

# Medical Safety Promotion

May 2016

**Medical Safety Promotion Office, General Affairs Division,  
Health Policy Bureau,  
Ministry of Health, Labour and Welfare, Japan**

# Background of medical safety measures in our country

- **2001 April**  
Medical Safety Promotion Office was established in the Ministry of Health, Labour and Welfare; medical safety measures review meeting was held.
- **2002 April**  
“Comprehensive medical safety promotion measures” were formulated at the medical safety measure review meeting
- **2002 October– amendment of ministerial ordinance**  
Hospitals and clinics with beds were mandated to establish a medical safety management system
- **2003 April ----- amendment of ministerial ordinance**  
Placement of medical safety managers, medical safety management department, and patient consultation counters was mandated in advanced treatment hospitals and clinical training hospitals.
- **2003 December**  
*“Minister of Health, Labour and Welfare’s Urgent Appeal for Measures Against Medical Accident”---medical safety as one of the most important issues of health policy.*
- **2004 October -- amendment of ministerial ordinance**  
Reporting of medical accidents was mandated to advanced treatment hospitals, etc.
- **2005 June**  
“Medical safety measures review meeting” report (measures to prevent medical accidents, etc.)
- **2006 April ----- 5<sup>th</sup> Amendment of Medical Care Act**
- **2007 April ----- 5<sup>th</sup> Amendment of Medical Care Act**  
In addition to hospitals and clinics with beds, clinics without beds and birthing center were mandated to establish a medical safety administrative structure and medical safety support centers in each prefecture .
- **2014 June-- 6<sup>th</sup> Amendment of Medical Care Act**
- **2015 October– Amendment of Medical Care Act**  
Medical Accidents Investigation System was enforced

# Medical Care Act (Article 6-10)

Administrators of hospitals, clinics or birthing center shall undertake measures, (...).

- [1] the establishment of policies to ensure safety in medical care
- [2] the implementation of training for employees
- [3] measures to ensure safety in medical care in other relevant hospitals, clinics, or birthing centers

# Ordinance for Enforcement of the Medical Care Act (Article 1 – 11(i))

Administrators of the hospitals, etc. shall ensure **medical safety system** based on regulations described in Article 6 - 10.  
(However, (ii) is limited to hospitals (etc.))

1. **Preparing guidelines** for medical safety control.
2. **Holding the committee meetings** on medical safety control.
3. **Training staff** in medical safety control.
4. Taking improvement measures aimed at ensuring medical safety, such as, **reporting of medical accidents** that occur within medical institutions

# Ordinance for Enforcement of the Medical Care Act (Article 9 - 23)

## **(Safety management system in advanced treatment hospitals)**

Article 16 - 3 (vii) of the Ministerial Ordinance shall stipulate the following:

1. Securing the following system:
  - a) Assignment of **full-time persons responsible for medical safety management** and **nosocomial infection control**.
  - b) Establish **a department in charge of medical safety management**.
  - c) Secure a system within hospitals to appropriately deal with **consultations on patient safety management**.

## Ordinance for Enforcement of the Medical Care Act (Article 9 - 23)

2. In case accidents and other cases demanding reports occur in the following medical institutions, reports shall be prepared on the relevant cases describing below items **within 2 weeks from the date of occurrence**.
  - a) Cases in which **treatment or management error is obvious** and have caused death or physical/psychological disabilities to patients or cases which required treatment unforeseen or exceeding expectations.
  - b) Cases in which **treatment or management error is not obvious** and have caused ··· (limited to cases whose occurrence was unforeseen including cases suspected to have been caused by the treatment or management performed)

# Medical accident information reporting system

## Medical accident

Mandatory participation of medical institutions (275)

- Advanced treatment hospital
- National Hansen's Disease Sanatorium
- Hospitals of National Hospital Organization
- University hospitals (Main hospital)
- National Research Center for Advanced and Specialized Medical Care.

