

A system to support children with severe cerebral palsy and their families as well as aim to improve the quality of obstetric care



The Japan Obstetric Compensation System for Cerebral Palsy

- Looking back over 10 years after System was launched -



公益財団法人 日本医療機能評価機構
Japan Council for Quality Health Care

Overview of System

Background and Objectives of the System

The Japan Obstetric Compensation System for Cerebral Palsy (referred to as “this System”, hereafter) was launched in 2009 for the following objectives, as part of building the environment in which obstetric care can be smoothly delivered and also as a Japan's first no-fault compensation system in the medical field with the background to improve the shortage of obstetricians and ensure the obstetric care provision system.

- Objective 1** Quickly compensating for the economic burden on the families and children with severe cerebral palsy developed related with delivery.
- Objective 2** Analyzing the cause of cerebral palsy and providing information that will help prevent the recurrence of similar cases
- Objective 3** Prevention and early settlement of conflicts and improvement of quality in obstetric care

Overview of This System

As the sole operating organization of this System, the Japan Council for Quality Health Care (referred to as “JQ”, hereafter) performs operations such as encouragement for childbirth facilities to participate in this System, collection of insurance premiums, approval of eligible cases for compensation, long-term payment for compensation (insurance claim procedure), cause analysis and recurrence prevention, and others.

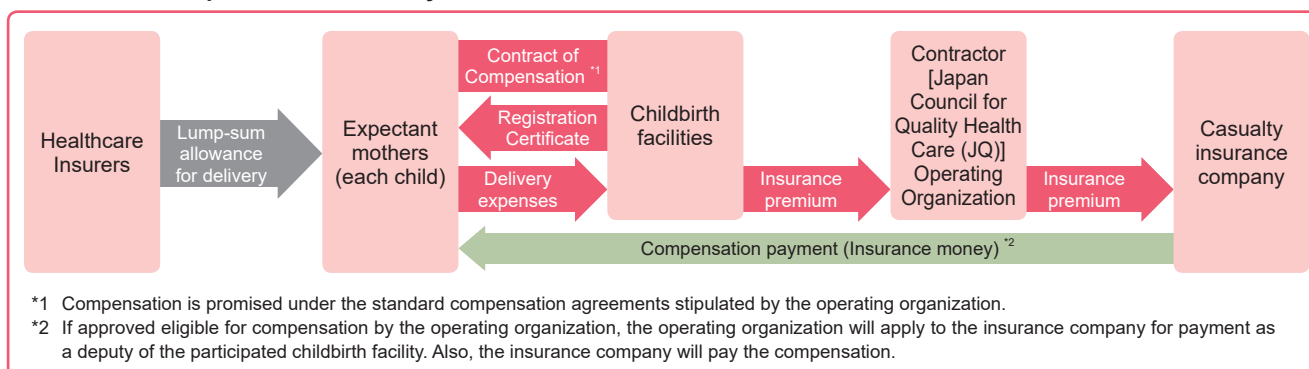
• Compensation

The childbirth facilities participating in this System make a contract with expectant mothers under their control for all eligible cases to be compensated. The childbirth facilities participate in casualty insurance under which the operating organization is the contractor and pay the insurance premiums accordingly.

If a delivery is approved to be eligible for compensation by the operating organization, insurance money will be paid to the expectant mother (child) as compensation payment from the insurance company.

Insurance premiums for compensation of this System are paid by healthcare insurers through childbirth facilities, but for deliveries (limited to deliveries after the 22nd weeks) in participated childbirth facilities, an amount corresponding to the insurance premiums is added to the insurer's lump-sum payment for delivery and nursing, and this total amount (approximately 420,000 yen) is paid to the childbirth facilities as part of the delivery cost. So, practically, there is no burden on the childbirth facilities.

Structure of Compensation in This System



Eligibility for compensation is judged according to the eligibility standard by the JQ as the operating organization. Specifically, it is judged by the “Review Committee” consisting of pediatricians, rehabilitation doctors, obstetricians and academic experts. Based on the judgment, the JQ approves the eligibility for compensation.

If judged as eligible, a total amount of 30 million yen is paid for compensation. Of that amount, a lump-sum payment of 6 million yen is paid for preparation for nursing care and another total compensation amount of 24 million yen (installment compensation payment) is paid every year as nursing care expenses (annual amount of 1.2 million, 20 times).

To provide the foundation expenses for nursing care

Lump-sum payment for preparation:

6 million yen

+

To provide nursing care expenses

Installment compensation payment:

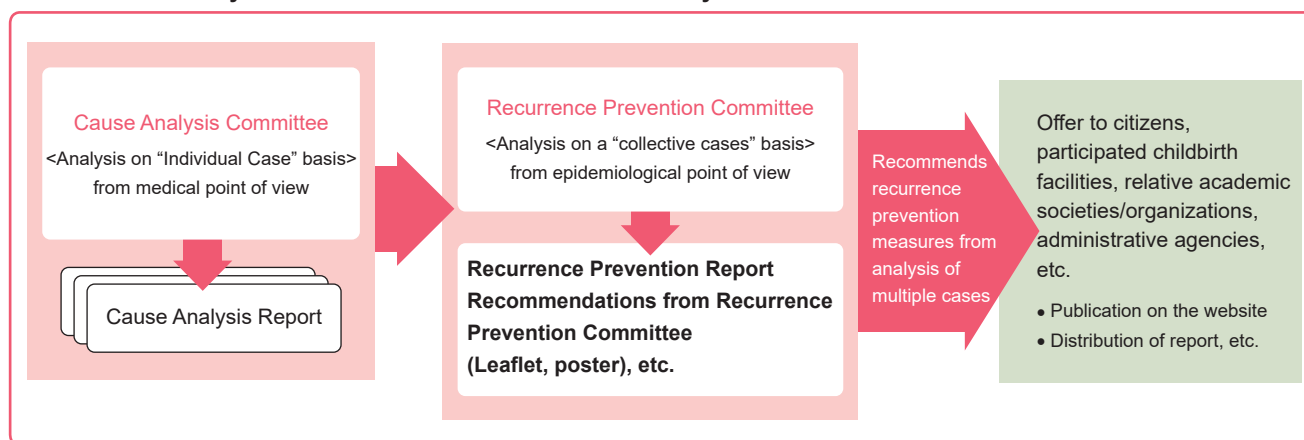
Total **24 million yen**
(1.2 million yen, 20 time-installments in a year)

