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Strategic management of medical incidents for patient safety and crisis management: Applications of the principles of crisis management and recent developments in Japan

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Abstract

Efforts to improve the management of medical incidents have derived from two main perspectives, namely, the promotion of patient safety and quality improvement, and the strategic management of organizational crisis. These two streams have produced different sets of policies and endeavors, although they are sometimes closely interrelated and supplementary. Around the turn of the century, promotion of medical safety came to focus mainly on systemic failures, institutional learning, risk communication, and a safety culture, which resulted in a shift away from risk management toward safety management, and then from safety management to a safety culture and (service/ treatment) quality management.

Although a crisis management perspective has thus moved away from being the central topic of public policy, its importance undoubtedly remains. With increased expectations of medical services, as well as lawsuits, effective management of health crises is called for, more than ever, and healthcare organizations and professionals should be sufficiently prepared to address these events. Depending on the phase of a crisis (i.e., before, during. and after a crisis), a set of actions is required, along with advanced planning and coordination. Basic principles for risk and crisis management should be applied to the management of medical incidents, which in turn improves patient safety. In addition, communications play a key part in this regard. Advance plans (for preparation, response, and recovery) are especially imperative, aside from efforts to prevent medical incidents.

This article first presents the basic components of crisis management, along with the promotion of patient safety, with a focus on communications. It then introduces recent policies regarding safety promotion, as well as efforts to manage the crises caused by medical incidents in Japan.

keywords: Medical incidents, Patient safety, Crisis management, Crisis communications, Japan

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I. Introduction

In 2019, September 17 was World Patient Safety Day, as designated by the World Health Organization (WHO). The WHO web site illuminates the fact that many adverse events take place each year due to unsafe care, 15% of hospital expenses can be attributed to treating patient safety failures in OECD countries, and four out of ten patients are harmed in primary and ambulatory settings [1]. After the launch of the World Alliance for Patient Safety in 2004, the WHO has become increasingly committed to improving safety, and has published a series of guidelines on patient safety [2], as well as educational materials for professionals [3].

Management of medical incidents, and especially with regard to malpractice crises, is an essential task for securing the stable and effective activities of medical organizations. In order to handle potential and real incidents and crises ef-

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fectively, it is important to act properly, in accordance with a set of well-prepared crisis communications plans. Crisis management, in general has also been discussed for a long time, and a set of conceptual frameworks have been developed to help understand the process of crisis development. Furthermore, best practices in management have been accumulated from different cases. Such expertise could continue to benefit crisis management in clinical settings.

Around the turn of the century, however, promotion of medical safety came to focus on systemic failures, institutional learning, risk communications, and a safety culture, which accompanied both the shift from risk management to safety management, and from safety management to a safety culture and (service/ treatment) quality management [4]. An implicit expectation was that the promotion of safety would also relieve concerns about crises caused by medical incidents. In addition, as analytic frameworks and study methods, signaling a departure from science in crisis management for organizations, a new set of approaches were introduced, including root cause analysis, failure mode and effects analysis, fault tree analysis, and the management oversight risk tree [5].

This shift of focus also took place in Japan. After the creation of the Office of Patient Safety within the Ministry of Health, Labor and Welfare in 2001, a series of public policy measures have been implemented [6]. In 2004, the annual report of the Ministry focused on safety issues, and a reporting system for medical accidents was introduced. The Medical Service Act (Amendment of 2006) designated a requirement for medical facilities to install a system for the management of patient safety. More recently, in 2018, the Third Global Ministerial Summit on Patient Safety was held in Tokyo. Most of these efforts have kept pace with the international trend to stress the importance of a safety culture, as noted. Accordingly, when the issues of medical incidents and patient safety have been considered in Japan, especially as an agenda for public policy, the management of (potential and real) crises caused by medical incidents has more or less been set aside, as peripheral from the central issues. In other words, the business continuation of care organizations is not largely within the scope of public policy, which targets the provider function of essential services to the community, so that the management of care organizations themselves (such as their survival and growth) has been left to each organization.

Nevertheless, the fact that failures with respect to the management of medical incidents have continued to pose a real threat to the reputation and businesses of organizations (and at the same time, damaged the performance of their core mission) has gradually become widely known. Penalties imposed for negligence, increasing risks of litigation, and larger amounts of compensation levied for damages have also come to serve as factor in once gain highlighting the crisis-management of medical incidents. Thus, the importance of perceiving medical incidents as a cause of crisis, as well as incorporating its management as part of, or even as one of the core issues in the strategic planning of medical facilities has also been renewed. Consequently, beyond a systems approach to medical safety, which is intended to simply reduce the occurrence of medical incidents, efforts to plan ahead for handling such incidents as sources of crises have continued to evolve, both in the public and private sphere in Japan.