Voluntary participation of medical institutions (718)

## Near-miss event

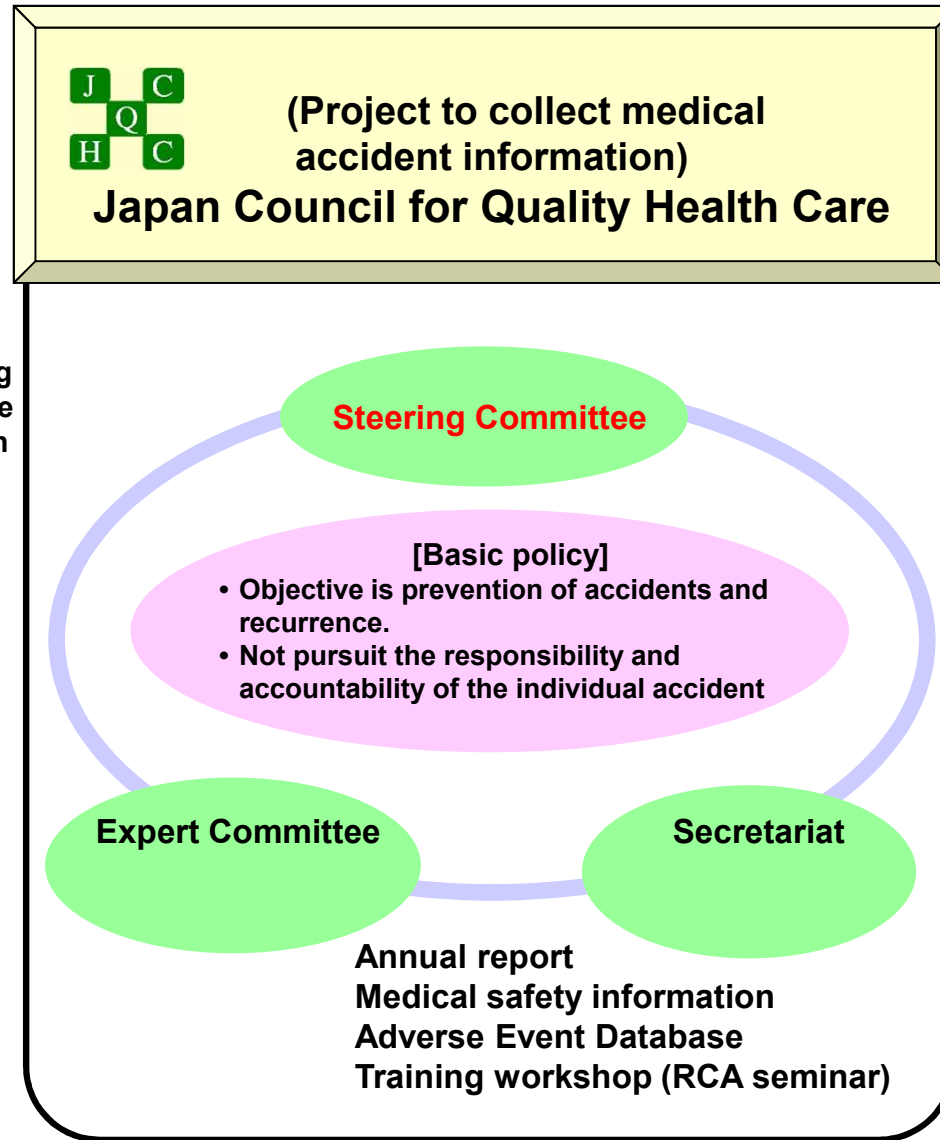
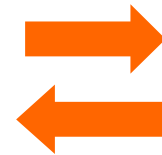
Voluntary participation of medical institutions (approximately 1200 sites)



Web reporting  
① Cord-choice  
② Description



Documents, on-site visit (voluntary survey)




  
**The general public,**  
**Medical institutions,**  
**Relevant academic conferences/ industry organizations,**  
**Government organizations,**  
 etc.

## Target Medical Institutions (as of end of December 2014)

### ○Mandatory Reporting Medical Institutions (275 hospitals)

Advanced treatment hospital

National Hansen's Disease Sanatorium

Hospitals of National Hospital Organization

University hospitals (Main hospital)

National Research Center for Advanced and Specialized Medical Care

### ○Registered Medical Institutions (718 hospitals)

Medical institutions other than mandatory reporting medical institutions who wish to participate can do so by registering necessary items.