• Cause Analysis and Recurrence Prevention

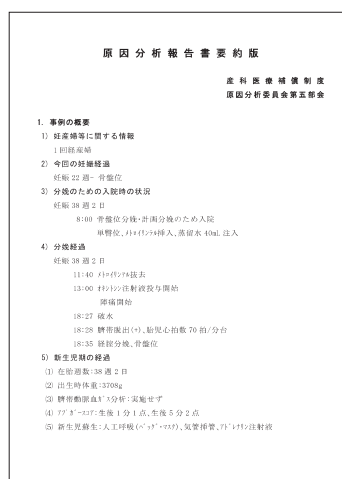
For all the cases approved to be eligible for compensation, the operating organization analyzes the cause from medical point of view based on the information described in the medical records and other documents submitted from the childbirth facilities and information from parents. Specifically, the “Cause Analysis Committee/Cause Analysis Committee Sub-committee” composed of obstetricians, pediatricians, midwives, lawyers, experts, etc., analyzes the cause, prepares a Cause Analysis Report for each case, and deliver it to the relevant childbirth facility and the child and his/her parents.

Also, the JQ systematically organizes and accumulates individual case information, and the “Recurrence Prevention Committee” compiles the recurrence prevention measures and other information found from multiple cases in the “Recurrence Prevention Report”. By providing these information to citizens, childbirth facilities, relative academic societies/organizations, administrative agencies, etc., the JQ is trying to prevent recurrence of similar cases and improve the quality of obstetric care.

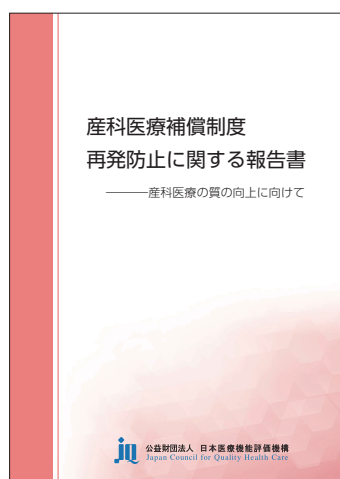
Flow of Cause Analysis and Recurrence Prevention in This System



Cause Analysis Report



Recurrence Prevention Report



Recommendations from Recurrence Prevention Committee (Leaflet)



Operation Records of The Japan Obstetric Compensation System for Cerebral Palsy

1. Number of participated childbirth facilities

(As at the end of June 2018)

Number of childbirth facilities	Number of participated childbirth facilities	Participation (%)
3,239	3,236	99.9%

Number of childbirth facilities is counted by cooperation of the Japan Association of Obstetricians and Gynecologists and the Japanese Midwives Association.

2. Review

(As at the end of June 2018)

Birth year	Number of cases processed	Eligible ^{*1}	Not Eligible		Cases in process	Application deadline
			Not Eligible	Reapplication possible ^{*2}		
2009 ^{*3}	561	419	142	0	0	Application acceptance ended.
2010 ^{*3}	523	382	141	0	0	ditto
2011 ^{*3}	502	355	147	0	0	ditto
2012 ^{*3}	516	361	155	0	0	ditto
2013	410	308	94	7	1	Until 5-years-old birthday in 2018
2014	311	233	59	15	4	Until 5-years-old birthday in 2019
2015	246	211	15	18	2	Until 5-years-old birthday in 2020
2016	130	120	7	3	0	Until 5-years-old birthday in 2021
2017	15	15	0	0	0	Until 5-years-old birthday in 2022
Total	3,214	2,404	760	43	7	-

*1 "Eligible" includes the cases that become eligible after reapplication and the cases approved eligible by the Opposition Review Committee.

*2 "Not Eligible (Reapplication possible)" is for the cases that are "Not Eligible" at the time of review for compensation but should be reviewed again when reapplication is submitted with specified requirements met in the future.

*3 For the children born in the years from 2009 to 2012, the review results were confirmed.

3. Cause Analysis

At launch of this System, the Cause Analysis Committee started with 6 sub-committees, reviewing one case for each per month. After that, along with an increase in the number of preparation, the Committee now has grown to a system to review 6 cases per month in 7 sub-committees and prepare Cause Analysis Reports on 500 cases a year. By June 2018, a total of 1,962 Cause Analysis Reports were sent to children, their parents and childbirth facilities. In order to ensure the transparency of the System as well as prevent the recurrence of similar cases and improve the quality of obstetric care, the "summary version" of the Cause Analysis Reports have been posted on the website of this System after obtaining the consents of the childbirth facilities and parents of the children and also the "full-text version (masking version)" has been published through specified procedures for research purposes.

4. Recurrence Prevention

By the end of March 2018, a total of eight times, the "Recurrence Prevention Reports" have been published and sent to the affiliated childbirth facilities, relevant academic societies/organizations, administrative agencies, etc., as well as posted on the website of this System.

