Guidelines for Handling Medical Adverse Events: Enhancing Safety Through Candid Communication
Introduction

In Japan, ensuring medical safety has become an increasing priority, with medical institutions nationwide making a united effort to improve the situation. The impetus driving the movement forward was two serious medical accidents that occurred in 1999 at around the same time: a patient mix-up at Yokohama City University Hospital and an erroneous injection of antiseptic solution into an IV drip at Tokyo Metropolitan Hiroo Hospital.

Responding to these incidents, the All Japan Federation of Social Insurance Associations (Zensharen) launched a joint project to establish guidelines in the same year, with Social Insurance Chukyo Hospital, led by Director Dr. Masato Shibuya, as its project leader. In 2001, it released the “Zensharen Medical Safety Manual” and distributed it to its member institutions along with a CD-ROM.

Since then, the federation has been devoting great effort to providing medical safety training. In 2003, prompted by increasing instances of medication error, Zensharen began offering a five-day, 40-hour medical safety manager training program that required participants to enroll in pairs comprising a nurse and a pharmacist.

In 2005, Zensharen set up the Medical Safety Office within its Operation Department and the Social Insurance Hospitals Medical Safety Committee, comprising the directors of member institutions, to revise the existing medical guidelines for its members and to promote other medical safety efforts.

What inspired us to create these guidelines was the Japanese version of the Harvard-affiliated hospital guidelines for medical accidents, "When Things Go Wrong: Responding to Adverse Events," translated by a group of volunteers who had completed the Health Care and Social Policy Leadership Program at the University of Tokyo. I was moved by the spirit behind the Harvard guidelines and decided to share them among all member institutions as well as making them our organizational guidelines. We also decided to create a new, Zensharen version to tailor them as appropriate for the current situation in Japan since some of the Harvard guidelines were written for those with a different background.

The principles underlying the Harvard guidelines, "medical care must be safe" and "medical care must be patient-centered" are universal or, I must say, more adaptable to Japan, and this spirit permeates the Zensharen version.

Encouraged by these guidelines, we hope even more medical institutions in Japan will join us in our efforts to foster participatory medicine.

Finally, I would like to express my special appreciation to the committee members who devoted themselves to publishing the guidelines.

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Kenji Iwata  Advisor, All Japan Federation of Social Insurance Associations
“Guidelines for Handling Medical Adverse Events: Enhancing Safety Through Candid Communication” covers the following seven aspects of response to adverse events:

1. **Initial response:**
   Explains what to do immediately after the adverse event (medical accident).

2. **Truth-telling:**
   Advocates telling the truth based on the guiding principle “Don't hide, don't evade and don't fudge.”

3. **Apologies:**
   Explains how an apology should be offered if there has been an obvious error.
   ⇒ If necessary, offer an empathetic apology\(^1\) or a responsibility-accepting apology\(^2\).

4. **Mediation:**
   The guidelines place great value on the role of mediation/mediator between the patient and caregivers, with an understanding that it is in the best interests of both parties to resolve the conflict through communication. It also helps them move forward. Zensharen offers a training program for mediators.

5. **Root cause analysis (RCA):**
   Explains how RCA, which focuses on systems and processes rather than individuals to determine the system vulnerabilities, supports measures to redress the vulnerabilities and prevents error recurrences.

6. **Compensation:**
   Provides compensation-related policies, such as suspending hospital billing if the error is obvious, or if there is a potential to be so, considering how it will affect the feelings of the patient.

7. **Reporting:**
   Explains how internal reporting and reporting to Zensharen should be performed (see Appendix #2).

1. **Empathetic apology:** An apology offered with empathy to those affected by the bad outcome. An apology that derives from remorse over a failure to respond to the patient's expectations.
2. **Responsibility-accepting apology:** An apology offered with an acknowledgment of the error,
admission that it triggered the bad outcome, and acceptance of responsibility.
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I. Guiding Principles

Hospitals must always strive for elimination of medical accidents and recurrences, and seek higher patient safety and treatment quality.

This document was created based on the guidelines of the Harvard-affiliated hospitals with the objective of preventing medical accidents through the promotion of organizational disciplines built on the principles stated below and of fostering an environment in which patients can receive safe medical care with a sense of security.

The guiding principles of this document for handling adverse events (medical accidents) are: 1. Medical care must be safe, and 2. Medical care must be patient-centered.

1. Medical care must be safe
Hospitals are considered to be adaptable organizations. Without compromise, they should always examine themselves, commit themselves to continuous improvements, and if they realize that they took the wrong path, take responsibility by caring for the affected patient and by changing the existing systems to prevent recurrence of the error.

2. Medical care must be patient-centered
The purpose of communicating with the patient after an adverse event (medical accident) is to maintain a relationship through which the affected patient can be supported and healed.

The patient and family have a right to know the details of the event and consequential prognosis, and hospital communication should be timely, open, continual and have a "don't hide, don't evade and don't fudge" attitude, in order to maintain a relationship.

The role of the caregiver is to alleviate the grief, to offer support and to attend to what the patient essentially needs. Openness and a cooperative relationship play pivotal roles in this regard.

Process: This document was approved by the Social Insurance Hospitals Medical Safety Committee on June 13, 2008, and adopted by Social Security Hospitals after a draft was written by the committee’s Manual Revision Working Group, which was formed based on the committee decision on November 15, 2007.

Special thanks: This document was created based on “When Things Go Wrong: Responding to Adverse Events: A Consensus Statement of the Harvard Hospitals” (the “Harvard guidelines”). We express our respect and gratitude for its creators and participants.

Note: We made efforts to simplify the guidelines for concrete actions. Please see the original Harvard guidelines or their Japanese translation for the guiding principles (http://www.stop-medical-accident.net/).
II. Definitions

Many terms have been used to refer to errors and adverse events, often causing confusion. To avoid this, we use the following definitions in this document (see Figure 1 on p. 4):

**Medical accident:**
A general term referring to an adverse event (includes serious error) resulting in human injury caused by medical management*.