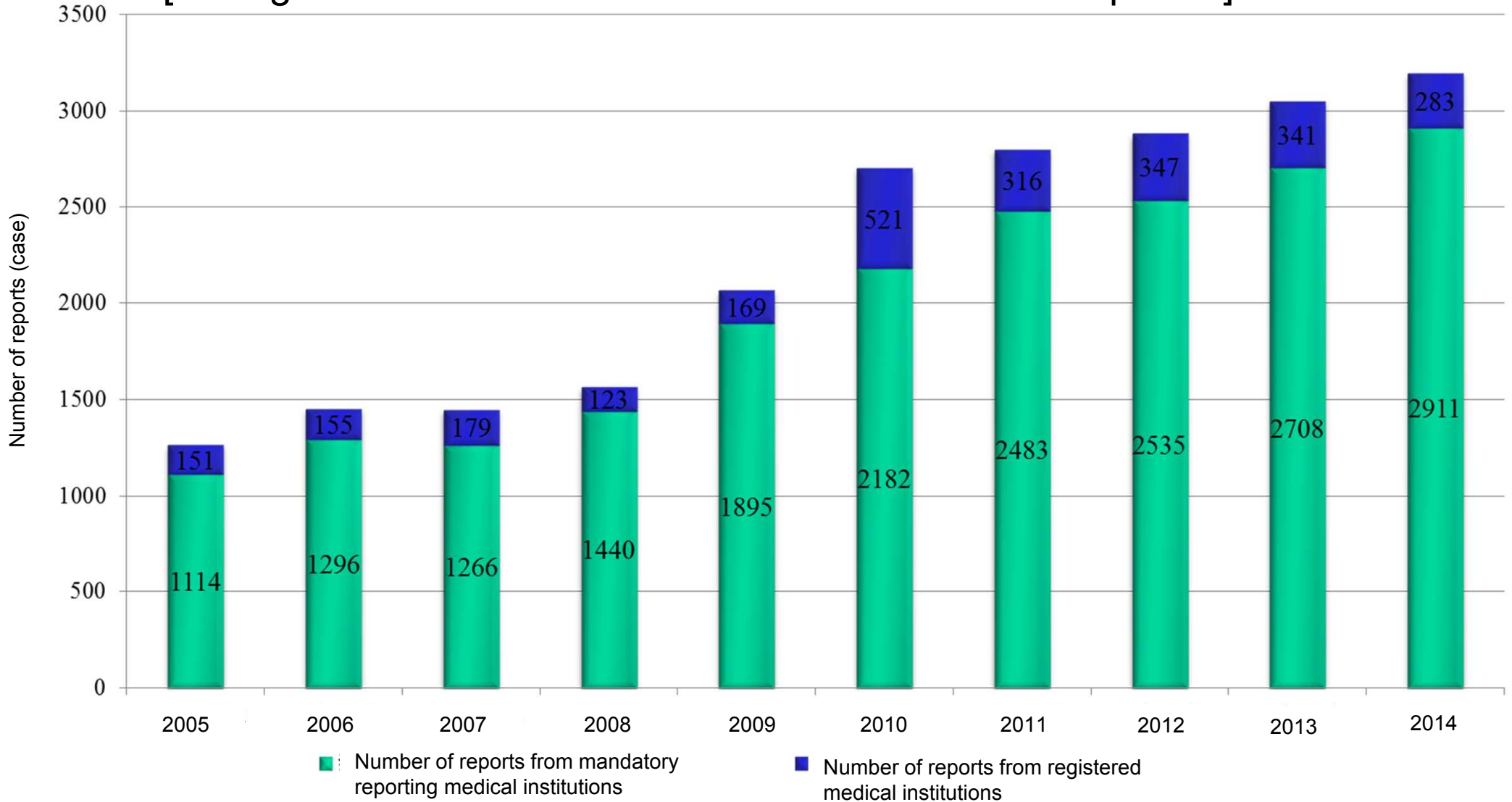
## **2014 Number of medical institutions and reported accidents**

	Number of mandatory reporting medical institutions (as of December 31, 2014)	2014 Number of reported accidents (January 1 to December 31, 2014 )	
		Total	Death
Total	275	2,911	225



# Status of Reporting for Project to Collect Medical Accident Information

[Changes in the number of medical accident cases reported]