This article aims to review the basics of crisis management, as well as application to the management of medical incidents and malpractice crises. Special focus is given to the importance of communications, efforts to prevent incidents from becoming crises, and the significance of advance planning. Then, after a brief history of public policy on patient safety, recent efforts in Japan to help improve the management of crises that are caused by medical incidents are presented.

II. Management of risks and crises

1. Risk, issues, and hazards

Risk management concerns potential issues. It addresses an issue that has not yet occurred, and tries to prevent that issue (undesirable event) from taking place, and to minimize the potential for harm due to that issue. While a hazard is something that has the potential to cause harm, risk is the likelihood that harm will occur due to exposure to, or contact with that hazard. The impact or severity of a potential/real problem is determined by a set of factors, namely, the characteristics of the phenomenon (hazard), the scale of the risk (likelihood or probability), the vulnerability of those affected, and the manageability of the associated events/ incidents [7].

When a certain risk is viewed as a problem to be handled, the approach employed to anticipate and manage the corresponding external and/or internal challenges to the society/ organization is referred to as issue management. This usually comprises a set of processes, i.e., identification of the issue, an analysis of processes and factors, the development and selection of policy options, and program design, and the implementation of programs and their evaluation.

2. Crises and Disasters

A crisis refers to a major, unpredictable event that has the potential to generate negative results, and the aftermath of which may cause significant damage to society or the orga-

nization. It is usually a low-probability, high-impact event that poses a threat to viability: It makes a threat to the organization with the element of surprise, allowing a short decision time, and might eventually necessitate a change in the existing system (e.g., the organization or its activities). As a similar term, a disaster refers to an unforeseen and often sudden event that causes great damage, destruction, and human suffering [8]. Although the words, crisis and disaster are often used interchangeably, the former highlights the unexpectedness and uncontrollability of an event, while the latter emphasizes its outcome and consequences.

Crises can be of different natures and types, according to their underlying causes and the social aspects involved. They can be economic, physical, informational, or technological, and can involve violence, rumors, incidents, or pandemics. Generally, crises can be classified into natural or man-made (intentional). Acute disasters (whether man-made or due to nature) are usually unexpected, and include hurricanes, earthquakes, volcanic eruptions, tornadoes, blizzards, mud-slides, tidal waves, forest fires, oil spills, building collapses, explosions, hazardous materials, transportation incidents, and nuclear accidents.

3. Crisis management

Crisis management is the process through which an organization deals with a major event that threatens its operation (i.e., to harm the organization, its stakeholders, or the general public). The purposes of such management are conceptualized as prevention, mitigation, survival, business continuity, recovery, and resiliency. Furthermore, some benefits (e.g., lessons) can be added. Management of a crisis consists of four interconnected steps: prevention, preparedness, response, and recovery, while assessment and evaluation can represent another step [9]. Leadership and coordination are both essential in crisis management.

First, prevention addresses what can be done to eliminate or reduce the risk to life, property, and efficacy. Primary prevention identifies risks and hazards in the environment, in an effort to eradicate them and prevent disasters (prevention of crisis, in a narrow sense), while comprehensive preparedness plans to mitigate the effects of disasters/ crises (mitigation of crisis). This step is sometimes conceived as a core activity of risk/ issue management. Secondly, preparation refers to planning for the worst-case scenario. The core of the action plan (contingency plan) is a proactive, overall plan for dealing with potential threats, which includes plans for the following steps: hazard assessment, formulation of policies and procedures (including planning for resources, assignment of responsibility, and communication plans), training and education, and record keeping. An important component of preparation is the business continuity plan (BCP), which represents the internal effort within an organization to ensure that mission critical business and service functions (essential functions) are resistant to disruption by crises.