**Adverse event:**
An injury caused by medical management rather than the patient’s underlying disease; also called “harm” or “complication.”
An adverse event may or may not result from an error.
See further classification of preventable and unpreventable adverse events below.

*“Medical management” refers to all aspects of healthcare, including the actions or decisions of physicians or nurses.

**Medical error:**
The failure of a planned action to be completed as intended or the use of the wrong plan to achieve an aim.
Medical errors include serious errors, minor errors and near-misses.

Note: A medical error may or may not cause harm. A medical error that does not cause harm does not result in an adverse event.

In addition, we define the following:

**Serious error:**
An error that has the potential to cause permanent injury or transient but potentially life-threatening harm.

**Minor error:**
An error that does not cause harm or have the potential to do so.

**Near-miss:**
An error that could have caused harm but did not affect the patient because it was prevented.

**Preventable adverse event:**
An injury (or complication) that results from an individual error or systems failure.
It is useful to distinguish three error categories:

**Type 1:** Error by the attending physician.

*Example:* Technical error during performance of a procedure.

**Type 2:** Error by anyone else in the healthcare team.

**Type 3:** Internal systems failure with no individual error.

*Examples:* IV pump failure that causes drug overdose; Failure of system to communicate abnormal lab results to physician.

**Unpreventable adverse event:**
An injury (or complication) that was not due to an error or systems failure and is not always preventable at the current state of scientific knowledge. There are two major categories:

**Type A:** Common, well-known hazards of high-risk therapy. Patients understand the risks and accept them in order to receive the benefit of treatment.

*Example:* Complications of chemotherapy.

**Type B:** Rare but known risks of ordinary treatments. The patient may or may not have been informed of the risk in advance.

*Example:* Side-effects of medications; wound infections.

**Disclosure and communication:**
“Disclosure” is to provide information to a patient and/or family about an adverse event.
We use instead the term “communication,” by which we wish to convey a sense of openness and reciprocity.

**Reporting:**
Providing information to an appropriate authority, internal or external, regarding adverse events or errors.
(See “Reporting and Announcement” on p. 25 for more details on what events are to be reported.)
### Figure 1  Definitions/Categories of Events

**Medical Accidents**

<table>
<thead>
<tr>
<th>Near-miss (intercepted error)</th>
<th>Minor error (error occurred but no harm was done)</th>
<th>Preventable adverse events</th>
<th>Unpreventable adverse events</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Type 1</strong></td>
<td><strong>Type A</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Error by the attending physician</td>
<td>Common, well-known hazards of high-risk therapy</td>
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<tr>
<td></td>
<td><strong>Type 2</strong></td>
<td><strong>Type B</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Error by anyone else in the healthcare team</td>
<td>Rare but known risks of ordinary treatments</td>
<td></td>
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<tr>
<td></td>
<td><strong>Type 3</strong></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Internal systems failure with no individual error</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Near-miss</td>
<td>Minor error</td>
<td>Serious error</td>
<td>Error (preventable)</td>
</tr>
<tr>
<td>Error (preventable)</td>
<td></td>
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</tr>
</tbody>
</table>
Part 1 Initial Response to the Event

III. What to Do Immediately After the Event

1. Take whatever action is needed to stabilize the patient, mitigate any injury and prevent further harm.

2. Take urgent action to eliminate any threat to patient safety, such as an impaired caregiver, faulty equipment, an unsafe system of care or a deficient protocol.

3. Immediately secure implicated drugs, equipment and records.

4. If the primary caregiver is impaired or suspended, immediately provide a substitute and inform the patient and/or family.

5. Brief all members of the care team as soon as possible, so all members are fully aware of the issues and all subsequent communications with the patient and/or family are consistent.

6. Decide immediately who will have primary responsibility for communicating with the patient and/or family about the adverse event.

7. Determine the circumstances surrounding the staff involved in the adverse event and other factors contributing to it as quickly as possible. This information can be crucial to the immediate clinical treatment plan for the patient.

8. Report the adverse event to the appropriate hospital administrator.

9. If the cause of death is unknown, always recommend autopsy.
   If the family does not consent to an autopsy, communicate that this would greatly increase the risk of not sufficiently identifying the cause of death.
   If an autopsy is not possible, recommend an MRI, CT or other Ai (autopsy imaging) options.

10. Article 21 of the Medical Practitioners Act in Japan requires the physician to report death by unnatural causes to the police within 24 hours.
    Reporting medical practice-associated deaths to the Medical Safety Investigation Committee and reporting in the “model project area,” as required, should be performed according to respective requirements.
Part 2 Sincere Support of the Patient and Family

IV. Communication between the Healthcare Institution and the Patient/Family

Prompt and compassionate communication with the patient and/or family following an incident is essential, but it is often managed poorly.

Because of the emotional impact of these events on both the patients and the caregivers, communication can be difficult for all parties.

Communication failures compound the emotions of the patients and are thought to be the major reason they file malpractice suits.

Consideration of this complex subject is divided into three sections:

A. Initial Communication 1
   What is communicated and when it should be done.

B. Initial Communication 2
   Who provides the information and how they do it.

C. Communication of follow-up information after the event
   When and who should provide the follow-up information.

A research report on the reasons why patients and families take legal action* reveals that 71.3% did so because they could not bear the way medical institutions handled the event more than the adverse event itself, suggesting how seriously the post-event responses affect the situation.

A. Initial Communication 1: What and When

1. Caregivers should promptly inform the patient and/or family about any adverse event or error that has affected the patient.
   When in doubt about whether communication is called for, a caregiver should consult an internal expert, such as the medical safety manager.

2. Caregivers should be open and honest about the adverse event and about what is being done to mitigate the injury and to prevent a recurrence.
   Honest communication conveys respect for the patient.
   Failure to acknowledge the event can be very distressing for the patient and is a powerful stimulus to complaint or litigation.