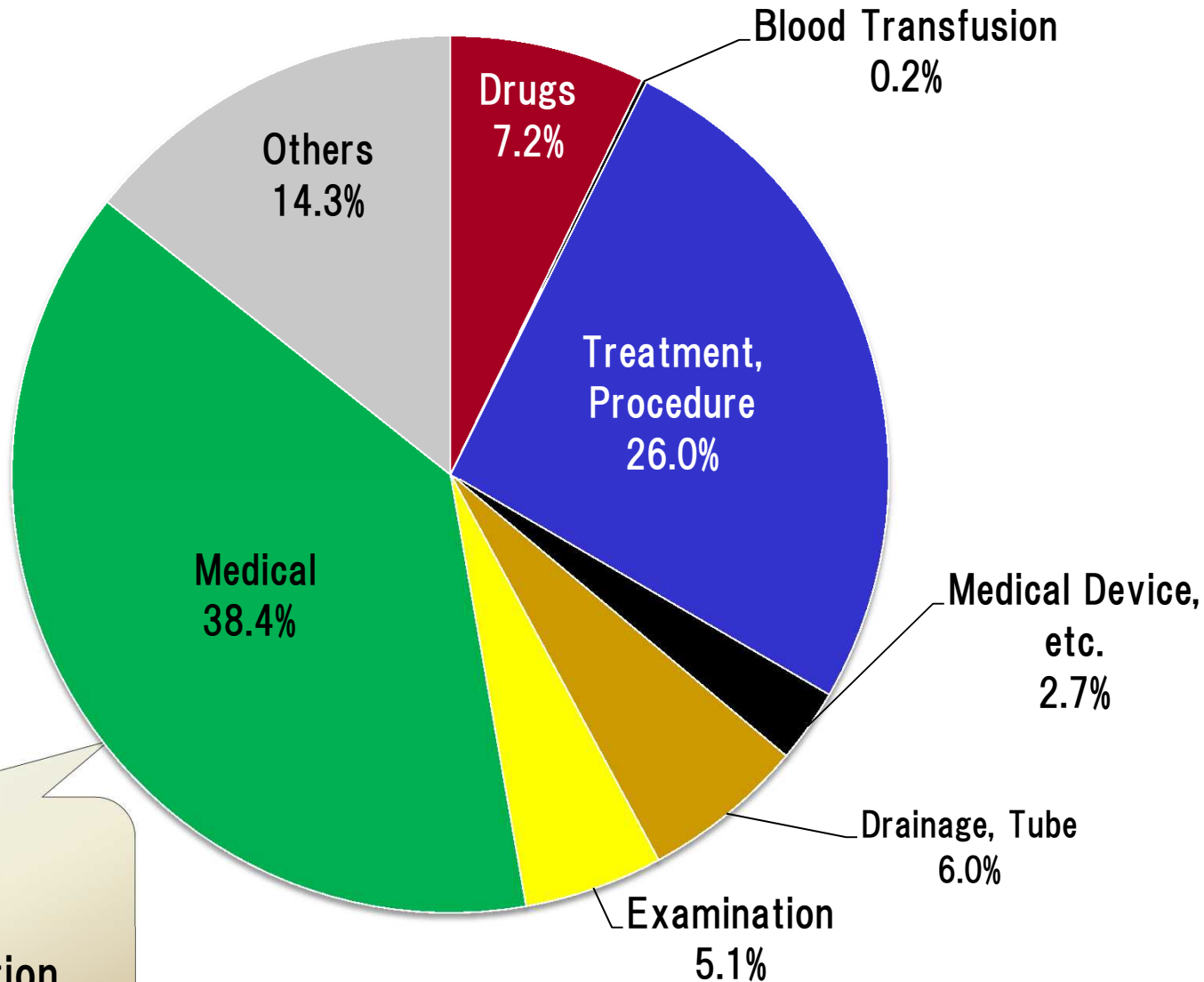


(as of December 31 each year)

Source: Project to Collect Medical Accident Information 2005-2013 Annual Reports & 37<sup>th</sup>-40<sup>th</sup> Reports (Japan Council for Quality Health Care)

# Classification by accident summary

(Mandatory reporting medical institutions: January to December, 2014)

