylocaine. Xylocaine in 1,000 mg ampules is usually used to prevent arrhythmia in medical drips in ICUs and CCUs, but it is rarely used in emergency departments. As the availability of 1,000 mg ampules of Xylocaine in wagons in the emergency department can result in mistakes, all of them were transferred from the wagon to a cabinet.

At the same time, the Committee investigated drug names that can easily be confused, in cooperation with the pharmacy. A list of these was distributed to all doctors. Now, all the drug names that can be easily confused are listed in our Manual.

In addition, the Committee emphasized the verification of ampules containing active drugs, especially dangerous drugs, at meetings of the department head.

I think that it is not possible to avoid mistakes such as mistaking a 1,000 mg ampule for a 100 mg ampule in a busy emergency department even though the volumes are obviously different.

I asked Astra Japan, a distributor of Xylocaine to make the difference in ampule volume more distinguishable both visually and impressibly. I even suggested that the 1,000 mg ampules could be triangular in shape. After around two months, I received a polite letter from the company saying that as they distributed medicines all over the world, they could not change their dosage forms for financial reasons. They said they would take my suggestion into consideration in future revisions. After all, they did nothing.

Further investigation revealed that many medicines are contained in ampules of the same shape. I hope that it would be possible to differentiate between these same-shaped ampules by making changes such as the addition of a few grooves as a minimum distinguishable mark.

The same thing can be said for oral medicines. For four years, I continually appealed to manufacturers regarding my concern that many oral medicines are similarly packaged. Packages or dosage forms should be designed
to be distinguished easily. For example, a red-based design for cardiovascular medicines, a yellow-based design for gastroenterological medicines, and a blue-based design for respiratory medicines. I believe that the pharmaceutical industry should seriously tackle this problem for the sake of risk management.

As the pharmaceutical industry is involved in commercial practices, it is the task of the Pharmaceutical and Medical Safety Bureau of the Ministry of Health and Welfare to supervise them.

Let me introduce another case of antibiotics overdosing.

A doctor ordered two types of antibiotics. The hospital has only two sizes of prescription forms with a similar basic format. The doctor ordered the administration of medicine A twice a day, and medicine B once a day on the same form. The time of administration was not set according to nurses' convenience. The incident happened in a ward where medicine A and B are reportedly often co-administered.

As the prescription form showed just '2' meaning 'twice a day' in the section for the administration time of medicine A, a nurse wrote in 2 a.m. and 2 p.m. The nurse was thinking of the same idea when she wrote the same thing for medicine B and started double the dose of medicine B. After about 2 days, she realized the mistake.

In response to this incident, the Committee established an integrated system for describing injections in the order form. Up to then, individual doctors had filled the form in at their own discretion. Subsequently, doctors were asked to fill in the form showing the actual administration time.

Doctors were asked to write the exact time of administration, or mornings and evenings for medicines for which the time is not designated and is at the discretion of the nurses. For medicines that should be administered once a day, they were asked to write the exact time, or mornings or evenings.

Establishment of a Risk Management System

Medical malpractice can be considered from the two perspectives, from that of a medical institution or an individual.

A medical institution should assign a general risk manager to establish a risk management system (Table 1). A president or vice-president should undertake the responsibility for this. Because hospital systems sometimes require modification for this purpose, an administrator should be responsible for implementation.

Next, department heads or head nurses should be made aware of their position as risk managers in the department or division.

I believe that the most appropriate method is the incident reporting system in order to gather internal information.

In addition, a committee for reviewing incident reports such as a risk management committee should be organized. The conclusion of such a committee based on incident reports can be of benefit to the whole hospital through a feedback system.

Furthermore, this committee can also function as a means of medical audit.

I call this the third eye. The possibility of a review of cases by 11 doctors from 11 departments encourages the medical staff to conduct medical practices with more care.

Additionally, medical records should be kept precisely based on the facts. Medical practices should also be standardized as much as possible. Clinical pathway has recently become more prevalent in Japanese hospitals. By reducing the potential for mistakes, standardization is very important in improving not only economic factors in health care, but also the quality of medical treatment.