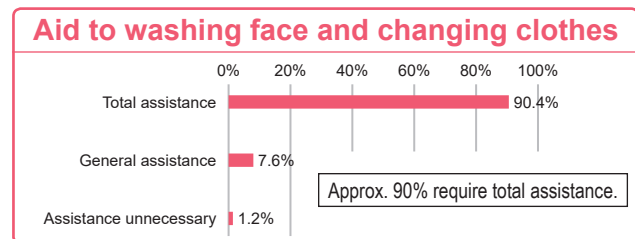
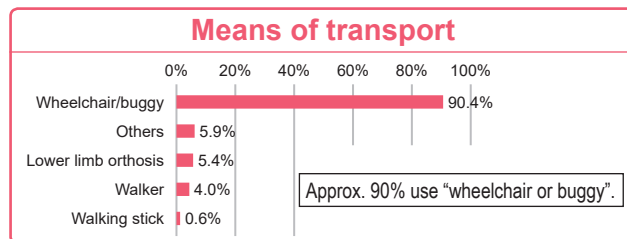
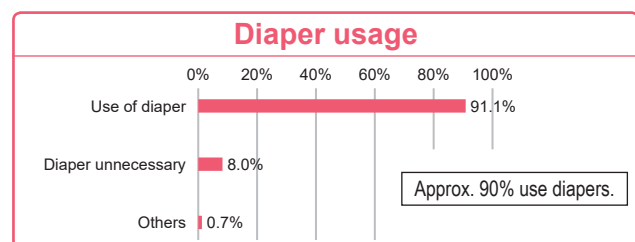
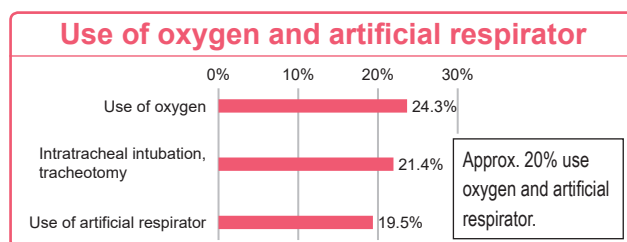
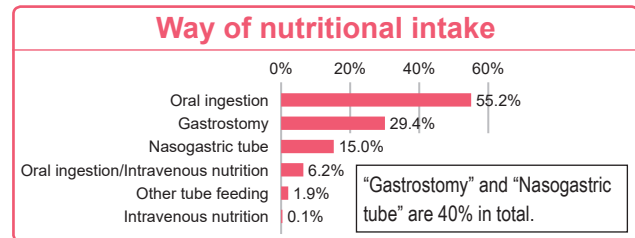
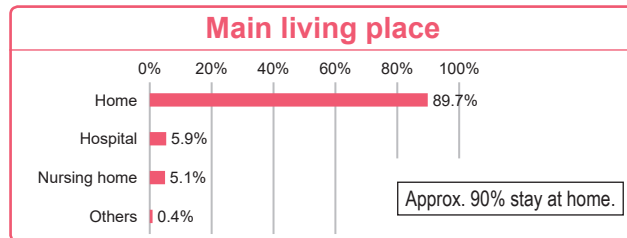
In addition, the JQ has provided tools to prevent recurrence, such as leaflets and posters on "Premature separation of normally implanted placenta" and "Early skin-to-skin contact for mothers and newborn infants".

What We Have Found during 10 Years Since Launch in January 2009

◆ What we have found in review and compensation

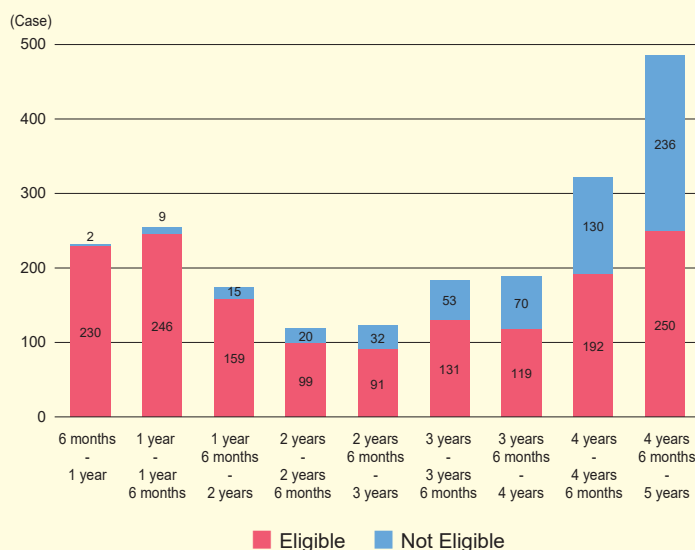
Situation of nursing care for children with cerebral palsy who were eligible for compensation

The JQ summarized and published as follows about the children with cerebral palsy who were approved eligible for compensation in February 2017.



- This data is a summary of the items listed in the medical certificates attached to the compensation installment applications of 1,282 cases, whose diagnosis date is in the period from January 2016 to December 2016, submitted by the end of December 2016.
- When there are answers in two or more options, the percentage may not be 100% because each item has to be calculated.
- If there is no answer, it is included in 1,282 target cases, but it is not included in the number of each item.

Number of compensation applications by age of child after delivery



- The number of compensation applications has two peaks. One is "1 year to 1 year 6 months" and the other is "4 years and elder" after delivery.
- A high proportion of eligible children is observed in the former group, while a low proportion of eligibility is seen in the latter group.

- For compensation application, a medical certificate (special medical certificate for compensation application) has to be submitted.
- This data was calculated for the children who were born from 2009 to 2012 out of the cases for which compensation applications was submitted.
- The period for compensation application is from the 1st birthday to the 5th birthday of a child. However, if medical condition is extremely serious and diagnosis is possible, compensation application can be submitted from 6 months after birth.

◆ What we have found through Cause Analysis

Cause Analysis Report

In this System, JQ performs Cause Analysis for all the cases approved as “Eligible” for compensation and prepare “Cause Analysis Reports”.

