



Nursing and patient safety in Japan

1. Patient safety in Japan

Japanese Nursing Association



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2. Nursing and patient safety
(to be issued soon)
3. Japanese Nursing Association
in action (to be issued soon)

Terminology

- **Medical Safety:** The term “Medical Safety” is used in Japan in the text of the Medical Care Act as well as in various guidelines of the Ministry of Health, Labour and Welfare (MHLW).
However, a clear definition of “Medical Safety” has not been published.
In 2002, the Medical Safety Management Council of the MHLW published a report titled, “Comprehensive Management for Medical Safety Promotion– for the Prevention of Medical Accidents,” in which the view is expressed that embracing patients’ safety as the highest priority will nurture a “Safety Culture” as the background for the safe provision of healthcare. This view has been maintained in a 2005 MHLW report titled, “On Future Medical Safety Management.”
At the same time the term, “Patient Safety,” which is often used overseas, is also used in Japan.
- **Patient Safety:** The WHO defines Patient Safety as, “... reducing the risk of unnecessary harm associated with healthcare to an acceptable minimum...”
(WHO International Classification for Patient Safety, World Health Organization 2009, Geneva;
http://www.who.int/patientsafety/taxonomy/icps_full_report.pdf (Accessed on July 8, 2015))
- **Medical Accidents:** This term refers to all accidents that occur anywhere and involve healthcare, and that result in physical injury or death, including cases in which healthcare professionals are the victim, as well as falls in corridors. (“Comprehensive Management for Medical Safety Promotion,” a report by the Medical Safety Management Council, MHLW, 2002)

History and Overview

Ensuring Safety in Healthcare

Healthcare interventions, by nature, exert some form of impact on a patient's body. Providing safe healthcare is the highest priority. Across the world, efforts are made to assure patient safety.

In Japan, ensuring safety in healthcare practice was considered the responsibility of individual healthcare professionals, such as physicians.

In 1999, a spate of serious medical accidents occurred within a short period, alerting society to the issue of ensuring safety in healthcare. The response led to acceptance of the concept that, instead of relying on individual efforts, organization-wide efforts are necessary to address this issue. Various measures have been put into place to ensure safety at various levels, and to establish a mechanism to ensure safety across an entire system at the human level (healthcare professionals), the material level, the organizational level, the software level, and so forth.