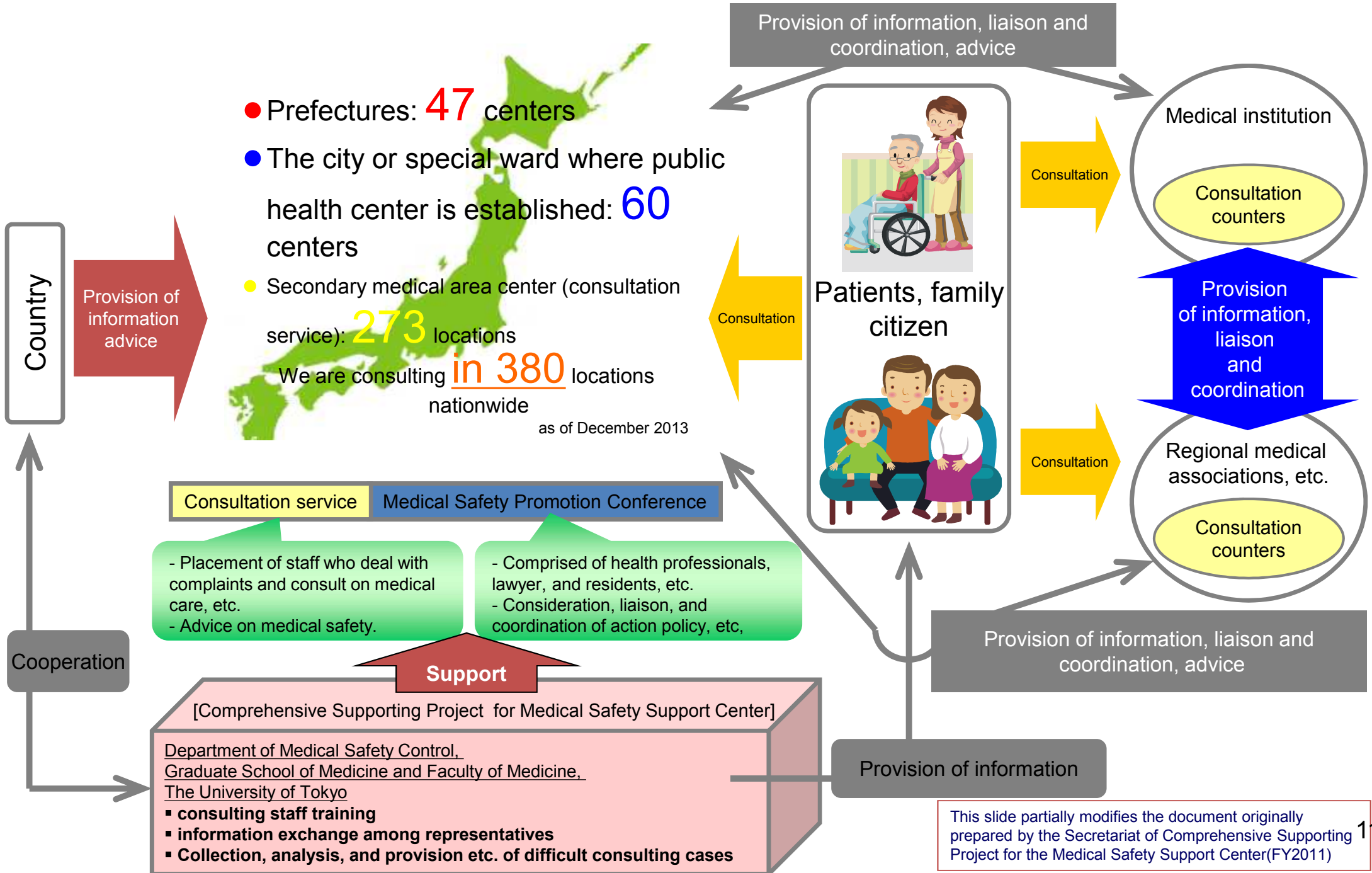


- Turnover
- Falls
- Pulmonary Aspiration

Source: Project to Collect Medical Accident Information (Japan Council for Quality Health Care)

# ◆◆◆ Structure of Medical Safety Support Centers ◆◆◆

- Prefectures: **47** centers
  - The city or special ward where public health center is established: **60** centers
  - Secondary medical area center (consultation service): **273** locations
- We are consulting **in 380** locations nationwide as of December 2013



This slide partially modifies the document originally prepared by the Secretariat of Comprehensive Supporting Project for the Medical Safety Support Center(FY2011) 11

# Summary of Japan Obstetric Compensation System for Cerebral Palsy [1]

## Background of system establishment

For medical accidents during delivery, judging whether there is negligence is often difficult, and tend to refer to a court. The high frequency of conflicts is one of the reasons for lacking obstetrician. Therefore, Japan Obstetric Compensation System for Cerebral Palsy was initiated by Japan Council for Quality Health Care from **January 2009 as part of the creation of an environment for comfortable medical treatment in obstetrics** to [1] give relief to patients who were disabled by medical accidents on delivery, [2] aim for early resolution of conflicts, and [3] aim for improvement of quality of care in obstetrics by analyzing the cause of the accident.