3. If the event was clearly not caused by an error (i.e., a Type A or B unpreventable adverse event), or the cause is unknown, the caregiver should express regret, explain what happened and discuss what will be done to mitigate harm.
   It is important to make sure the patient understands that the injury was not the result of a failure in care but an inherent risk.
   This is relatively easy when the risk of complications is high and well-known to the patient, as in chemotherapy (p. 4, Figure 1).

4. For less common unpreventable events (Type B), even when full attention has been given to obtaining informed consent, the patient's initial reaction is often to assume that an error has occurred.
   Therefore, it is important to provide a full and measured explanation about what happened, even when it seems straightforward to the caregiver.
   It is very important for the patient to perceive that the staff take the injury seriously and are sorry that it happened, but also to understand that preventing it was not under their control.

5. If it is not clear whether an injury was due to an error, the event still should be acknowledged and regret should be expressed.
   However, it is important not to jump to conclusions, to blame oneself or another, nor to take responsibility for an event before all the facts are known.
   A full investigation should be promised, together with a commitment to report back to the patient and/or family when more is known.

6. When an event is caused by an error or other type of systems’ failure (preventable adverse events in Figure 1, p. 4), a detailed explanation is necessary, as well as an apology and explanation of what will be done to prevent a recurrence.
   The main responsibility for communication with the patient falls on the attending physician.
There are four essential steps in the communication of preventable adverse events:

**Step 1. Tell the patient and/or family what happened**
1. Tell immediately what the patient needs to know. Leave details for later and tell what happened now.
2. Determining the causes of an adverse event requires careful analysis and is time-consuming. However, patients and their families want immediate answers.
3. Therefore, early after an adverse event, limit discussions to known facts and avoid speculation.
4. Speculation and preliminary conclusions are often interpreted by patients and/or families as definitive.
5. There is a limit to how much can be known in initial investigations and early impressions are frequently contradicted by subsequent, careful analysis.
6. If speculative information is shared with patients and/or families and later contradicted by the results of careful analysis, physicians are forced to correct themselves, which may cast serious doubt on the credibility of future information.
7. The patients and families should be informed of any system changes that have been made in order to prevent future adverse events when this information can be made public.

**Step 2. Respond as an organization**
1. Whether or not the adverse event resulted from a specific act, the attending physician should make a statement of responsibility to the patient and/or family.
2. Taking responsibility for an adverse event is an essential step in the communication of an event.
3. As the person to whom patients entrust their care, the attending physician should realize that it is his/her responsibility to respond even when s/he did not actually make the mistake that caused the
injury.  
The overall responsibility and accountability for an adverse event rests with the hospital.

4. Thus, it is incumbent upon the organization and its administrators to accept responsibility as well as to respond to and communicate that to the patient and/or family.

5. Because every event is unique, organizational leaders and physicians should make their best effort to communicate with the patient and/or family in an easy-to-understand manner.

6. On first consideration, it may seem odd that in situations where the physician had no direct involvement in an adverse event, s/he should take responsibility for it.

7. In this circumstance, taking responsibility does not mean assuming sole culpability for the adverse event. A host of factors likely contributed to the adverse event—many of them beyond any one person’s control. However, as the leader of the team, the attending physician is an integral part of the clinical system that delivers care to the patient in question.

- S/he is, understandably, the person whom the patient and/or family assume is responsible for the care.
- Patients look to their physician for care and comfort.
- The patient wants to know who is in charge of responding to the situation.

8. In assuming responsibility for the event, the physician and the hospital administrators accept responsibility for future actions.

9. They should try to find out the causes of the event, inform and update the patient and/or family, and consistently manage any complications of the adverse event.

10. The caregivers should improve systems that caused the adverse event to prevent similar events from happening.

If the physician was directly involved in the adverse event, s/he should make a statement of responsibility for his/her own role.

When explaining the factors contributing to the adverse event, s/he should not blame “the system” alone.

There are several ways to explain that s/he was involved in the adverse event:

“*We could not meet your expectations.*”

“*We regret that such an event happened.*”

“*Our internal systems broke down. We are going to find out what happened and do everything we can to make sure that it doesn’t happen again.*”
“I will let you know what we find out as soon as I know.”

Step 3 Apologize if it is an obvious error

1. When there has been an error, one of the most powerful things a caregiver can do to heal the patient—and him/herself—is to apologize.

2. Regardless of the cause, to promptly express empathy and sympathy (“expression of empathy”) is the first natural step, as a human being, when taking responsibility for injuring the patient by an error. Even if system failures are responsible for the error rather than one person, an apology should be made. Caregivers explaining the event, communicating remorse and making a gesture of reconciliation themselves can do much to defuse the hurt and anger that follows an injury.

3. All causes of an event may not be known immediately after it occurred. Patients are likely to feel hurt and vulnerable after the event, however. If an obvious error has occurred, whoever made the error should disclose it promptly, apologize and communicate his/her commitment to finding the reasons for the error.

   Example: “We made this error. I apologize.”

4. Although errors by individuals usually result from system failures (which need to be identified and addressed), most patients have no way of knowing that and are likely to hold the individual responsible.

5. It is immensely valuable for the person who made the error to apologize and show genuine remorse. However, consideration must be given to the caregiver’s psychological state, i.e., whether or not s/he can handle the situation calmly. If the caregiver is unable to adequately communicate with the patient, it may be desirable to have an internal healthcare mediator step in.

6. Because healthcare is a team effort, the attending physician should also apologize even if the error was made by someone else. In these cases, it may be wise to make the apology a joint effort, i.e., for the attending physician and the person who made the error to meet with the patient together to apologize. Contrary to what many physicians believe, there is little evidence that apologizing increases the risk of a malpractice suit. Some malpractice lawyers contend that many of malpractice suits stem from a failure to take responsibility, apologize and communicate openly. In fact, experience in malpractice cases indicates this (see Appendices).