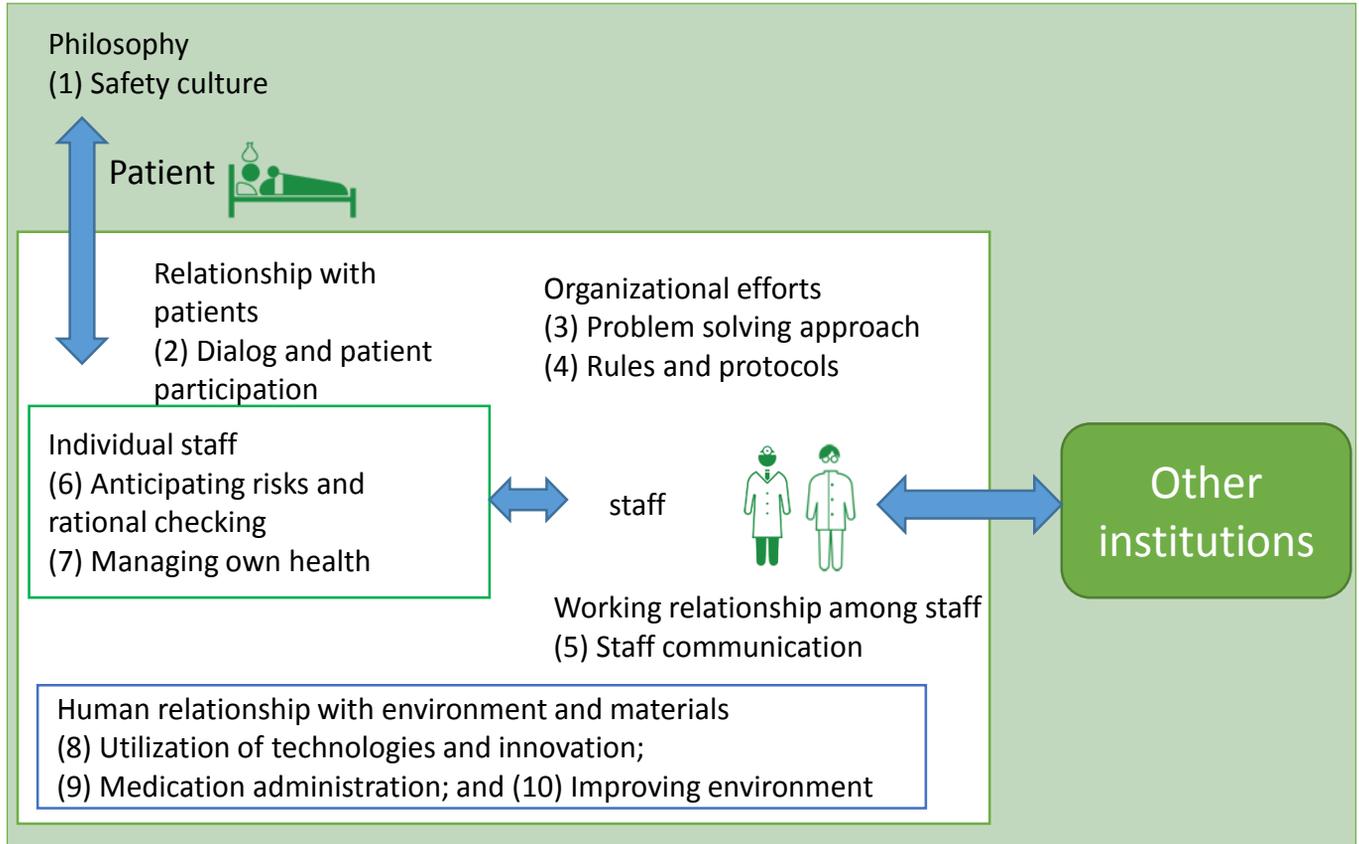
Events Concerning Safety in Healthcare

1999	A spate of medical accidents, the issue became social problem
2001	The year of Patient Safety Action (PSA) MHLW established a Medical Safety Promotion Office
2002	“Comprehensive Management for Medical Safety Promotion” published by MHLW Medical Safety Management Review Committee Partial amendment of the Ordinance for Enforcement of the Medical Care Act: Hospitals and clinics with beds were mandated to establish a medical safety management system
2003	Partial amendment to the Ordinance for Enforcement of the Medical Care Act: Stronger safety management system in advanced treatment hospitals and clinical training hospitals
2005	“On Future Medical Safety Management” published by a working group on the review of medical safety management
2007	The 5th amendment of the Medical Care Act came into force, and mandated all healthcare institutions, including clinics without beds and dental clinics, to have a medical safety management system; and stipulating the role of medical care safety support centers (prefectural level) Enforcement of the amendment to the Medical Practitioners Act and the amendment to the Dental Practitioners Act, mandating reeducation and training of medical or dental practitioners who were subject to administrative punishment
2008	Amendment to the Act on Public Health Nurses, Midwives, and Nurses enabled the Minister of Health, Labour and Welfare to order a nurse, etc., who was subject to administrative punishment, to undergo a reeducation course
2009	Creation of the Obstetric Compensation System
2015	Medical Accident Investigation System (To come into force on October 1)

Medical Safety Measures

Ten Key Points for Providing Safe Healthcare

An Overview of Medical Safety



Source: MHLW; “Ten Key Points in Providing Safe Medical Care” chart (partially edited)
<http://www.mhlw.go.jp/topics/2001/0110/tp1030-1f.html> (Accessed on July 13, 2015)

MHLW published the “Ten Key Points for Providing Safe Healthcare” in 2001. To provide safe care, healthcare institutions have to establish an organizational framework for medical safety and raise staff awareness. The Ten Key Points were developed to cover every staff at any healthcare institution. Concise expressions are used to present the ten particularly important key points ((1) Safety culture; (2) Dialog and patient participation; (3) Problem solving approach; (4) Rules and protocols; (5) Staff communication; (6) Anticipating risks and rational checking; (7) Management of one’s own health; (8) Utilizing technologies and innovation; (9) Medication administration; and (10) Improving environment) in the framework of the six important areas of medical safety management.

