APPROACH TO RISK MANAGEMENT IN MEDICAL PRACTICE: STANDPOINT OF A HOSPITAL*

Shozo MIYAKE**

Abstract: There had been a number of incidences of medical malpractice at Musashino Red Cross Hospital, and since 1995 the hospital has been engaged in “activities to prevent medical malpractice”. In the early days, efforts were focused on quality control (QC) by introducing an incident reporting system that was patterned after risk management techniques developed in the field of aviation. To evaluate these incident reports, a “Committee to Assess Medical Services” (later renamed the Medical Risk Management Committee) was established. Every month this committee reviews each incident from the standpoint of medical technology, medical judgment, human factors, labor conditions, hospital systems, and the supervisory functions of the hospital. The results of these evaluations are used to improve defects in the above system. The committee also conducts medical audits in the hospital. Our approach to the prevention of malpractice is described in this paper.

Key words: Risk management in health care; Medical risk management; Policies to prevent medical malpractice

Introduction

Generally speaking, when an accident occurs in an industry, every effort possible is made to prevent a recurrence, thereby minimizing the risk of recurrence of the same type of accident within that industry. In health care, however, accidents of the same type repeatedly occur in the same hospital. One might even suspect that it is impossible to learn from mistakes in medicine. Confronted with this situation, there is apprehension that doctors in a team practice may lose the trust that the other team members have always placed in them. To improve this situation, hospitals must make efforts systematically to change health care risk management so that medical malpractice can be prevented.

On the other hand, human beings always make mistakes, therefore, making every effort to prevent errors and provide safe and high-quality health care is the most important mission of health care organizations, and the practices employed at the Musashino Red Cross Hospital are described below from this standpoint.

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The first goal we set in our attempt to prevent medical malpractice was to raise the awareness of those in the frontlines of medical practice. We believed that quality control (QC) activity was the most appropriate means for this purpose and organized a QC group in each work unit in a top-down format. The head of each section was to lead the group, and a total of 11 groups were formed. First, they set the major goal of “prevention of malpractice” and selected topics accordingly. Each group held meetings once a month, from which we learned a great deal. However, the majority of the topics of the QC activities concerned problems related to nurses alone, and because the results of the discussions overlapped accident prevention activities in the nursing section and measures to improve nursing works, the burden on the nurses became even more onerous. After about 2 years, all QC group activities ceased.

These initial efforts, however, established the basis for future activities to prevent medical malpractice in our institution. We came to realize that the QC activities must be reorganized in the original bottom-up format, and we are currently engaged in reorganizing our improvement activities, with the support of the Union of Japanese Scientists and Engineers.

**Construction of a Medical Risk Management System within an Organization**

1. **The nursing section**

   The nursing section has traditionally been involved in efforts to prevent medical malpractice. In association with this new venture, they revised their accident report forms, organized a “committee to prevent accidents” within the nursing section, reviewed accident reports forwarded from the wards, and fed the results back to the meetings of the chief nurses. The nursing section drew up a manual called “Accident Prevention” within a period of 18 months. Since early 1999, a risk management nurse has been assigned to each ward to gather and analyze information on each incident and send back the details of the analysis in the form of feedback (Fig. 1).

2. **Doctors**

   There are numerous problems concerning doctors, and policies affecting doctors will be mainly presented in this section.

   Traditionally, doctors have seemed to regard themselves as privileged and expected everyone else to serve them, this attitude may have helped doctors to become self-righteous. Doctors have tended to avoid disclosing the details of their practice in investigations of medical malpractice, always leaving behind a so-called “gray zone”. However, the modern societies offer a wealth of medical information, and the public is better informed than ever. If doctors do not shake themselves free of their arrogant attitude, it may be impossible to prevent recurrences of medical malpractice, and doctors, as leaders of the health care groups, may lose the trust of the other team members. Faced with the situation described above, our programs were undertaken.

   Another motivation for starting these programs was doubts about the appro-
priateness of our former method of hospital management. There are a number of medical departments within a hospital, and each operates within its own specialty. If each operates independently without regard for the other departments, the cohesion desired in a hospital is lost. Organized health care becomes possible only when the goals and quality of medical service of the hospital as a whole are maintained and managed. We believe that there is a definite need for a system to monitor the health care actions of the hospital as a whole.

Introduction of an Incident Reporting System

Following the advice of Dr. Isao Kuroda, then a professor in the School of Human Science of Waseda University, who suggested “the introduction of risk management technology that had been developed in the field of aviation because malpractice in health care resembles the accidents that occur in association with aviation” (1995), we decided to adopt the risk management incident reporting system for doctors.