Thirdly, response refers to the activation of the operational plan (i.e., the activities invoked during a crisis). Among such a response (activation of the operational plan), notification (communication to relevant personnel of important information regarding the impact of an actual or potential hazard, and the response status of the organization) is an imperative component. Fourth, recovery refers to steps taken to return to normal (or new normal) operational levels (via a demobilization plan). This includes the restoration of resources, functions, and processes, in addition to clean-up, safety surveys, and public assurance, as rebuilding public trust is also crucial. Furthermore, an additional step involves assessment and evaluation. Situations should be assessed, and the response should be evaluated, so that the experience can be accumulated to help guide prevention and planning processes for the future. In this step, risks and hazards are (re-)analyzed, and the capacity of the organization to perform critical tasks is also (re-)examined.

To be effective and efficient, a policy for crisis management should have good characteristics, formulated as a cohesive set of policy components: good command and control, as a structure; sufficient commitment, appropriate knowledge/ intelligence, and physical supplies, as well as human staff as a resource base; advance plans and exercises, in terms of process; implementation of the ongoing analysis of capacity, response, and outcomes as evaluation efforts; and, good communication and media planning [10]. Specifically important and characteristic to crisis management is the Incident Command System (ICS) or Incident Management System (IMS). This system possesses a clear and common organizational structure, with clear and common operating procedures, defines roles/ responsibilities (chain of command) throughout the organization, and is equipped with clear reporting channels to enable quick and effective performance.

4. Risk and Crisis Communication

Risk communication can be defined as the interactive process of exchanging information and opinion among individuals, groups, and institutions, involving multiple messages about the nature of risks [11]. Three general and primary goals of such communications are to increase the knowledge and understanding of the concerned parties regarding the situation and responses, to enhance the trust and credibility of the responding agencies (and policies), and to facilitate dialogue to resolve disagreements regarding judgements and decisions. While the degree of time

pressure (urgent, unexpected) and message purpose (explanation, persuasion, or empowering decision-making) might vary among risk communication, issue(s) management communication, and Crisis communication, such distinctions are not in themselves significant.

It should be noted here that the general public and government/ organizational staff might have different expectations of communication. The public hopes to gain wanted facts, will allow communications to empower their decision-making, and believe it desirable to become involved as a participant, not a spectator. On the other hand, the primary goals in the minds of government/ organizational staff are to execute response and recovery efforts, gain support for crisis management plans, and ensure that decision-makers are well-informed. Accordingly, the roles of Public Information Officers are quite important, especially since they orchestrate communications with both internal staff and external stakeholders (including the media), and decide what information is to be released.

The goals of communication differ, depending on the phase of a crisis, including the pre-crisis (preparation) phase, initial response phase, response maintenance phase, recovery (resolution) phase, evaluation phase, and finally the evaluation phase [12]. Here, every step comprises more or less common components: assessing needs, constraints, and internal media-relations constraints; developing goals and objectives, plans, and stakeholder strategies; training the team, information officer, and lead spokespersons; preparing lists of concerns and messages; identifying media outlets and activities; delivering messages, and maintain visibility; and evaluating delivery and coverage, performance, and public responses.

As noted in Table 1, the aims of communications in the pre-crisis (preparation) phase are to develop crisis plans, formulate consensus recommendations, and foster alliances (in addition, to establish inter-agency protocols). These goals are usually accomplished through regular internal meetings, the monitoring of events and preparedness, the development and implementation of warning protocols, the arrangement of directions and orders, and the staging of equipment and personnel (mobilization of resources). In the initial response phase, the focus is to inform the public about risks and desirable courses of action. Well-planned and adaptive communications are quite important, since the reputations and credibility of organizations are frequently made or broken in this phase.

Later, in the response maintenance phase, communications aim to provide further explanations regarding risks by population group, empower their risk/benefit decision-making, and provide additional background. More practical purposes should also be pursued, such as gaining support for the response (and recovery plans), and obtaining and responding to feedback. Next, in the recovery (resolution) phase, crisis communications are intended to provide educational opportunities (including a consideration of audiences that are not directly involved in the crisis), and examine problems and mishaps, in addition to gaining support for new policies or resource allocation, and promoting the organization's capabilities.

The last phase, which should not be regarded as the least important, is concerned with evaluation. In this phase, communications efforts should capture lessons learned, attempt to improve crisis management plans, and finally return to pre-crisis planning. In addition to the activities undertaken in each phase, monitoring of events should be conducted throughout the crisis. Such monitoring includes media (including internet and SNS) monitoring, evaluation of responses and feedback, control of rumors and spin control, ongoing exchange of information with partners, and the monitoring of public opinions (desirable knowledge,

Table 1 Crisis Communication Lifecycle

	Objectives of Communication	
Precrisis	Prepare Foster alliances Develop recommendations	Test messages Evaluate plans
Initial	Express empathy Provide simple explanations regarding risk	Establish credibility Recommend actions Commit to stakeholders
Maintenance	Further explain risk by population group Provide further background	Gain support for responses Empower decisions Capture feedback for analysis
Resolution	Educate a primed public for future crises Examine problems	Gain support for policies and resources Promote the organization's roles
Evaluation	Capture lessons learned Develop an event SWOT	Improve plans Return to precrisis planning

(CDC, September 2002. Crisis Emergency + Risk Communication)

attitudes, and practice/behaviors).