Ten Key Points in Providing Safe Healthcare

1. Let us establish a culture of safety and a system to apply our efforts (Safety culture)
2. Patient participation for heightened safety; dialog to deepen mutual understanding (Dialog and patient participation)
3. Let us share our experiences; let us apply the lessons we learnt (Problem-solving approach)
4. Rules and protocols: Set, Adhere and Revise (Rules and protocols)
5. Let us break the inter-division barriers and create a workplace where everyone can share views (Staff communication)
6. Anticipate the risks ahead; keep the key points and check properly (Anticipating the risks and rational checking)
7. Manage one's own health: the first step as a healthcare personnel (Managing one's own health)
8. Prevent an accident using technology and innovation (Utilizing technologies and innovation)
9. Double-check the patient and the medicine, take care of the route and dose (Medication administration)
10. Improve the care environment; create a work environment (Improving the environment)

Source: MHLW "Ten Key Points in Providing Safe Medical Care"
<http://www.mhlw.go.jp/topics/2001/0110/tp1030-1f.html> (Accessed on July 13, 2015)

The Ten Key Points for Providing Safe Healthcare are as listed above.

The respective healthcare institutions use the Ten Key Points to raise staff awareness

Initiative to Collect Medical Near-Miss /Adverse Event Information

Healthcare institution
Reporting of medical near-miss cases and
adverse event information



Registered analysis organization

Citizens, healthcare institutions, related organizations, academic societies,
government organizations, and other similar parties
Dissemination of information, development of preventative and
improvement measures, their implementation, etc.

MHLW started the initiative to compile information about near-miss cases in 2001. Following a partial amendment to the Ordinance for Enforcement of the Medical Care Act in 2004, collection of adverse event data started, and National Center for Advanced and Specialized Medical Care, hospitals run by National Hospital Organizations (Incorporated Administrative Agencies), university hospitals, and advanced treatment hospitals, etc. were mandated to provide such data within two weeks after a medical accident occurs. Other types of hospitals are also asked to participate on a voluntary basis.

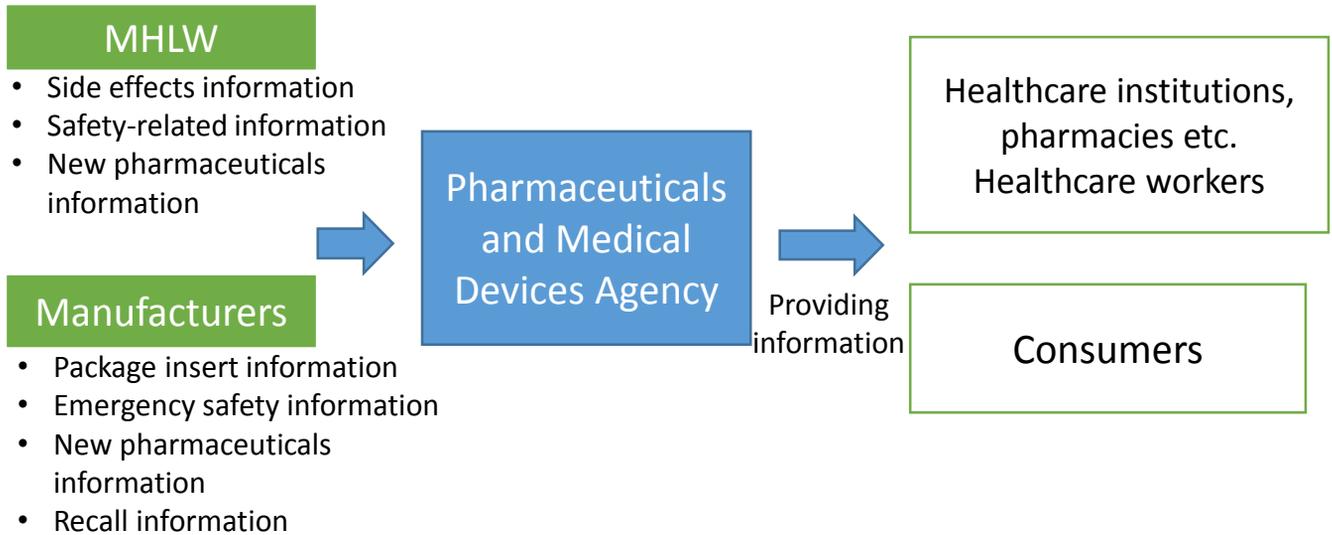
“Registered analysis organizations,” on the register of the Minister of Health, Labour and Welfare collect the information, perform comprehensive analyses and provide the results widely to such parties as healthcare institutions. Facilities utilize the provided information for the development and implementation of preventative measures and/or improvement measures. The information is also utilized for pharmaceuticals- and medical device-related improvement, such as name changes of medicine with similar names.

* An advanced treatment hospital is a hospital that is capable of: providing advanced medical care; carrying out the development and evaluation of advanced medical care techniques, and providing training on advanced medical care, and where the staffing and facilities are adequate for such a hospital, and have been approved by the Minister of Health, Labour and Welfare.