There is a well known saying that there is a “chain of events” in aviation accidents, because “3 or more minor incidents always occur in a row before a larger, more serious accident.” Every pilot is instructed to faithfully report every incident that occurs during a flight regardless of its seriousness (including near-miss
 requires Incident/ Accident Report

<table>
<thead>
<tr>
<th>Incident/ Accident Report</th>
<th>Date:</th>
</tr>
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<tbody>
<tr>
<td>Work site</td>
<td>Position</td>
</tr>
<tr>
<td>Patient’s name</td>
<td>Age (male or female)</td>
</tr>
<tr>
<td>Site of the accident occurred</td>
<td>Ward</td>
</tr>
<tr>
<td>Date and time of the accident</td>
<td>Date:</td>
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<tr>
<td>Date the accident was discovered</td>
<td>Date:</td>
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<tr>
<td>Time treatment was started</td>
<td>Date:</td>
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<tr>
<td>Time a report was made to the department head</td>
<td>Date:</td>
</tr>
<tr>
<td>Type of accident</td>
<td>[Classification] 1. oversight or misunderstanding, 2. misidentification, 3. error in dosage, 4. complication, 5. iatrogenic disease, 6. others</td>
</tr>
<tr>
<td>Process during which the accident happened</td>
<td></td>
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<tr>
<td>Response and steps taken after the accident</td>
<td></td>
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<tr>
<td>Explanation given after the accident and the subsequent response of the patient</td>
<td></td>
</tr>
<tr>
<td>Evaluation of the gravity of the risk involved in the accident</td>
<td>Life-threatening: □ very grave; □ grave; □ possible; □ little; □ none</td>
</tr>
<tr>
<td>Patient’s trust: □ greatly damaged; □ slightly damaged; □ not much affected</td>
<td></td>
</tr>
<tr>
<td>Health status of the medical personnel involved</td>
<td>□ good; physically fatigued [□ by work; □ for personal reasons]</td>
</tr>
<tr>
<td>psychologically fatigued [□ by work; □ for personal reasons]</td>
<td></td>
</tr>
<tr>
<td>□ others (remarks: )</td>
<td></td>
</tr>
<tr>
<td>Views on the cause of the accident</td>
<td>[Classification] 1. lack of observation, 2. delay in testing, 3. delayed diagnosis, 4. inadequate technology, 5. surgical mistake, 6. inadequate communication, 7. inadequate explanation, 8. others</td>
</tr>
<tr>
<td>Thoughts on the steps to be taken in future</td>
<td></td>
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</tbody>
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Fig. 2 Incident Report Form

Incidents) by filing an incident report. They are assured that filing such reports will in no way affect their chances for promotion or future pay increases. Accident prevention policies have been established and major accidents have been averted by gathering and analyzing these reports describing minor incidents.
When we introduced our incident reporting system, we distributed the following letter to doctors and pharmacists: “We all make mistakes at one time or another. Instead of feeling ashamed and hiding such mistakes, we would like you to share your mistakes with the hospital as valuable experiences that can be accumulated as an organizational asset. Individuals will not be accused of errors, so please report only the facts in the incident reports. The background of the incident or accident will be evaluated, and if a problem of the system in the hospital as a system is uncovered, it will be corrected immediately. The experiences will be used as a common asset to be shared by the entire hospital to enable us to offer safer and higher quality health care services. We hope that you will fill out the reports completely, and we assure you that there will be no personal repercussions.”

The form for reporting incidents has been designed to be as simple and easy to fill out as possible. It somewhat resembles the accident report forms now being used by nurses (Fig. 2).

As a rule, the incident report is voluntarily submitted by individuals, but the heads of the department have been assigned the role of risk managers and asked to urge their staff to prepare a report on any medical action that may be a cause for concern. In fact, however, few reports were submitted in the first 3 months. Therefore at a meeting of the department heads, the author stated the following: if there is no incident report from the department involved and a patient files a complaint, the management is forced to question the managerial responsibility of the department head. Department heads must have a thorough understanding of the medical actions of their staff, and if a problem is recognized, the head of the department is to instruct the staff member to file an honest report. I also emphasized that it is a non-punitive reporting system. In addition, when information has become available by some other route, the author has directly contacted the doctors in charge and asked them to submit a report.

As a result, reports started to trickle in. One member of the risk management committee in particular made a special effort to urge his staff to submit reports, and this seemed to have a priming effect. The number of reports has increased since then, and the increase is a reflection of the gradually increasing awareness among doctors that health care accidents can be prevented and that their reports are important in achieving this end. It also shows that the psychological burden of writing a report has gradually been alleviated.