5. Practical steps and caveats

The practical steps to develop and implement crisis communications can be delineated as follows [13]: (1) identify the crisis communication team and key spokespersons; (2) establish communications protocols; (3) identify and become familiar with the audience; (4) anticipate crises, and engage in preparations; (5) assess the crisis situation (ongoing); (6) identify key messages to communicate; and, (7) Decide on, and implement methods. The third point deserves special attention: it is sometimes be easy to deliver catch-all messages without envisaging concrete groups of audiences; however, this approach has the potential to reduce the effectiveness which might be otherwise be attained.

There is a set of caveats to be aware of when devising crisis communications. First, it is important to understand that the general public's perception of risks often deviates from the scientific understanding and/or statistical estimates regarding these risks. To put it briefly, all risks are not accepted equally. Risks can be taken voluntarily or imposed involuntarily, can be controlled personally or controlled by others, might be natural or man-made, can be distributed fairly or unfairly, affecting special or vulnerable populations, and even be statistical or anecdotal. In addition, hazards can be familiar or exotic, and their impacts can be either reversible or cause permanent damage. Depending on the nature of hazards and the course of events, people can behave quite differently, and even in an apparently irrational manner, when presented with the same levels of chance. It is essential to take such "outrage factors" fully into consideration [14]. Following the STARCC Principle (Simple, Timely, Accurate, Relevant, Credible, and Consistent), for example, initial messages must be short, relevant, informative regarding positive actions, and repeated, but should not use jargon, be judgmental, or make unrealistic promises [15].

The second point involves the importance of media relations. The media is certainly the fastest way to communicate information widely. It is advisable to stay on message, delivering consistent messages with a single, clear voice. It is better to provide some form of brief daily, and refrain from saying "no comment." Media triage might be appropriate, but should be carefully considered (no favoritism, focus on local issues first, and respond to all reasonable needs). Otherwise, valuable communication channels could be lost, or unfavorable effects might be incurred. Therefore, it is important to develop guidelines in advance, set ground rules for interviews, and establish media pools (a limited number of news media who represent a larger number of news media organizations).

The third point involves the importance of credibility and trust with regard to persons and organizations, as well as their statements and activities. Credibility can be fostered through the accuracy of information and the speed of delivery, while trust can be gained by expressing empathy and openness (impressing competence, honesty, commitment, and accountability are each imperative) [16]. To avoid unfavorable psychological reactions, careful communications should be devised so as to avoid unfulfilled expectations. In this regard, there are five points of advice: allow people the right to feel fear; don't over-reassure; acknowledge uncertainty: give people meaningful things to do; and, under-promise and over-deliver. The motto of the US CDC is quite impressive, declaring its goals: "Be First. Be Right. Be Credible" [17].

The fourth caveat is to keep in mind the non-negligible effect of, or rather the importance of social media. Undoubtedly, in tandem with the wide-spread use of social networking services (SNS), which form an online vehicle connecting people, communications through personal media have come to play a critical role in informing or misinforming during crises. Information from SNS is often the first publicly provided material, which can then serve as a source for traditional media [18]. Unlike the so-called mass media, SNS allows the public to act as both receivers and senders. Although scientific dynamics and theories remain to be formulated more clearly, empirical evidence suggests the importance of several points, which are similar to those that are apply when dealing with the mass media: use all basic communication principles; establish trust with users; collaborate with credible sources; and, maintain a good partnership with the public. However, it is evident that no person can fully control every message that is being sent or every response to his/her messages [19].

III. Management of crises and medical incidents

1. Crisis for health care professionals

Crises in health care settings can be triggered by a wide range of situations, and can involve either external or internal causes. The former include natural disasters, fires, and blackouts, epidemics and outbreaks, large-scale accidents, and terrorism, crimes, and violence, which directly or indirectly affect health care facilities and services [20]. The latter (i.e., internal causes) include medical safety issues, such as incidents, errors, and malpractice, food poisoning, and issues related to staff/ workers and human resources. In this article, special focus is given to the management of the crises caused by medical incidents and malpractice.