   To communicate openly, take responsibility and apologize are extremely important and a
failure to do so contributes to patients’ anger.

7. Explaining the truth about the adverse event and apologizing are the first step toward recovery from emotional wounds incurred by the patient and family. Gestures of sincere remorse can alleviate the sense of victimization that drives patients to blame the hospital, and pave the way for them to jointly discuss remedial actions against future recurrence.

Step 4 Explain what will be done to prevent future adverse events

1. Once the investigation is completed and corrective changes are planned, it is important to inform the patient and/or family of these plans.
   Injured patients have a strong interest in seeing to it that what happened to them does not happen to someone else. Caregivers often underestimate the importance of such responses.

2. Knowing that changes were made and that some good came of their experience helps the patient and/or family cope with their pain or loss. It gives a positive meaning to their experience to know that their suffering is not in vain.
B. Initial Communication 2: Who and How

1. The initial communication should be by, or at least in the presence of, a caregiver with a prior relation of trust with the patient. Ideally, this will be the attending physician who planned and carried out the treatment.

2. At the same time, to define the next steps in care, it is most helpful to the patient and/or family to have present the physician most responsible for those steps. If this is someone different from the attending physician (e.g., the patient was moved to ICU), the physician now responsible for their care should be present to assure the patient and/or family of the continuing commitment to provide care. If the discussion is anticipated to be complex or difficult, the patient should be encouraged to have another person present to provide support.

3. It may also be helpful to have the patient’s primary nurse present, to observe and support. It is not recommended at this initial stage that a hospital administrator participate, except in the most catastrophic situations. Similarly, including someone identified as a “medical safety manager (risk manager)” in these first discussions may set the wrong tone for the patient.

4. Discussions with patients and families under these circumstances may be difficult. In such cases, it is recommended that an expert, such as an internal healthcare mediator, be present. When the staff responsible for the initial communication is apprehensive him/herself, a teaching physician or other higher-level physician with experience should accompany or coach the staff ahead of the time. Institutions need to develop training in these techniques and make sure internal procedures, such as a reporting system, are in place.

5. The choice of the setting for communicating adverse events is important, particularly if an apology or restitution will be made. The meeting with the patient and/or family should be discussed and prescheduled, and be held in a quiet, private area that supports both confidentiality and their feelings. A single room in the hospital is ideal, as is a private office for ambulatory communications. A visit to the patient’s home may be necessary if the patient has been discharged or treated in a clinic. A double room or any public space, such as a hallway or a waiting room in the ambulatory area, should not be used for privacy protection reason. Moreover, considering the emotional state of the patient and/or family, it is not appropriate to summon them to an executive suite as it would appear overbearing.
C. Communicating follow-up information after the event

1. Follow-up sessions should be arranged as soon as significant additional information is available. If a delay is encountered, the patient and/or family should be frequently apprised of the situation, with apologies for the delay.

2. The attending physician and healthcare team members must conduct these follow-up meetings as needed.

3. In particularly serious or highly charged cases, hospital administrators should be involved. Senior administrative involvement is especially necessary if faith in the primary caregiver has been compromised or s/he has not been fully successful in communicating.
V. Support of the Patient and Family

1. Patients and families should be specifically asked by members of the team assisting in their case about their feelings related to the injury and about any anxieties they may have about future treatment and prognosis. Even when patients receive an apology and explanation about actions to be taken to prevent recurrence, the emotional trauma of the event and anxieties about future treatment may necessitate psychological support. This support may need to be provided by social workers, psychologists or psychiatrists in some cases, as determined by evaluation and assessment of the team of caregivers that has been involved in communicating with the patient and/or family.

2. Physicians should be attentive to patients who say their treatment has harmed them, even when a complication appears to have resulted from the patient’s disease. Given that complications may result from medical treatment, such a claim should be considered seriously. The patient may not fully understand the medical management. Even if the patient's concern is groundless, a complete and sympathetic explanation could be essential therapy. In any case, patients should not be ignored, as it can be unbearably painful for them.

3. Following an injury, it is important for physicians to take extra pains to ensure continuity of care and to maintain the therapeutic relationship. Patients and families need more support, not less, after an injury, even though both patients and physicians may feel a natural desire to distance themselves from one another.

4. Patients and families should be provided with the names, phone numbers and contact information of the institutions to address their questions, complaints and concerns. These include providers of internal and external support and counseling. Financial pressures may contribute to emotional concerns. Coordination of psychological and financial support may be best served by individuals in the social work department. It is important that the healthcare team discuss the support of the patient and/or family in advance.

5. Following an incident, regardless of whether or not the error is obvious, all billing for medical services should be suspended until "analysis of the adverse event is available,” considering how it will affect the feelings of the patient and/or family. Receiving an invoice at this serious juncture can be viewed by the patient as an insult, and not only adds to disappointment with the caregivers, but also further erodes the patient’s confidence that the institution is properly handling the adverse event.
VI. Follow-Up Care of the Patient and Family

1. The patient and/or family should be provided with needed psychological and social support. For that purpose, they should be allowed easy access to the principals (social workers or internal healthcare mediators) involved in the follow-up communications around the adverse event.

2. Follow-up encounters with the patient and/or family should occur not in an ad hoc way, but as scheduled, proactive overtures, to check on their clinical status and to give them updates on findings from internal investigations and any remedial actions taken.

3. A home visit may be considered, provided that the patient agrees, particularly if extensive follow-up information must be communicated.
   If the patient and/or family are invited back to the hospital, their needs in terms of transportation, meals and overnight accommodations, if appropriate, should be met by the institution.

4. If continuing reimbursement for injury-related expenses should be presented, those responsible for the reimbursement (head of administration) and for the patient’s follow-up care must be able to arrange for these efficiently.
Part 3 Supporting Caregivers

VII. Support of Caregivers

1. Hospital administrators should provide a mental health support program designed to provide aid (relief measures) to caregivers who are experiencing stress after going through abnormal adverse events. The objective is to help caregivers manage the stress of the adverse event so that they can better care for their patients, recover and comfortably return to the work environment.