**Establishment of the Medical Practice Evaluation Committee**

In introducing the incident reporting system, it was recognized that the reports should be evaluated objectively by a third party. Therefore, 11 persons considered capable of rendering sensible judgments were selected from among the department heads and assistant heads actively involved in clinical practice, and assigned to organize a “Medical Practice Evaluation Committee” (later renamed the “Medical Risk Management (MRM) Committee”). At the time the committee was established, its aims were explained at management conferences and department head meetings to obtain a consensus throughout the hospital. It is believed that the process to obtain this consensus was extremely important.
Based on the incident reports, this committee investigates various factors leading up to the occurrence of accidents and they look for answers to health-care-related questions such as: the possible existence of problems in hospital management and steps to correct them; problems related to medical technology; appropriateness of clinical judgments; the working conditions of the medical staff; the psychological condition of the medical staff when the incident occurred; and possible problems related to patients. It was also hoped that the committee would have the function of a medical audit.

Currently, the MRM Committee meets once a month. If a problem is discovered in the hospital system, the general risk manager immediately corrects it. When problems related to medical technology or clinical judgment are uncovered, specific plans to resolve them are studied by the departments involved. In the course of studying these problems, the labor conditions of doctors will inevitably surface, and they should be improved as much as possible through negotiation between the senior leaders and the doctors.

If a single incident involves more than one department, doctors from each of them (other than the committee members) are asked to participate in the investigation. The results of these investigations are transmitted to each department as feedback. If the problem involves the entire hospital, it is reported in the internal hospital newspaper (Musashino Nisseki Shinbun) as a “Report from the Risk Management Committee” so that all hospital employees will be informed.

Thus, the MRM Committee also has the functions of a medical audit.

The Risk Management System

In the United States, risk management is defined as “the science by which the risk for an economic loss is identified, evaluated, and managed”. Three approaches to organizing a risk identification system have been reported.1

1. Incident reporting system: Accident reports are expected to be voluntarily filed by employees: 5 to 30% of all accidents can be identified by this approach.

2. Occurrence reporting system: A list of potential accidents is prepared in advance and employees are expected to voluntarily report them whenever they occur. Approximately 40 to 60% of all accidents can be identified by this approach.

3. Occurrence screening system: Professional employees identify incidents by chart inspections based on written criteria. It has been reported that 80 to 85% of all accidents can be identified by this approach.

The risk management policies adopted in the United States include: (1) protecting the hospital’s assets; (2) improve the quality of health care (improvement of patients’ safety); and (3) following legally sound risk management policies.

Of the three policies listed above, (2) has been discussed, adopted, and regarded as the most probable approach in Japan at the moment. It appears to conform best to Japanese customs and traditions, which is most important. It is also related to [(1) protection of the hospital’s assets]; but more importantly, our efforts should be based on an intent to [(2) improve the quality of health care (and to ensure patient safety)].
Introduction of the Risk Predicting System

To introduce (2) an occurrence reporting system for the risk management system described above, the following steps were taken.

All of the department heads were assigned to the position of risk manager and asked to prepare a list of accidents that are most likely to occur in relation to medical care in their department and to formulate and submit measures to prevent them. These reports have been incorporated into appropriate chapters of the “Manual to Prevent Medical Accidents”. As reference material, informed consent to various procedures that are frequently conducted in each department are included (when the consent is written, it is often accompanied by statistics on risk). A list of drug names that are easily confused and photographs and names of ampules containing drugs for parenteral use are included in the manual so errors should not go unnoticed.

It is said that about half of the disputes concerning medical care involve financial settlement, whereas the other half concern the personality of the doctor (appeals are made just to punish doctors for their actions). According to the statistics in the United States, 70% of the medical disputes arise in the absence of errors on the part of the medical staff. These disputes stem from a lack of communication between the patients and doctors or other medical staff members. Apparently, what appears to have been a careless manner of speaking, attitude, or facial expression of the doctor generates distrust on the part of the patient, which eventually leads to medical complaint. With this in mind, the overview section of this “Manual to Prevent Medical Accidents” describes doctors’ methods and manner of dealing with patients under the heading of “Basic Rules to Prevent Medical Accidents”. In this section, attention is called to basic manners required by doctors, including the need for a patient-oriented medical process, confirmation of each procedure, assuming a humble attitude, with undivided attention given to what the patient wants to talk about, building a good patient-doctor relationship, and providing methods for filling out medical records.