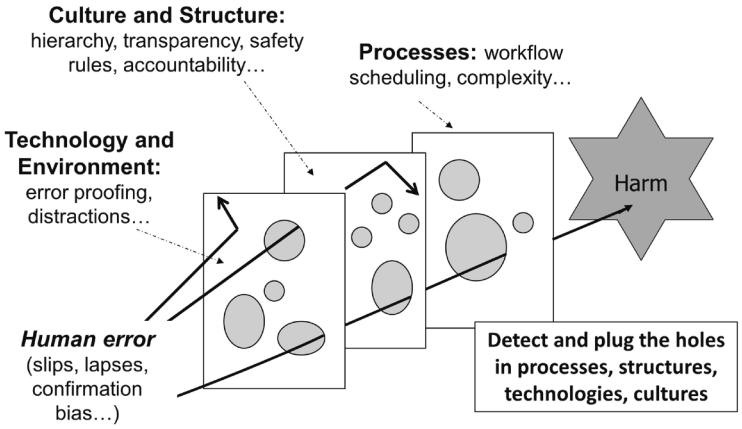

Figure 1 The Swiss Cheese Model and the Multi-layered Approach
Managing the Risk of Organizational Accidents (Reason, 1997)

2. Safety, errors, medical incidents, and malpractice

In its epoch-making report, "To Err is Human (2000)," the Institute of Medicine defines safety as freedom from accidental injury, while error is defined as a failure to complete an action as intended (i.e., an error in execution) or the utilization of the wrong plan to achieve an aim (i.e., an error in planning). It further conceptualized patient safety as the reduction and mitigation of unsafe acts within the health care system, as well as through the use of best practices that have been shown to lead to optimal patient outcomes [21].

Medical errors are inevitable. Furthermore, patients and their families now understand how to take their stories to the public. Nevertheless, many health care organizations continue to appear to be caught off guard, respond with arrogance, and reinforce pre-existing negative stereotypes. In these circumstances, when medical errors and incidents are handled inappropriately, they easily result in a crisis. The outcomes of media coverage and public attention can be critical. This is why the management of medical incidents has become increasingly important, and a crisis-proof reputation is sought after through advanced media relations.

Apart from the medical standpoint, two conditions act as sources of legal problems: negligence and malpractice. Negligence is a failure to exercise the standard of care required by law to protect others from an unreasonable risk of harm. Medical Malpractice can be further defined as Negligence on the part of the physician, allied healthcare provider, or hospital that causes physical or emotional damage to a patient. Negligence can take the form of a failure to diagnose, misdiagnosis of an illness, failure to refer, failure to obtain informed consent, inadequate communication, and many others. While not every misdiagnosis represents a case of malpractice or negligence (especially when the patient does not suffer injury due to the mistake), conditions caused by complications during procedures and patient dissatisfaction with outcomes (in some cases, due to unrealistic expectations) are frequently claimed and contested as such.

3. Crisis prevention and the management of medical incidents

In a health care setting, a crisis that results due to internal causes is an incident that occurs within the hospital and can damage its reputation. Such events take place unexpectedly (Augustine). Since errors, not necessarily those referred to as malpractice, can easily result in crises, their management is critically important. The principles of crisis management indicate that such management is accomplished through prevention (reduction of hazards, risks, and errors) and reactions (handling of incidents, errors, and crises).

Medical safety is pursued by promoting both a safe environment and a safety culture. The first of these aims to directly achieve a lower risk of accidents by reducing defects in processes and departures from correct procedures, and by establishing operational systems and processes that increase the reliability of patient care [22]. In contrast, the latter intends, more generally, to increase the overall commitment to apply core patient safety knowledge, skills, and attitudes to everyday tasks. Both of these efforts are facilitated by introducing a set of changes in processes, structure, and technology, such as simplification, standardization (process design and product design), training, a teamwork culture, and improved communication. These measures, which are sometimes referred to as a "multi-layered approach," are expected to reduce adverse events that are attributable to errors (preventable adverse events).