2. Because caregivers’ needs vary, the support system should incorporate a variety of offerings, including both private and group counseling and short- and long-term counseling.

3. Administrative policies should ensure that caregivers are provided with appropriate adjustments of responsibilities and time off, if needed, so that recovery can occur (this includes transfers to appropriate workplaces that reflect current work capabilities and temporary leave, if they wish).

4. Hospital administrators should also establish an internal process of reporting the adverse events and provide physicians with training to document the event for the medical record in their regular practice.

5. Coaching in communications with the patient and/or family during the emotionally intense period immediately following an incident can be critical for maintaining a relationship of compassion and trust.

6. Training programs need to be developed to teach department chairmen and administrators, as well as physicians, nurses and other clinicians, how to provide support for colleagues when they are the focal point of an adverse event.

7. Caregivers will benefit from mental health support during the mutual evaluation and root cause analysis (peer review) processes in the end. This includes instruction in the analysis process as well as direct support during the events themselves.
VIII. Training and Education

1. Hospitals need to provide the following professional education and training programs on communicating with and managing patients and/or families when things go wrong. These should be specifically designed at appropriate levels for caregivers (physicians, nurses, pharmacists, etc.) and for hospital administrators.

**Zensharen Medical Safety Training**

1. Medical Safety Management Personnel Training: A six-day training program on medical safety management (general theory, specific topics, exercises) for personnel acting as medical safety management personnel of hospital departments.

2. Medical Safety Manager Training (a follow-up, higher-level training for Medical Safety Management Personnel Training): A two-day course on recent trends of medical safety.

3. Hospital Healthcare Mediator Training: A program for consultation service personnel, based on the Japan Association for Healthcare Mediators training programs.

2. Both for consistency and for economies of scale, in terms of costs and needed expertise, the development of these training programs should be carried out at a system-wide level.

3. In addition to technical training in how to communicate with the patient and/or family, physicians and nurses also need training in how to deal with their own feelings when their actions are the proximate cause of a serious patient injury.

4. Caregivers, including managers, need to be trained in how to provide support to colleagues when they are the focal point of a serious adverse event.

5. Administrative staff need to be educated about their responsibilities, legal exposure and the importance of transparency and accountability to patients.

6. Courses on general principles and practices to follow should be required as part of orientation for all new nurses and physicians, including residents, and courses should be provided for all staff annually.

7. A broad array of training methods is indicated, including lectures, role-playing and interactive web-based tutorials, and they should be developed for understanding caregivers/patients as part of continuing education.
8. Because busy physicians are unlikely to attend courses annually or maintain their skills, “just-in-time” refresher modules (programs) should be developed for them to be given when needed at the time of a crisis.

9. Physicians should know whom to call when they have a serious adverse event and be able to count on receiving expert assistance immediately.

10. More extensive training should be provided to safety leaders (general risk managers) so that they can ensure that all patients receive appropriate care, and supervise and train others when the need arises.
Part 4 Managing Adverse Events

IX. Hospital's Philosophy for Handling Adverse Events

1. Communicate the organization's philosophy of and commitment (promise) to open and honest disclosure of adverse events to the patient and/or family through notice boards and other in-hospital publicity.

2. Provide “just-in-time” consultation and guidance to caregivers at the time of an adverse event.

3. Enable the education of caregivers in methods for responding and communicating about adverse events.

4. Ensure that caregivers communicate to the patient and/or family not only about system improvements but also about their commitment to empathetic and honest communication.

5. Provide a framework for analyzing and learning from adverse events, including redesigning systems when appropriate.

6. Emotionally, professionally and legally support the caregivers who have been involved in adverse events.

7. Ensure necessary documentation and reporting.

8. Address methods of communication with the public that demonstrate transparency and restore community confidence that systems are in place to minimize the likelihood of future accidents.

9. Address methods of reporting and disclosure standards both within the hospital/healthcare setting and externally to any relevant regulatory bodies.
X. Analysis of the Event

1. Root cause analysis (RCA) is an effective means of analyzing adverse events, as it focuses on the underlying systems and processes that contributed to the occurrences, rather than the responsibility of the individuals, to determine system vulnerabilities. RCA also supports measures to prevent error recurrences (more details on p. 22). Appropriate analyses should be performed including those for near-misses that present learning potential and the results should be reported back to the caregivers. Priority should be given to events that are fatal, cause significant morbidity or represent a significant breach in practice, and countermeasures should be taken promptly.

2. The institution’s safety management department should perform or direct the investigation of the event in order to ensure neutrality and transparency of the process. If necessary, an internal investigation committee should be formed and a third-party investigation committee should be summoned to report the event to the Medical Safety Investigation Committee (as of June 2008, a special panel in the Ministry of Health, Labour and Welfare is discussing legislation to introduce a nationwide medical accident investigation system). In the investigation committee meetings, confidentiality of the mutual evaluation (peer-review) process should be secured, including reviews for the focal-point personnel of the event.

3. The institution’s medical staff bylaws should provide peer-review protection for physicians and other healthcare providers participating in RCA. To promote institutional learning, hospital administrators and the safety management department should also be encouraged to request or conduct RCA whenever it is considered necessary, observing the confidentiality of investigation and peer-review processes.

4. The internal investigation committee should comprise senior staff members and personnel in different positions who were not directly involved in the event and who can thus maintain objectivity and lead discussion in a nonpunitive and supportive manner. Medical safety managers, quality improvement leaders and clinical leaders should all be trained to fulfill this role. The input of a third-party systems expert and those with other areas of expertise may also be vital for the organization to thoroughly understand and analyze the circumstances of the event.