## Covered by insurance

- In cases of cerebral palsy despite usual pregnancy and delivery:

### Applied from labors on and before December 31, 2014

- Fetus week number: 33 weeks or older
- Birth weight: 2000 g or more
- Disability level: Persons with severe physical disabilities (equivalent to 1<sup>st</sup> and 2<sup>nd</sup> grade)
- Exclusion of cases that meet exclusion criteria such as congenital factor
- Even for those who have lower birth-weight or under the gestational-age specified in the criteria, cases where the gestational-age is at least 28 weeks will be individually reviewed.

### Applied from labors on and after January 1, 2015

- Fetus week number: 32 weeks or older
- Birth weight: 1400 g or more
- Disability level: Persons with severe physical disabilities (equivalent to 1<sup>st</sup> and 2<sup>nd</sup> grade)
- Exclusion of cases that meet exclusion criteria such as congenital factor
- Even for those who have lower birth-weight or under the gestational-age specified in the criteria, cases where the gestational-age is at least 28 weeks will be individually reviewed.

# Summary of Japan Obstetric Compensation System for Cerebral Palsy [2]

Improvement of quality of care in obstetrics

## Examine

- Integrally examine whether cases are covered by the insurance (Application period: Generally between 1 to 5-years old; over 6 months if extremely severe)

## Analyze the cause

- Analyze the cause from a medical point of view, and give feedback to the delivery institution and expectant nursing mothers.
- Post abstracts on the website with consideration personal information, etc.. Fully disclose(masked) texts to requesters.

## Prevent recurrence

- Systematically categorize and analyze cases with analyzed cause, and prepare prevention measures against recurrence.
- Provide this information to citizens, delivery institutions, and academic communities, etc.

Review, analyze the cause and prevent recurrence

Each delivery institution

Installment deposits (insurance fee)  
30,000 yen per one delivery \*

Japan Council for Quality Health Care (administration organization)

**Promotion for participation** Participation to the system was added as the requirement for calculation of medical treatment fees, and 30,000 yen \* of lump-sum payment for childbirth added for the delivery in participating institutions.

Insurance company

Compensation (insurance benefits) 30 million yen  
[6 million yen lump-sum payment + 24 million yen in installment payments  
(1.2 million yen yearly for 20 times)]

\* From labor on and after January 1, 2015, insurance premiums per delivery 24,000 yen (Installment deposits per delivery 16,000 yen).

Expectant and nursing mothers, children

# Medical Accidents Investigation System

## ○ Definition of Medical Accident

**Medical accidents subject to this system are** "death or stillbirth which are caused or suspected to have been caused by care provided by employees of the medical institutions, and which are unforeseen by the administrator".