Reference: Initiative to Collect Medical Near-Miss/Adverse Event Information, Japan Council for Quality Health Care, Public Interest Incorporated Foundation <http://www.med-safe.jp/> (Accessed on July 14, 2015)

Safety Management Tasks for Pharmaceuticals and Medical Devices

Flow of Safety Management Tasks



The Pharmaceuticals and Medical Devices Agency (PMDA), Incorporated Administrative Agency takes the three roles; assessment and approval of pharmaceuticals and medical devices, safety management and relief services for adverse health effect.

As safety management tasks related to medical safety, PMDA centralizes the collection and analysis of such safety information including information about adverse events, malfunctions, infections, etc. concerning pharmaceuticals or medical devices after their market release, as well as information about adverse events in the development stage; and considers necessary safety management. PMDA also provides information to healthcare workers and consumers so that pharmaceuticals and medical devices can be used safely and with a sense of security.

PMDA provides consultation services for the corporations concerning better safety for individual pharmaceuticals or medical devices, and also addresses citizens' inquiries about the safety of pharmaceuticals and medical devices.

Source: Pharmaceuticals and Medical Devices Agency, Incorporated Administrative Agency (PMDA)
<https://www.pmda.go.jp/index.html> (Accessed on July 17, 2015)

Incorporated Administrative Agency System is aimed to separate some administrative activities and tasks from the policy implementation division of the Cabinet or ministry to a responsible organization that has the status of an independent legal person, to improve the quality of work, and to vitalize and improve efficiency to facilitate autonomous operation and better transparency.

Source: Ministry of Internal Affairs and Communications

http://www.soumu.go.jp/main_sosiki/gyoukan/kanri/satei2_01_01.html (Accessed on July 16, 2015)

Obstetric Compensation System

Purpose:

- To provide compensation covering the economic burden on the family of a child who suffers severe cerebral palsy associated with a birth-related cause
- To analyze data to determine the cause and provide helpful information to prevent recurrence
- To strive for the prevention of disputes, for early resolution of cases and to improve the quality of obstetric care

Amount of compensation payment:

- ¥30 million (including a lump sum payment of ¥6 million and another ¥24 million paid in installments over 20 years)

¥1million US\$ 8,022.00
(as of August 11,2015)

Japan Obstetric Compensation System for Cerebral Palsy is a framework that utilizes a private insurance scheme to pay compensation to persons who suffer cerebral palsy despite having undergone a normal pregnancy and childbirth process. By having childbirth facilities join a casualty insurance scheme in which operator of this scheme is a contractor, compensation payment is made to children who are subject to compensation. Childbirth facilities pay premiums per birth case.

The compensation system was reviewed to improve the environment so that families can receive obstetric care with a sense of security. This system was established in 2009.

Source: MHLW

http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryuu/iryuu/i-anzen/sanka-iryuu/index.html

(Accessed on July 17, 2015)

Medical Accident Investigation System

System overview

- When a medical accident occurs at a healthcare institution, it is mandatory to report to a medical accident investigation support center and to perform medical accident investigation to identify the cause of the accident.
- An internal investigation of a medical accident is performed, and the investigation outcome report is then collected by a private third party institution (Medical Accident Investigation Support Center) to analyze it with the aim of preventing recurrence and improving the safety and quality of healthcare.

Amendment of the Medical Care Act in 2014 established the Medical Accident Investigation System, which will start on October 1, 2015

The medical accidents in this system refers to the provision in the Article 6-10 of the Medical Care Act, "... a death or stillbirth caused by or considered caused by healthcare provided by a healthcare workers who works in the said hospital, but without anticipation of the said death or stillbirth by the manager, as stipulated by the Ordinance of the Ministry of Health, Labour and Welfare"

Reference: MHLW website

<http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000061201.html> (Accessed on June 23, 2015)

Medical Care Safety Support Center

Main tasks of the Medical Care Safety Support Center

- To handle complaints and inquiries from patients and their families, and to offer advice to them as well as the managers at their healthcare institutions
- To provide the information on ensuring medical safety to the healthcare institutions, their patients and their families, and/or the citizens within the center's precinct
- To implement training at the healthcare institutions within the center's precinct
- To provide the support necessary to ensure the safety of healthcare within the center's precinct