5. Participants of RCA on the internal investigation committee should include physicians and other staff members involved in the adverse event. Participation of all involved in the event should be encouraged so as to have input from as many perspectives as possible, and to understand all the factors behind the event. Hospital leadership, including managers, directors and those with departmental responsibility, should also participate in
order to ensure follow-through of corrective actions.

6. Medical safety is an evolving discipline, and the best analysis strategies and techniques will change over time. The organization should incorporate the best available practices in its analysis of adverse events and design of interventions.

7. While patients and families do not participate in RCA, they should be interviewed concerning the facts and circumstances of the events and be informed, by hospital mediators, of the institution’s commitment to keep them informed of the RCA’s findings.

8. Serious events and the results of all RCAs should be reported to senior administrative and clinical leadership as a critical step in the institutional learning loop.

9. Medical institutions need to establish processes to ensure that corrective actions developed as a result of the RCA are implemented and that feedback is provided to stakeholders regarding the corrective actions.
   Because not all departments have good systems of accountability, it is necessary to develop additional mechanisms to ensure that recommended systems changes receive a high priority, are tracked to ensure that the changes do, in fact, occur, and are assessed for effectiveness.

10. System changes made in response to analysis of adverse events may have unanticipated negative effects. Therefore, any changes should include a plan to monitor both the effectiveness and possible undesirable effects of the changes.

11. Data from the RCA should be aggregated and tracked to identify patterns and trends and to prioritize improvement initiatives.

12. In order to report the incidents to the Ministry of Health, Labour and Welfare, institutions in the model project area should provide information to the third-party investigation committee. Those that have registered with the Japan Council for Quality Health Care as a participant of the Project to Collect Medical Near-Miss/Adverse Event Information should be committed to data collection and submit incident information to the Council promptly. Because it is important to actively contribute to the government effort, those not yet registered should do so and begin submitting information.
RCA (Root Cause Analysis) is a process for identifying the hidden systems vulnerabilities and human factors that led to an adverse event or a near-miss. Staff members of different positions and backgrounds commit themselves to intensive discussions to trace back the event details in order to identify the potential risks, and to find corrective measures.

The following are features of the RCA process of identifying cause factors:

1. Performed by members of different positions and backgrounds who may know the processes associated with the incident.
2. Focuses on organization and processes rather than individual actions.
3. Repeatedly digs deeper by asking “What?” and “Why?” until all processes are reviewed and the factors behind the event have all been identified.
4. Identifies needed changes for systems and processes that would improve medical management and reduce the risk of future near-misses.
XI. Documentation

1. Clinical details concerning the adverse event should be recorded by the most involved and knowledgeable member(s) of the healthcare team, and include the following:
   • Objective details of the event, including date, time and place.
   • The patient’s condition immediately before the time of the event.
   • Medical intervention and patient response.

2. For the following responses immediately after the event, the dates, time, persons in charge and details should be recorded. These records are subject to later reviews for promptness and appropriateness of the responses, and serve as the basis of process improvements.
   • Securing of the objects that may have contributed to the event.
   • Change in attending caregivers.
   • Designation of primary communicator with the patient and/or family.
   • Clarification of circumstances surrounding the staff involved in the event and other factors.
   • Reporting to hospital administrators.
   • Explanation of autopsy (if the event results in patient's death).
   • Reporting to the police (if the event results in death by unnatural causes).
   • Reporting to the Medical Safety Investigation Committee.

3. The person designated as the primary communicator with the patient and/or family concerning treatments should provide them with accurate information as soon as possible.
   This individual may be the physician involved in the event or the attending physician in charge of the treatment.

4. Documentation about the conversation(s) should include the following:
   • Time, date and place of discussion.
   • Names and relationships of those present at the discussion.
   • The discussion of the event.
   • Patient reaction and the level of understanding exhibited by the patient.
   • Additional information that has been shared with the patient and/or family or legal representative (if applicable).
   • Any offer to be of assistance and the response to it.
   • Questions asked by the patient and/or family and responses to the questions.
   • A notation that, as further information becomes available, it will be shared with the patient, family or legal representative.
   • Next steps to be taken by the patient and any caregivers or the facility staff.
   • Any follow-up conversations.
5. Documentation should avoid derisive comments about other caregivers and entries that appear self-serving.
XII. Reporting and Announcement

1. In the event of an adverse incident, caregivers should first commit themselves to minimizing the patient's injuries and report the event to senior staff (senior physician, director of nursing services, etc.) promptly.

2. Especially in sentinel events resulting in death or serious damage, report it to the administrator first and take heed of the following:

   1. Immediately report to the administrative staff in charge. Make a verbal report first and then create a fuller written report, as soon as possible, providing the details of the event and responses.
   2. Keep records for all processes.
   3. Keep accurate records of diagnoses, test results, medical procedures and other information (these can be reorganized later).
   4. After initial responses are made, all stakeholders should be summoned to discuss the cause of the event and what should be communicated to the patient and/or family.

3. Reporting to Zensharen headquarters

   The following should be reported to the Medical Safety Office in the Operation Department at Zensharen:

   1. If a patient is seriously affected by an adverse event, a near-miss or an event deemed serious by the institution has occurred, or media attention is anticipated, report the outline of the event to Zensharen promptly.
      Report information on the circumstances, causes, consensus of the institution and future direction when it becomes available.
   2. Submit an adverse event report using the standard form.
      The report should be submitted without delay after communicating with the patient. The report should reflect the patient's complaints and claims.

4. Reporting to external agencies

   In the same manner as reporting to Zensharen, reports must be made to the appropriate medical safety sections of the local government and health offices if a patient is seriously affected by an adverse event, a near-miss or an event deemed serious by the institution has occurred, or media attention is anticipated.

5. Disclosure

   The event should be disclosed to the public based on the institution’s disclosure policy.
   An individual incident should be disclosed according to the policy, but only with the consent of the patient and/or family affected by the incident.
6. The system should be responsive. Those who report should be aware that the report is important for carrying out investigation and corrective actions.