The "Manual to Prevent Medical Accidents" mentioned before should be developed as a risk prediction system. Our manual provides the principles for the prevention of medical malpractice in a general statement. It includes the basic appropriate manners and behavior for a
doctor, patient-oriented thinking, importance of confirmation, a responsive attitude for listening to colleagues and medical co-workers, establishment of a relationship with mutual trust between the doctor and patient, and the means of obtaining informed consent.

It is also important to incorporate a checking system into the institutional system. Pharmacists and nurses contribute to this in the Musashino Red Cross Hospital.

Finally, education of the medical staff is extremely important. As almost 40 new doctors come into the hospital every year, special guidance for incoming doctors has been given twice a year as well as for residents. I make a speech using the Manual to Prevent Medical Accidents on these occasions.

It is quite difficult to foster risk managers. I am struggling to appropriately raise the awareness of managers in this regard.

**Risk Management by Individuals**

To establish risk management systems at the individual level (Table 2), QC (Quality Control) activity is one of the best methods of raising the awareness of medical professionals even though we failed to introduce it in the first two years. It should be understood that incident reports are a basis for improvement of the institutional system, and that they are not to be used as a means of reprimand. We encourage medical professionals to write the reports honestly as writing these reports helps raise awareness.

The third revision of the “Manual to Prevent Medical Accidents” has recently been completed. The drafting by risk managers of preventive measures for listed accidents that are most likely to occur also helps raise awareness, and we do not aim at completion of a perfect manual. It will also be revised in a few years.

I repeatedly emphasize this, the basic attitude such as manner and behavior, patient-

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**Table 1  Risk Management by a Medical Institution**

1) Appointment of a general risk manager
   - Responsible administrator (President or vice-president)

2) Assignment of risk managers
   - Department heads, head nurses, and division heads

3) Collection of information
   - Incident reporting system

4) Medical Risk Management (MRM) Committee
   1) Reviewing incident reports:
      - Medical technique, judgement, working conditions, human factors (background)
   2) Feedback of conclusions: information shared by the whole hospital
   3) Medical audit: Institutional monitoring

5) Correct recording based on facts

6) Standardization of medical treatment: utilization of clinical pathway

7) Establishment of a risk prediction system
   - Development of a manual for the prevention of medical malpractice
   - Principles for the prevention of medical malpractice:
     - manner and behavior of doctors, patient-oriented thinking, importance of confirmation

8) Introduction of checking systems into the institutional systems

9) Education of doctors, nurses, and medical staff
   - Fostering risk managers
   - Guidance to incoming doctors
   - Guidance for residents
I think that the relationship among medical professionals is extremely important.

Characteristics of Medical Disputes

There are some common characteristics in medical disputes. A lawyer involved in medical disputes often said, while half of the medical disputes involve a financial settlement, the other half concern the personality of the doctor. Appeals are made just to punish the doctor. I think that the relationship among medical professionals is extremely important.

Table 2  Risk Management by Individuals

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<tr>
<th>1) To raise the awareness of medical professionals</th>
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<td>Raising the awareness through QC (Quality Control) activities and incident reports</td>
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<td>Listing accidents that are most likely to occur, and formulating preventive measures</td>
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<td>Development of a Manual to prevent medical accidents</td>
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<td>2) Manner and behavior of the doctors and medical staff, patient-oriented thinking, importance of confirmation, humility, awareness</td>
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<td>3) Communication (reduction of human error)</td>
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<tr>
<td>Medical staff and patients</td>
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<td>Among medical professionals (between doctors and nurses, doctors and technicians, nurses and technicians): horizontal person to person relationships with mutual monitoring</td>
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Fig. 1  Relationship with patients
70% of medical disputes arise even in the absence of errors on the part of the medical staff. They stem from a lack of communication between the medical professionals and the patients.