What is Cause Analysis Report?

The Cause Analysis Report is a report in which Cause Analysis is done by the “Cause Analysis Committee/ Cause Analysis Sub-committee” composed of obstetricians, midwives, pediatricians (including neonatologists), lawyers, experts, etc. from a medical viewpoint based on the medical record, maternity record, clinical examination data, and information on medical treatment system, etc. submitted from the relevant childbirth facility, information from parents, and so on.

The prepared Cause Analysis Reports are delivered to children, their parents and childbirth facilities.

Major contents of the report

- Outline of the case
Describes the information on pregnancy, delivery, course of neonatal period, etc.
- Cause of cerebral palsy
Lists up everything at the present time as the causes of cerebral palsy onset.
- Medical evaluation on clinical course
Medically evaluates pregnancy, delivery management, and medical treatment.
- Items to consider for improving obstetric care in the future
Recommends possible measures to prevent the onset of cerebral palsy to childbirth facilities, relative academic societies/organizations, administrative agencies, etc.

In order to ensure the transparency of the System as well as prevent the recurrence of similar cases and improve the quality of obstetric care, the “summary version” (not involving information such that individuals and childbirth facilities can be identified) of the Cause Analysis Reports have been posted on the website of this System after obtaining the consents of the childbirth facilities and parents of the children and also the “full-text version (masking version)” (masking (blackening) the information such that individuals and childbirth facilities can be identified) has been published through specified procedures for research purposes.

Possible causes of cerebral palsy

In the 8th Recurrence Prevention Report published in March 2018, 968 cases (60.3%) out of 1,606 analyzed cases have stated pathological conditions as the main cause of the onset of cerebral palsy.

Out of these cases, 773 cases (48.1%) noted a single pathological condition, and 195 cases (12.1%) noted multiple pathological conditions.

On the other hand, no cause was identified in 638 cases (39.7%). In these cases, even experts were unable to identify the cause.

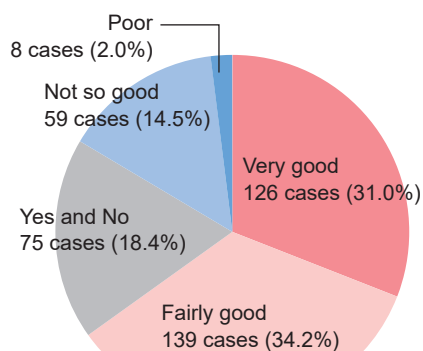
Pathological condition	Number of cases	%
Pathological conditions are noted as the major causes of the onset of cerebral palsy.	968	60.3
Single pathological condition is noted.	773	48.1
Separation of placenta or bleeding from placenta	272	16.9
Umbilical factors	214	13.3
Infection	57	3.5
Uterine rupture	34	2.1
Fetomaternal transfusion syndrome	31	1.9
Others	165	10.3
Two or more pathological conditions are noted.	195	12.1
Main cause is not clear or hard to identify	638	39.7
Total	1,606	100.0

Evaluation of Cause Analysis Report from parents/childbirth facilities

The JQ conducted questionnaires on “Evaluation of Cause Analysis Report” for the parents and childbirth facilities to whom or to which Cause Analysis Reports were delivered four times by 2017. The results of each questionnaire were as follows.

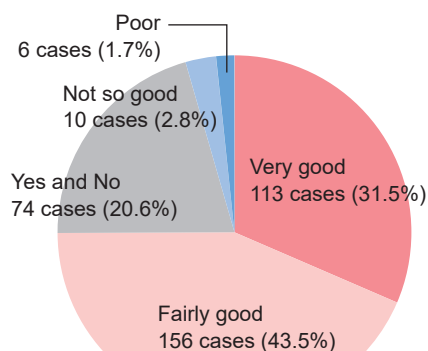
The best reason for having answered “Very good” or “Fairly good” was “Analysis was done by a third party” for both the parents and childbirth facilities.

[Evaluation from Parents]



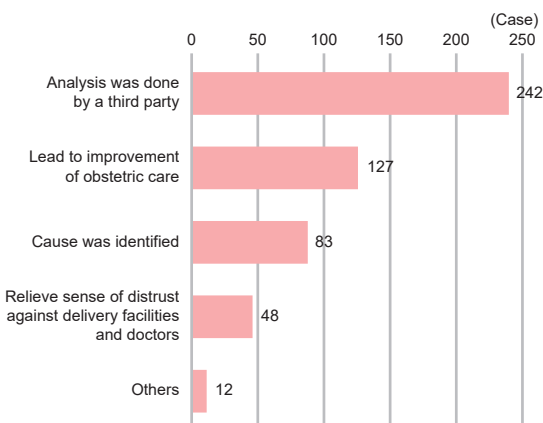
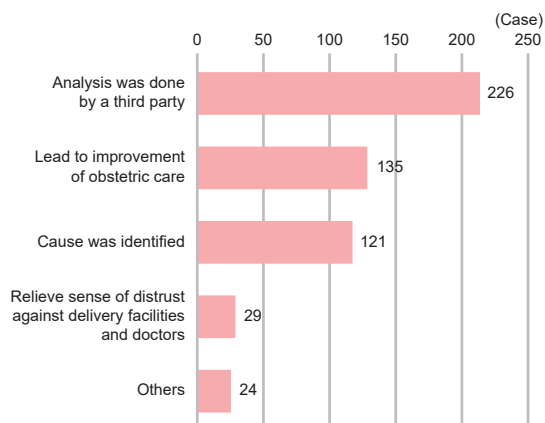
Number of responses: 407

[Evaluation from Childbirth facilities]