Source: Article 6-11, Medical Care Act

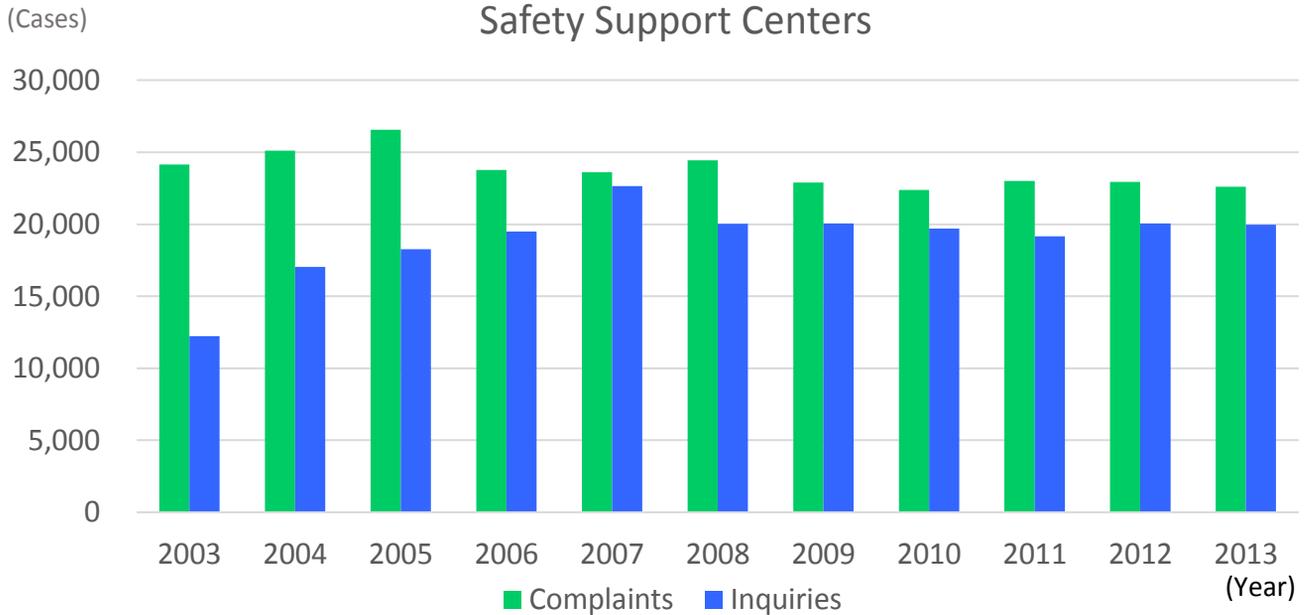
Establishment of medical care safety support centers started in 2003. Their position was recognized by the Medical Care Act of 2007. Over 300 centers across the country have been established including those belonging to prefectures and cities and special wards with public health centers.

Source: Medical Care Safety Support Center Website

<http://www.anzen-shien.jp/aboutus/index.html> (Accessed on July 1, 2015)

Medical Care Safety Support Center

Number of inquiries received at prefectural Medical Care Safety Support Centers



* When the data were collected in 2003, one prefecture was yet to establish a center. The data from Shimane and Mie are also not classified into complaints and other inquiries, therefore they are not reflected in the data presented in the above chart.

Source: Medical Care Safety Support Center Website <http://www.anzen-shien.jp/aboutus/index.html>
(Accessed on July 1, 2015)

The chart above shows the number of complaints and inquiries handled by prefectural Medical Care Safety Support Centers. In addition to the prefectural centers, the Medical Care Safety Support Centers at cities and special wards with public health centers and the secondary healthcare service areas also handle complaints and inquiries.

In terms of complaint handling classification, the two most often received complaint categories are “Medical act and content of healthcare” followed by “Attitude of healthcare workers at the institution,” which make up more than half of all complaints. In terms of other inquiries, the top category was “Matters concerning health or disease”.

Medical Safety Management System in Organization

Organization-wide Safety Management

Organization-wide Safety Management

	Hospital	Advanced Treatment Hospital	Clinic	Maternity home
Guideline concerning medical safety	○	○	○	○
Committee concerning medical safety	○	○	○ (Not applicable to clinics without beds)	○ (Not applicable if there is not a facility to admit inpatients)
Staff training	○	○	○	○
Measures for improvement	○	○	○	○
Full-time medical safety manager		○		
Safety management division		○		
Inquiry/consultation system for patient		○		

The partial amendment to the Medical Care Act in 2002 mandated hospitals and clinics with beds to establish a medical safety management system including establishing their guideline concerning medical safety, holding of committee meetings on medical safety, running of staff training for medical safety and improvement measures to ensure medical safety such as internal accident reporting within the healthcare institution.