In anticipation of a crisis, however, it is always a good policy to have medical error-related crisis management plans in place. Such plans should include all of the steps

Table 2 Preventing incidents from becoming crises

	Prevention	Preparation	Response	Recovery
Risks and Crisis Management	Analysis and reduction of hazards and risk, mitigation	Advance plans, ICS, Alliance	Notify, React	Restoration, Assessment of plans and operations
Risk and Crisis Communications	Information sharing, Trust, Notification	Advance plans	Inform, Guide, Empower	Restoration, Assessment
Healthcare settings (medical errors)	Safety promotion, Minor incident management	Advance planning, Team and ICS	Disclosure, Remedy, Compensation	Root cause analysis and remedies
Communications	Risk communication, Trust building	Advance plans, Trust building	Inform, Empathize	Trust and Reputation restoration

necessary to avoid, prepare to manage, recognize, contain, resolve, and profit from (through learning) the crisis. Together, these steps are sometimes referred to as the Hospital Incident Command System (HICS), which consists of a command and control system, an incident action plan, and a recovery plan. However, since this system generally focuses on a somewhat narrower scope, without incorporating the processes of avoidance and learning, recasting this system into a more general plan for crisis management would be helpful in understanding the scope of these plans.

Since communications play a critical role in managing a crisis, sufficient preparation for crisis communication is warranted. To make strategic communications possible, such preparations should ensure that detailed operational plans, effective internal and stakeholder communications channels, and well-trained spokespersons are in place. As a pre-condition, strong credibility and good relationships with patients and their families, the public, government, and the media should be established before incidents occur. Communication after errors/ incidents should express empathy (understanding and acknowledgment), disclosures, assessments, apology (without blame or excuses), support and follow-up, and finally resolutions (offering of choices or alternatives). Disclosure of unanticipated outcomes is considered to be a professional responsibility, and skillful conversations and follow-ups are certain to reduce the risk of litigation, and the risk of a crisis. This is a principle that applies not only to the management of medical incidents, but also to that of critical incidents, in general [23].

There are also several caveats concerning communications when dealing with medical incidents, two of which are briefly presented here. First, patients and medical professional might have somewhat different definitions of error. Gallagher reported that patients tend to conceive errors very broadly, as those including some non-preventable events, poor service quality, and poor communication, while physicians perceive errors more narrowly as deviations from accepted standards of care. This gap in perception leads to differences regarding how an error should be disclosed. While physicians consider the disclosure and explanation of an error to be undertaken truthfully, objectively, and professionally, patients expect such disclosures to be provided in not only a truthful, but also compassionate manner.

The second is the fact that trust and credibility always matter. In particular, since what happens prior to any error influences the subsequent course of events, it is even more important to build a solid and positive relationship (of trust) with the patient, family members, and your own staff prior to any incident. It should also be noted that patients see themselves as equal partners, and they might be sharing their views on the Internet. Without building such basic relationships, the risk of litigation, and hence that of a crisis increases.

IV. Recent efforts to manage incident-related crises in Japan

1. Promotion of medical safety in Japan

The MHLW published a Manual for the Prevention of Medical Incidents in 1999, made it an obligation for advanced treatment hospitals to construct a system for safety management in 2000, and began providing training courses for hospital directors and safety managers in 2001. The Comprehensive Measures to Promote Medical Safety of 2002 proposed a set of measures, including safer designs for medical devices, standardization of treatment measures and care, clearer assignment of the responsibility for medical safety, and enhanced educational efforts, many of which are discussed in this article as measures of incident prevention and safety promotion [24]. In 2002, the Board of Japanese National University Hospital Directors established the Committee for Preventing Medical Accidents, and has started providing support to university-affiliated hospitals to improve their ability to improve patient safety and manage medical incidents [25]. Risk management guidelines, such as the Guidelines for Nursing Administrators, were first embodied in 1999 and 2002, and soon incorporated patient safety as part of the core curricula of the Japanese Nursing Association [26].

The MHLW Annual Report of 2004 featured the manage-

ment of health risks, presenting issues regarding medical safety along with systematic approaches for improvement [27]. Afterwards, a reporting system for medical accidents was soon established. In 2007, a specialist group of the MHLW prepared guidelines on the educational program to foster medical safety officers [28]. For practicing physicians, in 2009 the Japan Medical Association (JMA) published its manual for medical safety, in which the importance of standardized procedures and communications for incident management is extensively discussed [29].