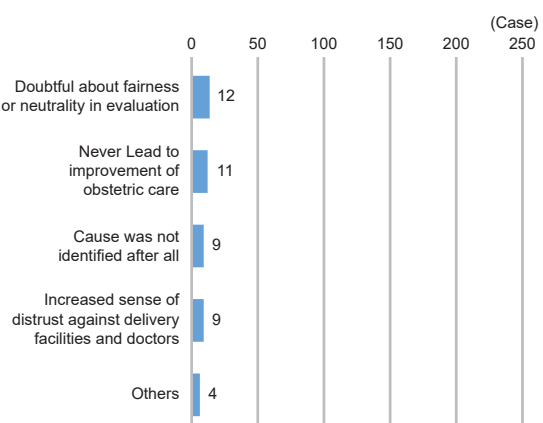
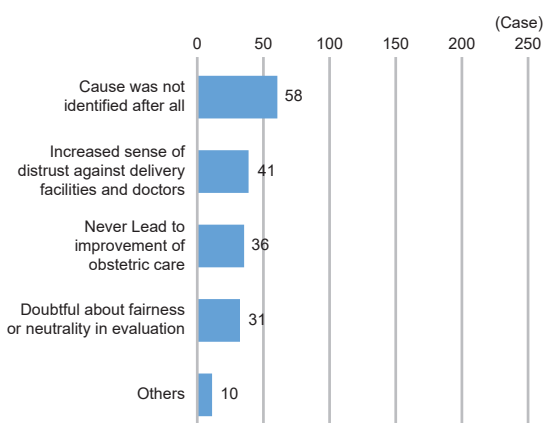


Number of responses: 359

**Reasons for
“Very good” and “Fairly good”**



**Reasons for
“Not so good” and “Poor”**



This data is a summary of the responded cases out of 659 cases for which the Cause Analysis Report was delivered by May 2015. (With duplicate answers)

◆ Provision of Recurrence Prevention Information

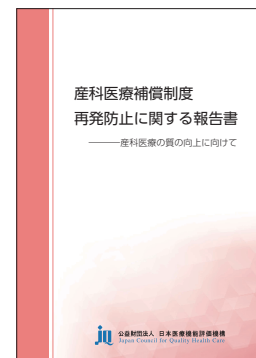
Recurrence Prevention Report

The JQ systematically organizes and accumulates individual case information, and the “Recurrence Prevention Committee” compiles and publishes the recurrence prevention measures and other information found from multiple cases in the “Recurrence Prevention Report”.

The main themes discussed up to March 2018 on causes of cerebral palsy and its background factors are as follows.

(As at the end of March 2018)

Main theme	Report involving main theme on left
Monitoring fetal heart rate during delivery	1st report, 3rd report
Reading of cardiotocogram (CTG)	8th report
Umbilical cord prolapse	1st report, 3rd report
Premature separation of normally implanted placenta	3rd report, 6th report
Health guidance for premature separation of normally implanted placenta	2nd report
Uterine contraction drug	1st report, 3rd report
Neonatal resuscitation	1st report, 3rd report, 5th report
Record of medical records, etc.	2nd report



Recurrence Prevention Report

Monitoring/reading cardiotocogram (CTG)

In the current obstetric care, monitoring fetal heart rate is one of the useful methods to infer the conditions of the fetus. For this reason, it is said that reading of cardiotocogram (CTG) is important for grasping the conditions of the fetus in the course of delivery.

In order to correctly evaluate the conditions of the fetus in the course of pregnancy/delivery and lead to subsequent responses, this System has analyzed monitoring/reading of the cardiotocogram (CTG) over three times in the past.

Proficiency is necessary to accurately read the cardiotocogram (CTG) since it shows various waveforms depending on the situation during delivery. So, the JQ makes recommendations and prepares teaching materials for obstetric medical personnel based on the actual cardiotocograms (CTG) of the children with cerebral palsy who were approved eligible for compensation.

Recommendations to obstetric medical personnel (partially excerpted.)

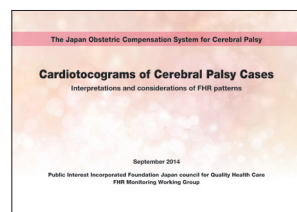
- Participate in-hospital study sessions in each facility and out-of-hospital workshops so as to enhance the ability to read cardiotocograms (CTG).
- Understand the physiological meaning of the emergence of the waveform pattern of the fetal heart rate and master the skills to infer the fetal conditions from the cardiotocogram (CTG).
- Evaluate the cardiotocogram (CTG) according to the “Guideline for Gynecological Practice” and note the findings from reading in the medical record regardless of whether the evaluation results are normal or abnormal.

Preparation of teaching materials for obstetric medical personnel

Based on the specific cardiotocograms (CTG) of the children with cerebral palsy, points for reading are explained concretely.

Japanese version: Published in January 2014.

English version: Published in September 2014.