Since 2003, advanced treatment hospitals have been mandated to assign a full time safety manager, to establish a safety management division and to ensure the provision of a patient inquiry/consultation service, as means to further enhance the safety management system.

Since 2007 all healthcare institutions including clinics without bed and maternity homes have been mandated to have a medical safety management system. In addition, such matters as prevention of healthcare-associated infections, pharmaceutical safety management and medical device safety management, were stipulated.

* Full-time: a staff member who mainly performs the tasks, though can perform another range of tasks

“On Trial of a Part of Ministerial Ordinance for the Partial Amendment of the Ordinance for Enforcement of the Medical Care Act” A notice of the director of the Health Policy Bureau, Ministry of Health, Labour and Welfare (HPB Notice No. 0830001 of August 30, 2002)

[http://www.wam.go.jp/wamappl/bb13GS40.nsf/0/49256fe9001ac4c749256c29000b3836/\\$FILE/siryou1.PDF](http://www.wam.go.jp/wamappl/bb13GS40.nsf/0/49256fe9001ac4c749256c29000b3836/$FILE/siryou1.PDF) (Accessed on June 25, 2015)

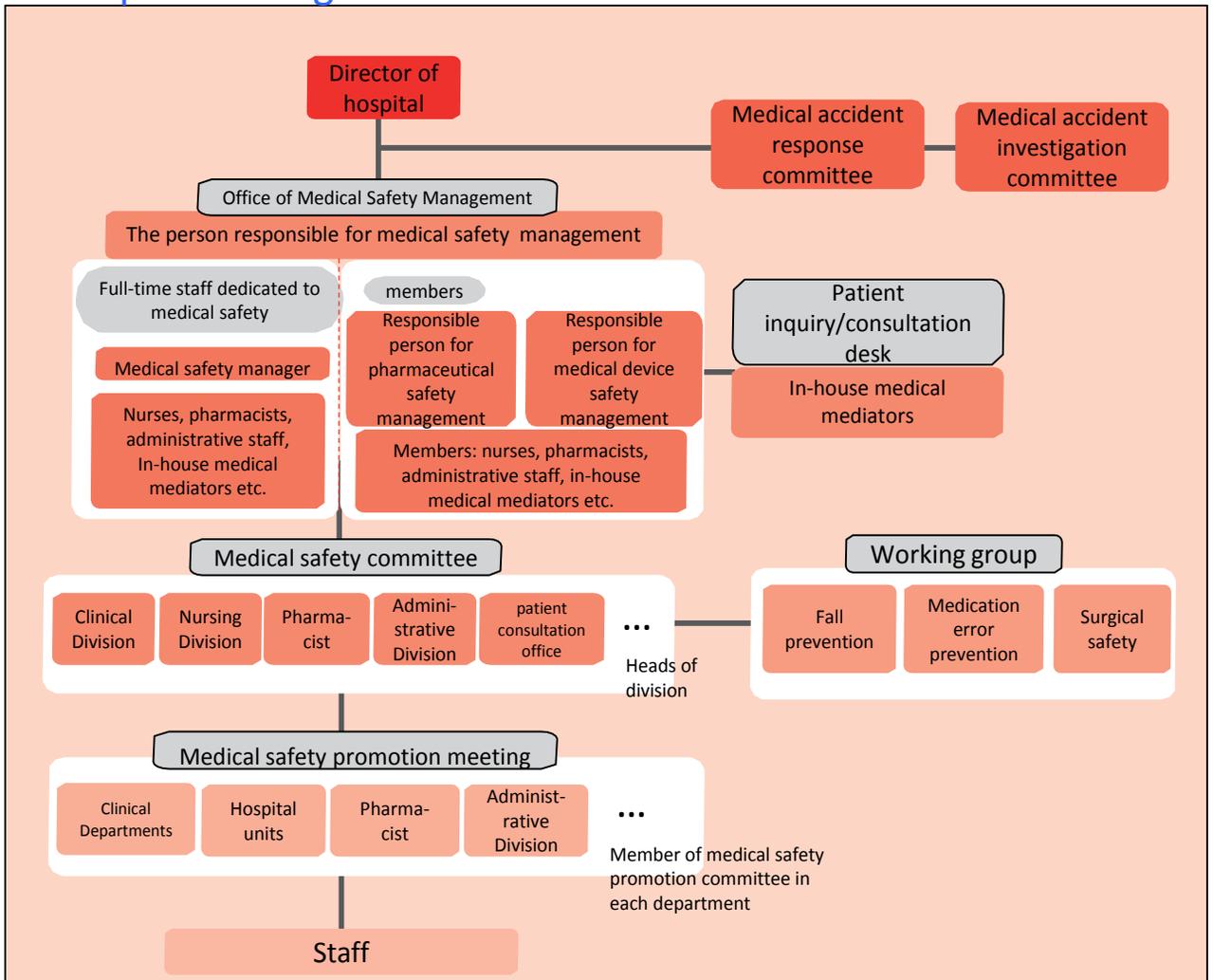
“On Enforcement of a Part of the Ministerial Ordinance for the Partial Amendment of the Ordinance for Enforcement of the Medical Care Act” A notice of the director of the Health Policy Bureau, Ministry of Health, Labour and Welfare (HPB Notice No. 1007003 of October 7, 2002)