More recently, the revision of the Medical Care Act in 2014 mandated (implemented in 2015) the administrators of all medical facilities (hospitals, clinics, maternity centers, and dispensaries) to designate staff member(s) who are responsible for medical safety, and led to the establishment of the Japan Medical Safety Research Organization, and its Medical Accident Investigation and Support Center (MedSafe). Medical accidents are hereby defined as deaths or stillbirths that are caused, or suspected to have been caused by the care provided by an employee of the medical institution, and which were unforeseen by the administrator [30]. The Reporting and Investigation System for Medical Accidents was also established, which consists of the investigation of incidents by the medical organization itself, as well as by the Investigation and Support Center, upon request [31]. In addition, the All Japan Hospital Association and local medical associations have also developed their own manuals for the prevention and handling of medial incidents [32,33].

2. Crisis management for medical incidents, revisited in Japan

As part of risk and crisis management in medical facilities, the management of medical incidents and the aversion of the risk of lawsuits has become manifestly (re-) positioned as an indispensable component. Supported by the Ministry of Economy, Trade and Industry (METI), educational materials for medial executives were published in 2006, which, in addition to stressing the importance of promoting medical safety, aim to train hospital directors and managers to act strategically, in anticipation of possible crisis situations resulting from incidents and malpractice [34].

Organized efforts towards conflict resolution (prior to litigation) became have also gradually been put in place. The sixth amendment to the Medical Care Act of 2007 established the Medial Safety Support Centers, which act to handle patients' concerns and complaints, provide both patients and medical facilities with information and advice, and implement services to train safety managers. In response, many medical organizations have introduced or revised their plans and protocols for managing medical incidents. For example, as part of the management of incidents, well-planned and considerate communications are stressed in the guidelines for the management of adverse events prepared in 2008 by the Japan Federation of Social Insurance Associations. Later, this approach (disclosures and apologies) proved to be effective in decreasing the number of lawsuits [35]. The Global Forum of Crisis Management and Crisis Communication for Health Care was held by the IARMM/URMPM in 2010, which included a special session on issues regarding medical safety and crisis management, including related communications [36].

In more recent years, professional associations and societies, private consulting services, and law firms are increasingly providing services to strengthen the governance and management of medical organizations, including their capacity to manage crises, including the management of medical incidents and malpractice. For example, The Japan Society for Clinical Anesthesia held a symposium on criminal trials for medical malpractice[37]. The Japan Medical Association provides information and educational services on medical safety, which extensively discuss the management of crises caused by medical incidents [38].

V. Conclusions

As described thus far, efforts to improve the management of medical incidents have derived from two main perspectives, namely, the promotion of patient safety and quality improvement, and the strategic management of organizational crises. While these two streams have produced different sets of policies and endeavors, they are sometimes closely interrelated and supplementary. Although the crisis management perspective is not the central topic of public policy, its importance undoubtedly remains. Basic principles for risk/ crisis management should be applied to the management of medical incidents, which in turn improve patient safety. Advance plans (for preparation, response, and recovery) are especially imperative, in addition to efforts to prevent medical incidents.

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医療・患者の安全および組織危機管理の向上に向けた医療事故の戦略的管理
―危機管理・コミュニケーション原則の応用と日本における施策動向―

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抄録

医療事故の管理・対策を向上させる努力は，医療・患者の安全向上および医療の質の向上，また医療機関の戦略的危機管理という二つの側面がある．これらは相互に関連し補完的であるが，異なった政策や取り組みを生んできた. 2000年頃より医療安全向上への取り組みは，体系的な欠陥，組織的学習，リスクコミュニケーション，安全文化の醸成などに注力するようになり，結果的にリスク管理から安全管理へ，また安全管理から安全文化・質の向上へと力点の変化が見られる．組織の危機管理という視点はこのように公共政策の中心的課題からは外れてきたものの，その重要性は不変である．医療への期待の増加，さらに訴訟リスクの増大など，組織の効果的危機管理がますます求められる所以であり，医療や医療関係者は十分な備えを要する．事前，事中，事後などの各段階に応じての計画や行動が必要であるが，リスク・クライシス管理における基本的な原則・手段は医療事故管理にも適用されるべきものであり，医療・患者安全の向上にも寄与すると期待される．ここではコミュニケーションが重要な役割を担い，事前準備（危機の予防）が特に必須である．本稿は，危機管理および医療安全向上における基本的事項を簡潔に述べ，医療患者安全の向上，さらに組織危機管理能力の向上として医療事故への対策を捉えた施策の日本における最近の動向について報告する．

キーワード：医療事故，患者安全，危機管理，危機コミュニケーション，日本