7. Hospital administrators must ensure that all staff understand that reporting poses no risk of censure or discipline to the person who reports the adverse event.

8. It is also essential that administrators continue improving the event reporting system and make improvements known to all staff regularly. Public relations departments should be promptly informed of serious events so they can handle media inquiries.

**Revisions to the guidelines**
These guidelines are subject to changes and revisions as deemed necessary, as medical safety is an evolving discipline.
Appendices

1. How Apologies Are Treated in Malpractice Lawsuits, by Yoshimitsu Yamazaki, MD (also completed coursework in the Kyoto University Law School)

2. Post-Event Reporting and Responses to Patient/Family

3. Disclosure Standards for Healthcare Accidents


5. Definitions of the Main Terms Used in the Guidelines
Appendix 1

How Apologies Are Treated in Malpractice Lawsuits

Yoshimitsu Yamazaki, MD (also completed coursework in the Kyoto University Law School)

I. Background and Objective
Whether or not making an apology works unfavorably to caregivers in medical malpractice lawsuits is a matter of concern for all healthcare providers. Adopting legislation similar to the "I'm Sorry" laws of the United States has been discussed in Japan, but applicability is very low because of the differences in litigation systems. Our study focuses on how apologies have been utilized in Japanese malpractice cases.¹

II. Methods
1. Keyword searches ("apologies," etc.) on the online Supreme Court database and TKC legal information database.
2. Review of Supreme Court cases in which apologies were a point of dispute.

Limitation of these methods
- Details on cases that ended with reconciliation or withdrawal are not available, and the search was limited to cases with court rulings.
- The search range was limited to cases with court rulings and those that were on the database.
- Some cases may have been missed due to the nature of keyword searches.

III. Results
1. Number of references made to "apology," by instance and by litigation type (civil/criminal) (total of 34 references)

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<td>3 (all in fact-finding)</td>
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<td></td>
<td>(plaintiff claim)</td>
<td>(both in fact-finding)</td>
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<tr>
<td>Total</td>
<td>29 references</td>
<td>5 references</td>
<td>34 references</td>
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Note:
- Plaintiff claims: References counted as "plaintiff claims" are those referred to by the plaintiff but not determined to be facts.
- Fact-finding: Facts the court decided to be premised facts in the "undisputed facts" section.
- Nearly 1,000 cases of malpractice lawsuits are processed every year, of which 40% are concluded with court rulings.
2. Study of cases in which the court made a decision based on an apology or determined an apology to be admissible evidence

We presumed that if apologies had been determined to be facts, the court must have made some kind of decision that apologies were premised facts. The following is a further breakdown:

1. Civil

Cases in which apologies were determined as facts, and the court ruled based on a decision about the apologies: 10 cases

Among these cases:

A. Apologies were determined as a partial basis for malpractice: 2 cases
B. Discussions took place to determine whether apologies suggested errors: 2 cases
C. Compensation
   - Lack of apology is considered the motivation for the plaintiff's request to increase the amount of monetary compensation: 2 cases
   - Apology is considered the motivation for the plaintiff's request to reduce the amount of monetary compensation: 4 cases

2. Criminal

In all five rulings in which apologies were referred to, the court commuted the sentence on the grounds that an apology took place. One ruling mentioned that the apology of the caregiver was not admissible as evidence of error.²

IV. Analysis

- Caregiver apologies are not often referred to in malpractice suits.
- Under certain circumstances, apologies were considered evidence of error. However, no ruling has used an apology alone as a direct basis of error determination. In criminal cases, the risk that apologies constitute evidence for error is lower.
- One ruling focused on the intention of the apologies made. This was apparently based on the court's assumption that the type of apology could constitute an evidence for error.
- In some cases, apologies are taken favorably and contributed to a reduction in the monetary compensation amount.

² Translation of the March 28, 2001 ruling of the Tokyo District Court:

"Given that the mistake is not determined by the defendant's admission at a later date, as a general nature of the determination of the mistake, it is a matter of course that the determination should be based on the evaluation of judgment made by the defendant at the time, from a normative point of view, and the evaluation should be based on the facts concerning the circumstances at that time and these facts are determined by the relevant evidence. In the first place, these statements (confessions, apologies) made by the defendant in response to the inquiries of the prosecutor themselves carry no significance in this case."
Appendix 2

Post-Event Reporting and Response to Patient/Family

[Hospitals/Zensharen headquarters]

1. When an adverse event (medical accident) occurs:
   1. Take action to minimize the injury to the patient.
   2. Commit to administering the needed treatment.
   3. Make a first report of the event to senior staff (senior physician, head of nursing services, etc.) promptly.

2. In a sentinel event resulting in death or serious damage:
   1. Report to the hospital administrator first.
   2. Report to the administrative staff in charge as soon as possible.

3. When to Report to Zensharen
   1. If the patient is seriously affected or a near-miss has occurred.
   2. If an accident deemed serious by the institution has occurred.
   3. When media attention is anticipated.

4. Reporting to various agencies
   (medical safety sections of local governments)

[Responses to Patient/Family]

Four Steps to Communicate Adverse Event Information

Step 1
Caregivers should inform the patient and/or family about any adverse event or error that affected the patient, even if no harm was done.

Step 2
Clarify where responsibility lies and respond as an institution.

Step 3
Regardless of the cause, express empathy and sympathy promptly (make an empathetic apology).

Step 4
Explain what will be done to prevent recurrence.
Appendix 3

Disclosure Standards for Healthcare Accidents

Prior to disclosing the accident publicly, institutions must inform the patient and/or family of the institutional intention to do so and obtain their consent. Privacy of the patient and/or family and the caregivers, as well as the patient’s/family’s feelings and social circumstances must be fully taken into consideration (the same applies for online disclosure).

Disclosure Process
#1 Make the disclosure expeditiously after the event.
#2 After the investigation, disclose the findings through the hospital website.
#3 Keep records and submit reports to Zensharen headquarters annually.