<http://www.mhlw.go.jp/topics/bukyoku/isei/i-anzen/hourei/dl/021007-1.pdf> (Accessed on June 25, 2015)

Safety Management in Organization

Medical Safety Management Framework

Example of a large-scale healthcare institution



Japanese Nursing Association: Standard Text for Promoting Medical Safety 2013

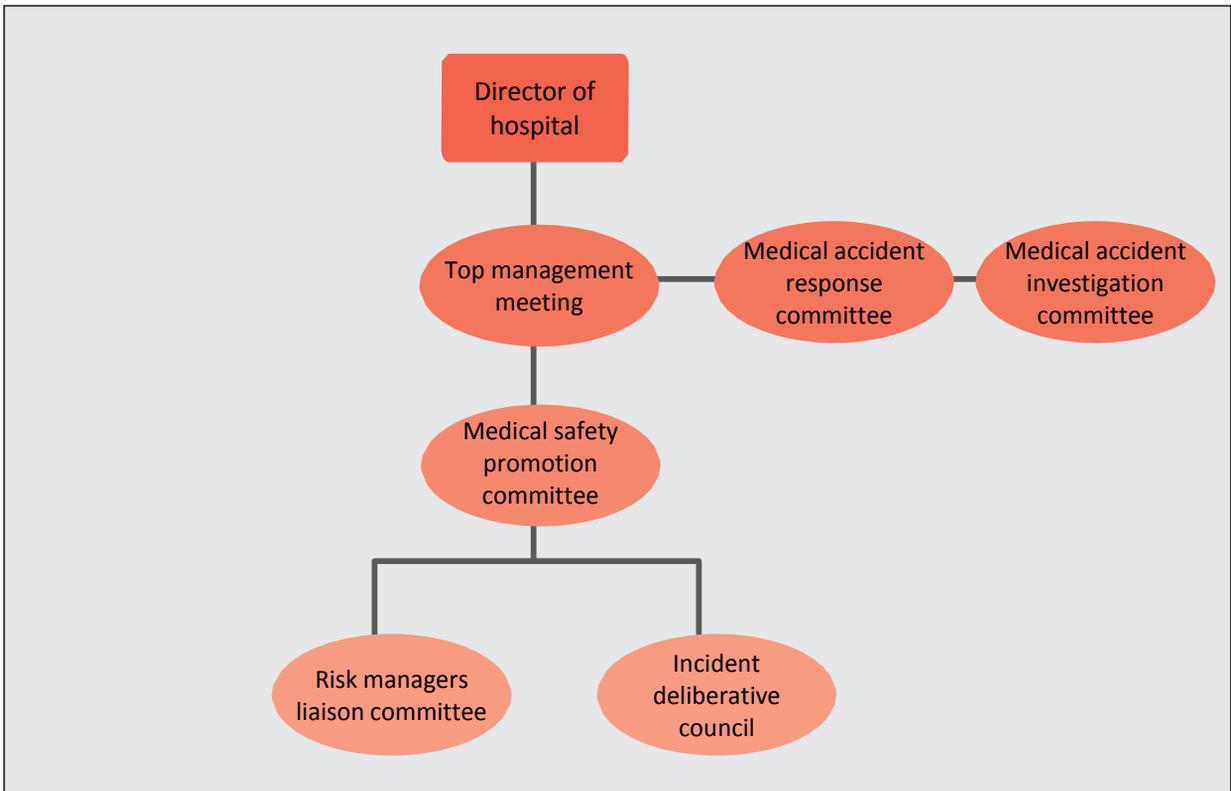
The chart above shows an example of a medical safety management framework in a large-scale healthcare institution.

* Though there is not an established definition of a large-scale healthcare institution, a reference to the medical treatment fee category classification suggests it to be either an advanced treatment hospital or a general hospital with at least 500 beds.