Although communication seems to be related to conversation, patients reportedly feel distrust based on expression of the face and eyes, as well as the behavior of medical professionals. An initial germ of distrust can grow gradually through consecutive medical treatment, finally leading to a medical dispute even in the absence of errors.

We cannot omit the factor of personal problems in cases of medical disputes. In fact, they are related to the quality, personality, and technical level of medical professionals.

Learning from the Risk Management System in the Field of Aviation

I will address some advantages of risk management technology in the field of aviation from which we can learn a lot. I have not yet implemented them, but I am planning to do so.

Risk management system in the field of aviation is called CRM (cockpit resource management). It is now called Crew Resource Management, which is a more comprehensive term (Fig. 2).

In a cockpit, there are three persons, a pilot, an assistant pilot, and an engineer, and now there are two in almost all cases. CRM aims at utilizing every item of information and resources in a cockpit to the greatest extent possible. In the past, as pilots had absolute authority, no other crews were available to warn them and this often resulted in accidents.

In CRM, it is most important to develop a parallel relationship between crews in the cockpit in order to avoid human errors. The training system for this is called LOFT (Line Oriented Flight Training). In the simulator, three crews operate an aircraft in various settings from Tokyo to Osaka, for example. They review the recorded flight process, and find some means of improving the situation by themselves. I think that this can be introduced into the medical field.

The awareness that I mentioned before is on the basis of teamwork. It is important to consider other people’s problems as your own, to pay continuous attention to the surroundings, and to exchange information. In addition, what is required of the pilot as the leader is clearly established. This can be applied to doctors.

A pilot should be a confident person capable of being responsible for his or her actions, a self-controlled person based on creative judgment, a person with a high learning capacity,
and a person who can detect the problem and resolve it by himself or herself. This can also be applied to doctors.

In conclusion, a leader should be a self-controlled person. An organization consisting of people with self-control can flexibly respond to various crises or pressures and overcome various obstacles. Therefore, the field of aviation reportedly emphasizes the fostering of self-controlled people.

In the medical field, the doctor is responsible for the cure, the nurse for care, and the technician provides skills to ensure the safety of patients. Other staff involved in the medical field, including clerks, all contribute to the treatment of patients.

Based on this concept, a parallel relationship to allow free mutual monitoring can be established by recognizing that all staff including doctors, nurses, technicians and others have their own roles to play. This mutual monitoring only is a matter of preventing normal human errors.

The techniques of the pilot are divided into flying skills and “airmanship”. The term “airmanship” originated from noblesse oblige, what is called aristocracy in the United Kingdom, meaning leadership based on quality, morality, responsibility and obligation. It is as highly desirable a quality as operating skills.

This can be applied to doctors. Doctors are required to have both medical expertise and medical skills, and “doctormanship,” which is a humane quality and involves a sense of obligation and responsibility. This has not been emphasized in medical education in Japan.

7 Points to Prevent Errors

All Nippon Airways (ANA) distribute “7 points to prevent field errors” to employees, as a practical approach to dealing with human factors (Table 3). I take it up because it can be applied to the medical field.

1) Self-monitoring with a humble attitude,
2) Team-monitoring with sensitive attention to others,
3) Raising awareness in unusual and high-risk conditions,
4) Information sharing through sufficient communication,
5) Risk prediction leading to safety,
6) No violation of basic understandings,
7) Proposals for improving oneself and others.

I believe that these can be combined into the concept of transparency in medicine. In other words, it concerns recording, accountability, patient-oriented medicine, and disclosure of information.

The hospital convenes a Medical Council consisted of the president, vice-president, head of the nursing department, corporate secretary, and chief manager of the general section to discuss corrective measures when a medical dis-

Table 3 Practical Approaches to Human Factors in ANA

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pute occurs. I serve as the general risk manager, supported by a Risk Management Committee consisting of 15 members including doctors, pharmacists, laboratory technicians, clerks and risk management nurses.

I have spoken about the control and prevention of medical malpractice based on experiences at the Musashino Red Cross Hospital. Thank you for listening.

REFERENCES