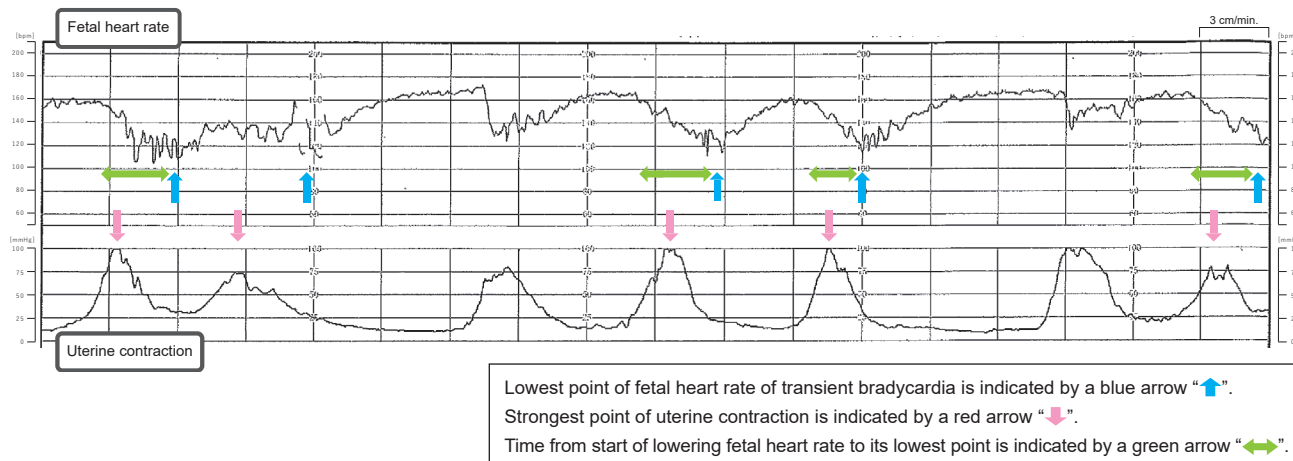


Cardiotocogram (CTG) in cerebral palsy cases

In the “8th Recurrence Prevention Report”, the JQ has made recommendations to the obstetric medical personnel so that he/she can properly judge as to the reading of the cardiotocogram (CTG) in the course of delivery.

Differentiation between late transient bradycardia and variable transient bradycardia

Differentiation between late transient bradycardia and variable transient bradycardia.



• Comments from Recurrence Prevention Committee

- The fetal heart rate has slowly decreased with the contraction of the uterus and gradually recovered, so it can be judged as a late transient bradycardia.
- The lowest points of the fetal heart rate of the transient bradycardia occurred repeatedly behind the strongest points of uterine contraction.
- If it is difficult to visually distinguish whether the decline in the fetal heart rate is rapid or gentle, check whether the time from the start of declining fetal heart rate to the lowest point is less than or more than 30 seconds. It is more than 30 seconds from the start of declining fetal heart rate to the lowest point, which indicates a gentle waveform.

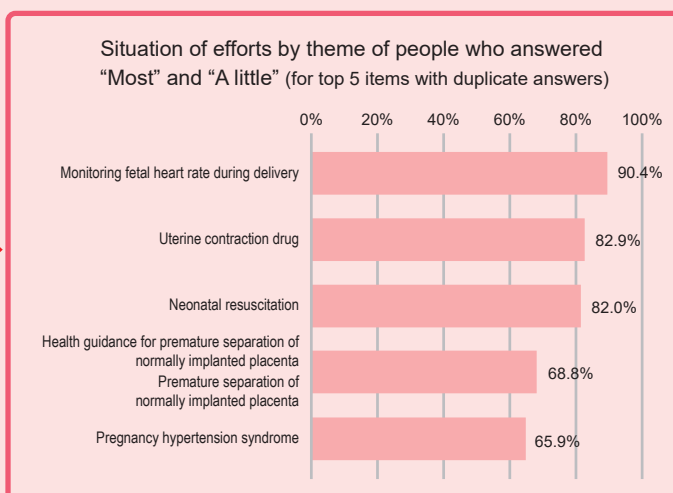
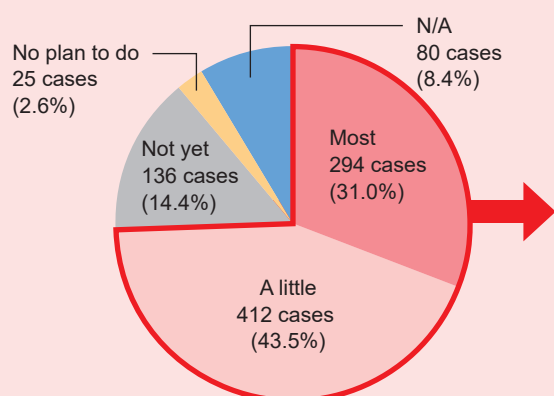
[Reference]

Late transient bradycardia: Observed when the fetal oxygen is deficient.

Variable transient bradycardia: Observed when umbilical cord is pressed.

Efforts to “Recommendations from Recurrence Prevention Committee”

We conducted questionnaires for childbirth facilities twice by 2017 as to utilization of “Recommendations from Recurrence Prevention Committee” in the clinical practices. The results of the questionnaires were as follows. The most utilized recommendation is about “Monitoring fetal heart rate during delivery”.