Safety Management in Organization

Medical Safety Management Framework

Example of a medium- to small-scale healthcare institution



Japanese Nursing Association: Standard Text for Promoting Medical Safety 2013

The chart above shows an example of medical safety management framework in a medium- to small-scale healthcare institution.

* Though there is not an established definition of a medium- to small-scale healthcare institution, a reference to the medical treatment fee category suggests it to a hospital with fewer than 200 beds.

Safety Management in Organization

Medical Safety Manager

Tasks of a medical safety manager

- To establish the safety management system
Participation in steering team of a multidisciplinary safety management committee, safety management division, etc., and development of a safety management guideline, etc.
- To implement staff education and training on medical safety
- To collect and analyze data for the prevention of medical accidents, to devise measures, to provide feedback and to evaluate it
- To handle medical accidents
- To nurture a safety culture

The medical safety manager shall perform the tasks ordered by the administrator of the healthcare institutions with 1) delegation of the authority necessary for safety management, and 2) provision of the resources necessary for safety management (such as human resources, budget and infrastructure).¹⁾

Previously, the guideline of tasks for the manager and training concerning medical safety had been the responsibility of the respective healthcare institutions. However, in 2007, MHLW published work guidelines for the medical safety managers and a guideline for formulating training programs.

1) Source and reference: MHLW Medical Safety Management Review Council
“Guideline for tasks of the medical safety management officer and guideline for training program development – for improvement of the quality of medical safety management officers,” Working group for review of improvement of quality of medical safety management officers. March 2007

<http://www.mhlw.go.jp/topics/bukyoku/isei/i-anzen/houkoku/dl/070330-2.pdf>

(Accessed on June 25, 2015)

Safety Measures and Medical Treatment Fee

2002	Start of the provision to reduce the amount of medical treatment fee if a medical safety management system has not been established.
2006	Establishment of a medical safety management system, a safety management system guideline, holding of committee meetings, measures for improvement and staff training were included in the facility-related schedule for the basic admission fee calculation. A medical safety premium was added to the medical treatment fee if a healthcare professional with a certain level of education was appointed as a medical safety manager.
2010	Two requirements were set for a medical safety manager to receive the medical safety management premium; raising the value of the medical treatment fee if the manager engages the work of safety management exclusively.

Medical treatment fee schedule sets the price of insurance-covered healthcare services in Japan. There are also provisions concerning safety measures in the medical treatment fee.

A provision was introduced in 2002 to reduce the value of medical treatment fee if a medical safety management system was not established. However, this measure was abolished in 2006.

In 2006, establishment of a medical safety management system became a requirement for the basic admission fees, including the fees for provision of basic medical care, nursing service and a care environment on admission. In other words, the facilities that failed to take medical safety management became unable to claim the basic admission fees. In addition, it was allowed to add a medical safety premium to the value of the medical treatment fee if a person with a certain level of education was appointed as a medical safety manager.

Reference: Japanese Nursing Association: Standard Text for Promoting Medical Safety 2013
Public notice of the Ministry of Health, Labour and Welfare No.93 of March 6, 2006
Public notice of the Ministry of Health, Labour and Welfare No.72 of March 5, 2010

Legal Liabilities Arising From a Medical Accident

Medical Accidents and Legal Liabilities

- Criminal liabilities (Penal Code)
- Civil liabilities (Civil Code)
- Administrative liabilities (Act on Public Health Nurses, Midwives and Nurses, National Public Service Act and other similar legislations)

The liabilities of a nurse in case of a medical accident may be Criminal liabilities, Civil liabilities and/or Administrative liabilities.

In Japan, the Act on Public Health Nurses, Midwives and Nurses stipulates administrative punishment when one faces administrative liabilities. Article 9 of the Act stipulates the Grounds for Disqualification. Article 14 stipulates three types of administrative punishments: Admonition; Suspension of practice for up to three years; and Revocation of License.

The Act stipulates that the opinions of the Medical Ethics Council shall be sought before handing down an administrative punishment. The Medical Ethics Council shall take the following four viewpoints into particular consideration when deliberating: i.) Respect for life; ii.) Assurance of physical and mental inviolability; iii.) Nurse's responsibilities about the proper use of their knowledge and skills and to inform patients; and iv.) Morals and dignity as a professional.

In 2008, it became mandatory for a nurse who was given admonition or suspension of practice, or who had his/her license revoked, to undergo a re-education program under the order of the Minister of Health, Labour and Welfare.