This “Manual to Prevent Medical Accidents” was distributed to all doctors working at the hospital. Doctors are expected to peruse even the sections that do not actually involve them. Their critiques are useful in preparing the next edition, and three revisions were made. It required 8 months to prepare the first edition, which was published in August 1997. The second edition was completed in October 1998. In each of the revised editions we hope to include the experiences of doctors who have learned from the accident prevention steps taken in other departments and re-evaluated and reinforced the accident preventive measures in their own department. We also hope that the manual will be used by all doctors in the hospital, but the process of preparing it is even more important. The author believes that by experiencing the process by which policies to prevent accidents are drawn up, they will become more sensitive to the possibility of accidents. In other words, the manual to prevent medical accidents is most meaningful when each hospital prepares its own unique version.
Introduction of the Occurrence Screening System

The nursing section of our hospital assigned a risk management nurse late in 1999 and prepared its own screening system. We expect good results from this movement.

In the areas in which doctors are involved, the medical care in each department is extremely diverse and the magnitude of the risk involved is several times that of nursing section. Since the area involved is believed to be too large to be managed by a single risk manager, the department heads may have to be asked to act as risk managers; and doctors will be expected to improve their awareness of the need to prevent medical accidents.

Response to the Development of Medical Disputes

When a medical malpractice that might develop into a medical dispute occurs, the basic rule is that the doctor in charge immediately reports the accident to the head of the department, and that the department head in turn reports it to the head of the administrative department, the vice president (general risk manager), or the president of the hospital. The doctor then waits for their directions before responding further.

What is important in these procedures is that those involved express their sincerity and consideration toward the patients and their families by their attitudes and speech. Next, there is a need to establish a single channel to handle the procedures for dealing with patients or their families. At our hospital, the general affairs section is in charge. It is essential that the doctors in charge or the head of the department involved not apologize to patients or their families on their own nor tell them about the possible future response of the hospital based on their own interpretation. Doctors or department heads should always discuss the matter with the management of the hospital before they respond to outsiders. They should explain to them that the matter will be handled by the general affairs section, and then quickly report and discuss any future steps with hospital management through the procedures explained above. The initial response by the doctor in charge or department head often determines future developments.

After taking the steps described above, those who are directly involved in the accident should promptly fill out an “accident report” (a form that has been prepared by an insurance company) and submit it to the general affairs section. Based on this accident report, future steps to be taken will be discussed at the Medical Affairs Conference (composed of the president, vice president, head of the nursing section, business manager, and head of the General Affairs Section). At Red Cross Hospitals, such reports are sent to Red Cross Headquarters and the insurance company.

When the evidence is seized or a patient files a claim leading to a legal dispute, a conference is held between the attorney representing the patient and the insurance company, and the response by the attorney is discussed at a Medical Affairs Conference.
In reality, personal elements (e.g., personalities or personal attainment) are involved in medical accidents. However, even when an accident appears to have been the fault of a single individual, the cause may be in the management system of the hospital. Therefore, it is important that the person involved report the accident faithfully and that a system capable of evaluating such incidents objectively be in continuous operation in the hospital. When such a practice is established in a hospital, a more trusting relationship between doctors and the hospital management will be established. Backed up by a system such as described above, doctors can be assured of their positions and can concentrate on their own jobs. At the same time, they are reminded that their medical services are being monitored by a third party. Such an environment should produce a change in the doctors’ attitude toward the medical care they provide. It is hoped that this change in the doctors’ attitude will result in reduced medical malpractice.

It has been five years since we instituted the steps described above to deal with medical accidents. The changes in the amounts of money that our hospital has paid for financial settlements since 1973 are displayed to show the results of our efforts over the years (Fig. 3). Fortunately, no major disputes have occurred (except for one incident early in 1996, when we had just undertaken activities to prevent malpractice). However, valid evaluation should be conducted at 10-year intervals. We hope that the effort by the hospital as a whole will continue.

**Conclusion**

In reality, personal elements (e.g., personalities or personal attainment) are involved in medical accidents. However, even when an accident appears to have been the fault of a single individual, the cause may be in the management system of the hospital. Therefore, it is important that the person involved report the accident faithfully and that a system capable of evaluating such incidents objectively be in continuous operation in the hospital. When such a practice is established in a hospital, a more trusting relationship between doctors and the hospital management will be established. Backed up by a system such as described above, doctors can be assured of their positions and can concentrate on their own jobs. At the same time, they are reminded that their medical services are being monitored by a third party. Such an environment should produce a change in the doctors’ attitude toward the medical care they provide. It is hoped that this change in the doctors’ attitude will result in reduced medical malpractice.

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REFERENCES