Transition of Japan Obstetric Compensation System for Cerebral Palsy

	Topics	Efforts to make System known
Up to 2008	<p>Feb. 2007 1st Operating Organization Preparation Committee meeting held.</p> <p>Jan. 2008 "Preparatory Committee Report" summarized.</p> <p>July 2008 1st Operating Committee meeting held. Participation procedure of childbirth facilities started.</p> <p>Oct. 2008 Registration of expectant mother information started.</p>	<p>July 2008 Operation of dedicated call center started.</p>
2009	<p>Jan. The Japan Obstetric Compensation System for Cerebral Palsy launched.</p> <p>Feb. 1st Cause Analysis Committee meeting held.</p> <p>June 1st Review Committee meeting held.</p> <p>July Acceptance of applications for compensation started.</p> <p>Sep. Cause Analysis Report on virtual case created.</p> <p>Nov. 2nd Review Committee meeting held. (Case review started.)</p>	<p>June "Guideline for preparation of medical certificate" (special medical certificate for compensation application) prepared.</p>
2010	<p>Feb. 12th Cause Analysis Committee meeting held (Review of Cause Analysis Report started) and delivery of Cause Analysis Reports started.</p> <p>Mar. Cause Analysis Reports "summary version" published (posted on this System website.)</p> <p>Apr. Disclosure of Cause Analysis Reports "full text version (masking version)" started.</p> <p>July 1st Recurrence Prevention Committee meeting held.</p>	<p>Jan. "Cause Analysis Report Preparation Manual (How to prepare Cause Analysis Report)" prepared.</p> <p>May "Explanation of Cause Analysis" for childbirth facilities prepared.</p> <p>July "Guide to Cause Analysis" for parents of children who were approved eligible for compensation prepared.</p>
2011	<p>Feb. 1st Opposition Review Committee meeting held.</p>	
2012		
2013	<p>Aug. Emergency Countermeasure meeting for promoting compensation application held.</p>	<p>Aug. "Reference cases approved eligible" prepared.</p> <p>Dec. "Reference cases on severity of cerebral palsy" prepared. Special medical certificate for compensation application revised to a checkbox type.</p>
2014	<p>Jan. System revision implemented (how to analyze causes, how to coordinate compensation and damage compensation, efforts toward prevention of conflicts and early resolution, etc.)</p> <p>May 1st Recurrence Prevention Working Group meeting held.</p> <p>Sep. Cases approved eligible for compensation exceeded 1,000 in total.</p>	<p>Sep. "Explanation of criteria for cerebral palsy eligible for compensation" prepared.</p> <p>Nov. "Examples of reference cases on eligibility for compensation" prepared.</p>
2015	<p>Jan. System revision (criteria for cerebral palsy eligible for compensation, insurance premiums, etc.) implemented.</p> <p>Nov. Disclosure of Cause Analysis Report by a new disclosure method based on "Ethical guidelines on medical research targeting people" "full-text version (masking version)" started.</p>	<p>Oct. "The Japan Obstetric Compensation System for Cerebral Palsy News" first-issued.</p> <p>Nov. "Compensation Application Review Guidebook" prepared.</p>
2016	<p>July Total number of delivering Cause Analysis Reports exceeded 1,000 cases.</p> <p>Nov. 100th Review Committee meeting held.</p>	
2017	<p>May Cases eligible for compensation exceeded 2,000 in total.</p>	<p>Jan. "Cause Analysis Report summary version search function" added to this System website.</p>
2018	<p>Jan. 10th anniversary of System launched</p>	

Approach to recurrence prevention

Aug.	"1st Recurrence Prevention Report" first-issued.
May Dec.	"2nd Recurrence Prevention Report" issued. Leaflet on "Premature separation of normally implanted placenta" prepared.
May	"3rd Recurrence Prevention Report" issued.
Jan. Feb.	"Reading and cautions of cardiotocogram (CTG) waveform pattern of cerebral palsy cases" (Japanese version) prepared. Leaflet on "Importance of informed consent when using uterine contraction drug" prepared. Posters on the flow chart of "Use of Metreurynter" and "Implementation of Artificial Rupture" prepared.
Apr. Sep.	"4th Recurrence Prevention Report" issued. "Reading and cautions of cardiotocogram (CTG) waveform pattern of cerebral palsy cases" (English version) prepared.
Mar.	"5th Recurrence Prevention Report" issued and "Recommendations from Recurrence Prevention Committee" prepared.
Jan. Mar. July	"A Paper on Comparative Study between Cases of Cerebral Palsy Approved for Compensation of This System and Perinatal Registration Database of Japan Society of Obstetrics and Gynecology" posted in open access journal "PLOS ONE". "6th Recurrence Prevention Report" issued. Leaflet on "Early skin-to-skin contact for mothers and newborn infants" prepared.
Mar.	"7th Recurrence Prevention Report" issued.
Jan. Mar.	"A paper on Perinatal Factors in Delivery Period of Children with Cerebral Palsy Birthed from Mothers of Pregnancy Hypertensive Syndrome" posted in open access journal "Wiley". "8th Recurrence Prevention Report" issued.