-If it is an error (medical error)
  • An error resulting in patient death ->Process #1
  • If the patient is affected by a serious injury requiring permanent care ->Process #1
  • If the patient was seriously injured, received intensive care, and recovered after the treatment->Process #2 (serious error->Process #1)
  • If the injury was not serious or permanent->Process #3 (serious error->Process #2)
  • If the injury was not serious and only temporary->Process #3

-If it is not an error (includes complications and side-effects)
If the event was unpreventable or had a more serious impact than an event considered to be preventable, follow Process #3, perform analysis/review at Zensharen, and disclose the results through the institution’s website.
Appendix 4

Report No. 1 on Medical Accidents and Medical Practice-Related Issues¹
(excerpts)

Medical Accident Citizens’ Ombudsman MEDIO

1. Objective
This report is an attempt to identify issues that should be resolved in order to support the victims of medical accidents and to provide base information for establishing remedial systems for the victims. The research is based on analyses of a survey into reasons why the victims (including their families and bereaved families) take legal action against physicians or healthcare institutions, and the impact of medical accidents. The survey questions were selected from the paper, "Why Do People Sue Doctors?: A Study of Patients and Relatives Taking Legal Action" by C. Vincent, M. Young and A. Phillips, published in The Lancet magazine in 1994.

2. Outline
The survey was conducted during the period between September 2002 - April 2003, by mailing survey forms to three groups: 1. Those associated with MEDIO (members and former members who took legal action, or to whom MEDIO referred lawyers); 2. Those associated with other groups of medical accident victims; and 3. Those associated with plaintiff lawyers. MEDIO was responsible for the collection and tally of the survey. MEDIO collected 241 valid survey forms.

3. Reactions to how healthcare institutions handled accidents
The following are responses to a survey question on how respondents felt about the way institutions handled accidents (not limited to how the hospital explained the event).

Figure 16: How did you feel about the way the hospital handled the accident?

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Disagree</th>
<th>Strongly disagree</th>
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<tbody>
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<td>The hospital showed consideration for my feelings.</td>
<td>14.2</td>
<td>79</td>
<td>0.9</td>
<td>5.9</td>
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<td>The way the hospital handled the accident was more unforgivable than the accident itself.</td>
<td>55.6</td>
<td>15.7</td>
<td>10.8</td>
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<tr>
<td>It would have been easier to accept the situation if the hospital had offered sufficient compensation.</td>
<td>12.5</td>
<td>16.8</td>
<td>17.3</td>
<td>53.4</td>
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<td>In general, I am satisfied with the way the hospital handled the accident.</td>
<td>0.5</td>
<td>0.9</td>
<td>5.5</td>
<td>93.1</td>
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</table>
Asked if the hospital was considerate of their feelings, 79.0% of those polled showed strong
disagreement, and combined with the percentage points for those who disagreed, a total of 93.2%
responded negatively. Asked whether the hospital's handling of the event was more unforgivable than
the accident itself, 55.6% strongly agreed and 15.7% agreed, showing that 71.3% of respondents
suffered a secondary damage on top of the accident.

Asked whether it would have been easier to accept the situation had the hospital offered sufficient
compensation, 29.3% strongly agreed or agreed, while 53.4% strongly disagreed. Combined with those
who disagreed, 70.7% of respondents thought it was not a matter of money, or the money was not the
focus of litigation.

Asked if they were satisfied with the way the hospital handled the event in general, 93.1 % of
respondents strongly disagreed, indicating serious problems lie in the way the hospitals deal with victims
or their families (bereaved families) or in their communications.

4. **Observation of the healthcare institutions' responses after an accident**

Victims harbor intense feelings after being injured by an accident. The survey revealed that 98.7% of
respondents felt that the event was avoidable, indicating that the event can trigger intractable grief and
anger. To questions about whether they feel sad and angry about the accident, 92.9% and 94.9% of
respondents strongly agreed, respectively, showing the magnitude of grief and anger over the accident.

However, as Figure 16 shows, over 70% of respondents consider the way the hospital handled the
accident to be unforgivable, meaning that the victims are hit first by grief and anger, and their anger is
amplified by the way healthcare institutions responded. This motivates them to take legal action.

We believe that more than a few lawsuits, which naturally impose a heavy burden on both parties, could
be avoided if adverse events are followed by thorough explanations and compassionate responses.

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1 The content of this section was taken from p. 2, p. 3, p. 14, and p. 28 of the report (issued December 2003).
The study is supported by the Iryo to Jinken Kikin (Medical and Human Rights Fund).
Appendix 5
Definitions of the Main Terms Used in the Guidelines

Medical accident:
A general term referring to an adverse event (including serious error) caused by a medical management, resulting in human injury.

Adverse event:
An injury caused by a medical management rather than the patient’s underlying disease; also called “harm” or “complication.” An adverse event may or may not result from an error.

Medical error:
The failure of a planned action to be completed as intended or the use of the wrong plan to achieve an aim.
Medical errors include serious errors, minor errors and near-misses.

Near-miss:
An error that could have caused harm but did not affect the patient because it was prevented.

Informed consent:
An interactive process of decision-making, rather than the consent of a patient to a one-way explanation by a physician.

Autopsy imaging (Ai):
A combination of autopsy and imaging (“virtual autopsy”) that utilizes computer tomography (CT) and other imaging technology to perform diagnostic imaging on the deceased for more accurate autopsy.

Hospital mediator:
A person who acts as a facilitator of bilateral discussion between the patient and provider using mediation models for patient claims, or in the initial stages after an accident.

Root cause analysis (RCA):
A process for identifying the hidden systems vulnerabilities and human factors that led to an adverse event or a near-miss. Staff member of different positions and backgrounds commit themselves to intensive discussions to trace back the event details in order to identify potential risks and to find remedial actions.
### Social Insurance Hospitals & Others

As of April, 2010

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