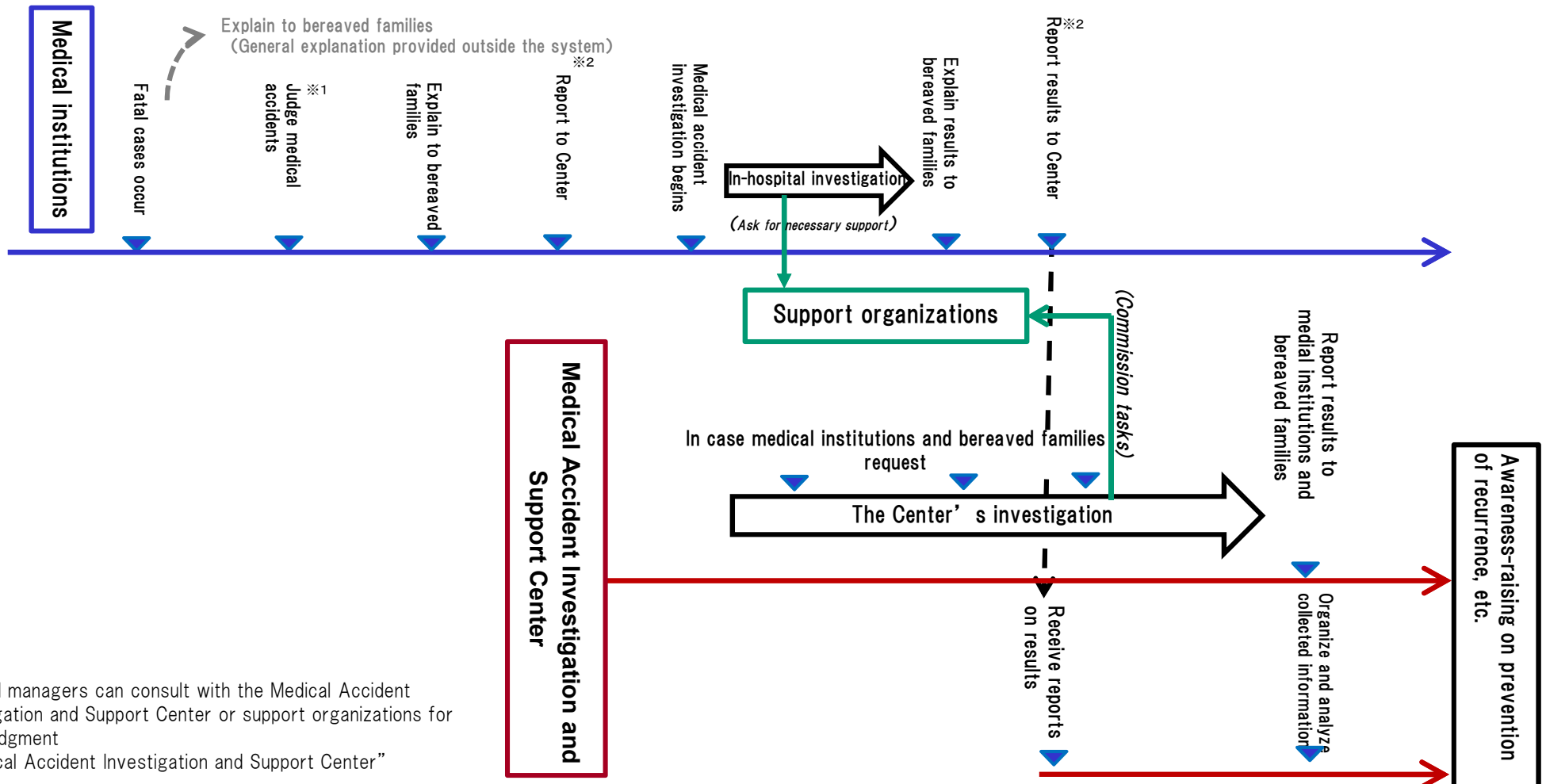
## ○ The investigation flow of the system

■ When medical accidents subject to this process occur, the medical institution provides an **explanation to the bereaved family, reports to the third party organization, conducts necessary investigation, provides an explanation of the investigation results to the bereaved family and reports them to the Medical Accident Investigation and Support Center (※).**

■ **The Medical Accident Investigation and Support Center conducts investigation** on accidents as requested by medical institutions or bereaved families and **reports the results to medical institutions and bereaved families.**

■ The Center **sorts out and analyzes** the investigation results reported by the medical institutions, and raises awareness to prevent recurrence of medical accidents.

\* (1) Supporting medical institutions, (2) Sorting out and analyzing in-hospital investigation results, (3) Implementing investigation requested by medical institutions or the bereaved, (4) Public awareness to prevent recurrences, (5) Designation of a **new private organization** that properly and reliably performs training, etc. for persons involved in medical accident investigation.



# Medical Safety Education and Training

Model Core Curriculum of Medical Education – Educational Content Guidelines – ver. 2010  
(Research and Development Project Committee for Medical Education Program, MEXT)

- A Basic Principles 2 Securing of Medical Safety
- (1) Safety Management
  - (2) Handling and Prevention of Medical Accidents
  - (3) Health and Safety for Health Care Personnel

Attainment Objectives of Residency

(Notification from Director General, Health Policy Bureau, MHLW. March 31, 2015 attachment 1)

- I Performance Objectives (The basic stance and attitudes required to be health care personnel)
- (4) Safety management

Guideline for System Establishment of Medical Specialists System (ver. 1) (Japanese Medical Specialty Board July 2014)

- II Development of Specialists Training 2. Curriculum for Specialists Training
- ② Attainment Objectives (Knowledge, Techniques and Attitudes that should be mastered)
    - iv. Morality and Sociality as a Medical Doctor  
Communication ability, Medical Ethics, Medical Safety, Medical Law, System of Health Care and Welfare, Health Economics, Clinical Care based on Theory of Community Medicine
- III Certification and Renewal of Medical Specialists 1. Certification of Medical Specialists
- ② Certify the content of Specialists Training
    - iv. Record on Completion of Educational Training  
Mandatory course on Medical Safety (Patient's Safety and Security)