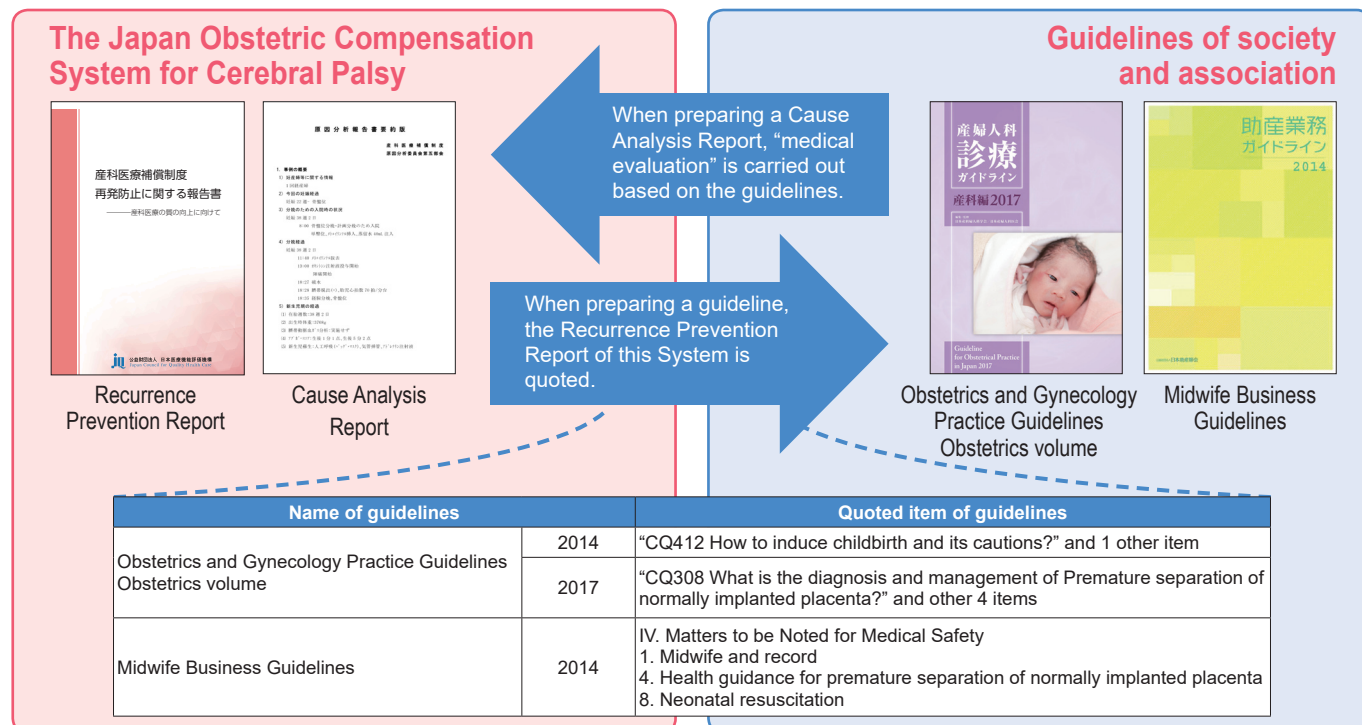
Events around System

Oct. 2004 Apr. 2008	"Midwife Business Guidelines 2004" first-issued. "Obstetrics and Gynecology Practice Guidelines Obstetrics volume 2008" first-issued.
Dec.	"Midwife Business Guidelines 2009" issued.
Mar.	"Obstetrics and Gynecology Practice Guidelines Obstetrics volume 2011" issued.
July	Meaning of this System mentioned in the "Report on verification concerning speedup of trials (Social Factors edition)" issued by the General Secretary of the Supreme Court.
Mar. Apr.	"Midwife Business Guidelines 2014" issued. "Obstetrics and Gynecology Practice Guidelines Obstetrics volume 2014" issued.
July Nov.	A pharmaceutical company announced "Request for proper use of uterine contraction drug", and the Pharmaceuticals and Medical Devices Agency posted this document on its website. In response to the recommendations of "Recurrence Prevention Report", four societies such as Japan Society for Neonatal Health and Development requested release of adrenaline at the concentration recommended by Neonatal Resuscitation Guidelines 2010 (Japanese version).
Jan. July	An article on "Adjustment, etc. of the compensation and damage compensation of the obstetric medical compensation system" posted in the "HANREI TIMES" widely read by legal personnel. In response to the recommendations of "Recurrence Prevention Report", Japan Society of Perinatal and Neonatal Medicine launched "Working Group to Consider 'Points to remember to improve rooming-in safety'".
Apr.	"Obstetrics and Gynecology Practice Guidelines Obstetrics volume 2017" issued.

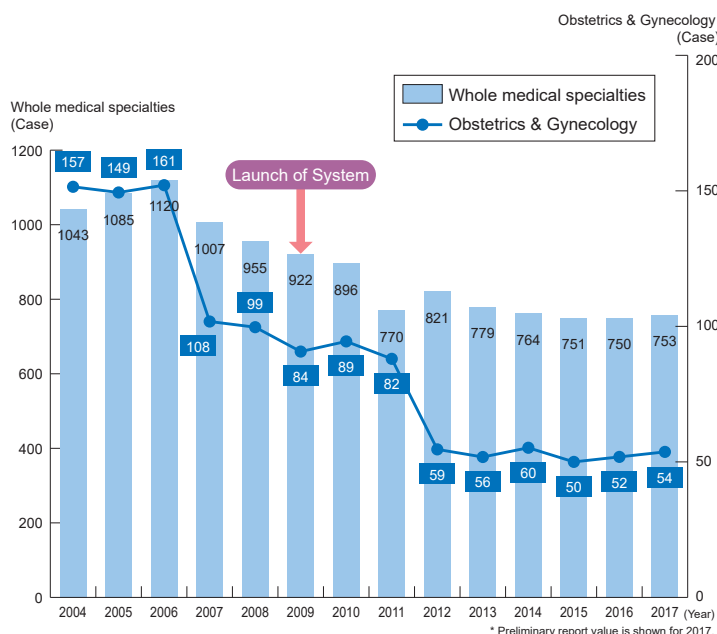
The Japan Obstetric Compensation System for Cerebral Palsy and Its Guidelines

Use of “Recurrence Prevention Report” in Guidelines

In the “Obstetrics and Gynecology Guidelines Obstetrics volume” prepared by Japan Society of Obstetrics and Gynecology and the Japan Association of Obstetricians and Gynecologists and “Midwife Business Guidelines” prepared by the Japanese Midwives Association, the “Recurrence Prevention Report” of this System used as a cited reference.



Trends in lawsuit cases in obstetrics and gynecology



Quoted from “Number of medical lawsuit cases in each medical department” of the Supreme Court Medical Affairs Litigation Committee.

- The Japan Obstetric Compensation System for Cerebral Palsy, although the target is limited to obstetrics, has an important significance in the points that a mechanism was launched in which a public third party organization analyzes the cause of an accident and that a no-fault compensation system was introduced from the viewpoint of socially burdening this risk on the premise that risks are involved in medical treatment (especially obstetric medical treatment). So, it is also noticed that no-fault compensation system may develop to fields other than obstetrics.
- The Japan Obstetric Compensation System for Cerebral Palsy has dealt with a considerable number of cases after its enforcement, and it is thought that a certain influence is also given to the number of the medical-related lawsuit cases.

Excerpt from “Report on verification concerning speedup of trials (Social Factors edition) in July, 2013” issued by the General Secretary of the Supreme Court.

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- Global Patient Safety John H. Tingle, Clayton Ó Néill, Morgan Shimwell. 2019 – Routledge Chapter 17: The Japanese Obstetric Compensation System for Cerebral Palsy – A Case Study of a No-Fault Compensation System