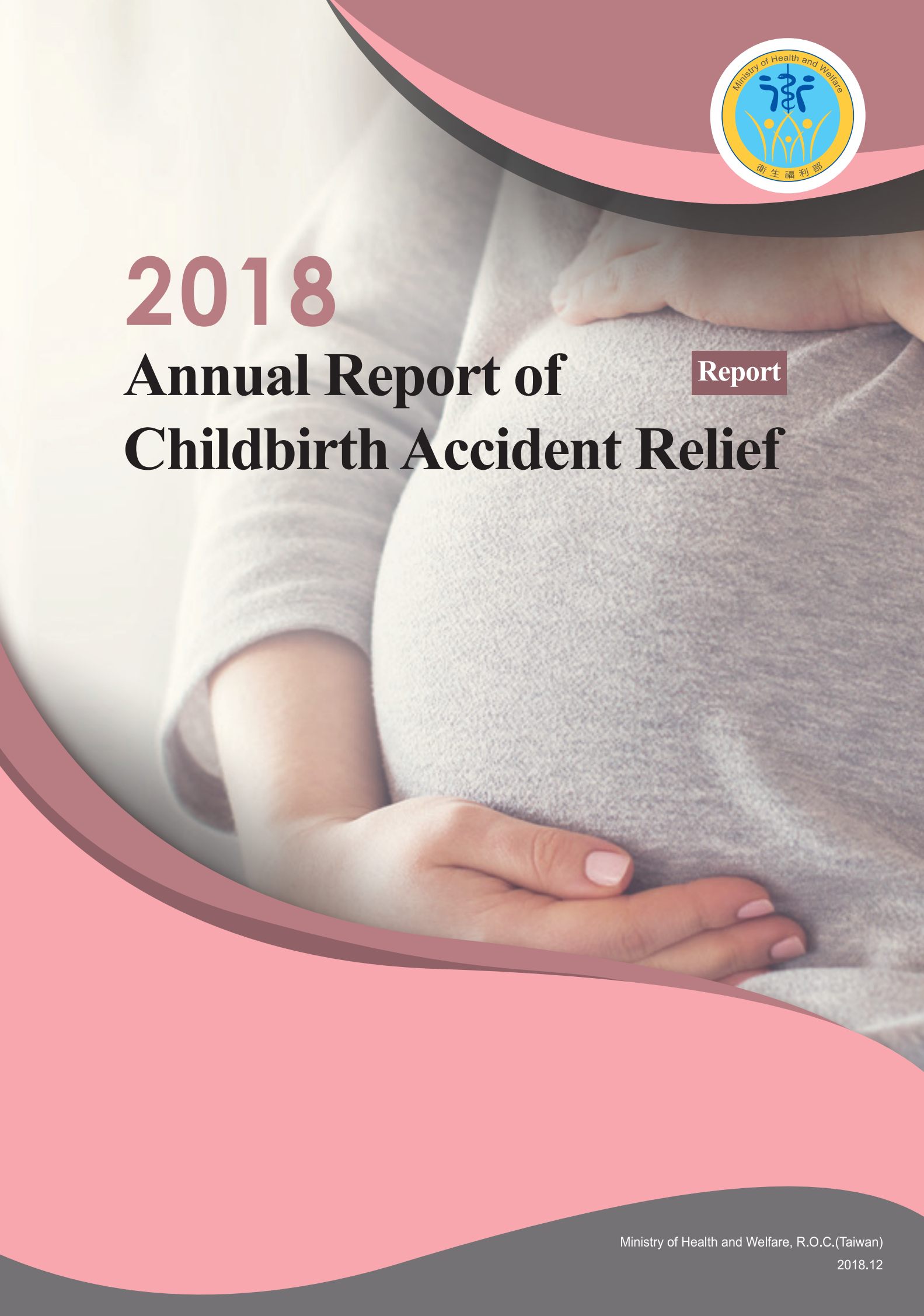


2018 Annual Report of Childbirth Accident Relief

Report

Ministry of Health and Welfare, R.O.C.(Taiwan)
2018.12

2018

Annual Report of Childbirth Accident Relief

Minister's Preface

In order to alleviate the ever increasing childbirth accident disputes, allow our people to receive adequate protection when exposed to medical risks, and meanwhile protect doctors' and patients' rights, the Ministry of Health and Welfare proposed the Birth-Related Dispute Incident Pilot Plan to the Executive Yuan in 2011. The plan encourages health care institutions, including hospitals and obstetrics and gynecology clinics, to engage in proactive communication and outreach with patients and their families in the event of a childbirth accident. For cases of death or moderate to severe disability caused by childbirth, the government will provide up to NTD 2 million in relief fund. Although there were howls of incredulity during implementation of the plan in 2012, after active communications and promotions, the medical disputes and litigations in obstetrics and gynecology had drastically reduced by 70%. Moreover, over 95% of the participating institutions had recognized the benefits of the plan in improving the obstetrics and gynecology practice settings. Therefore, with the supports and efforts of all the relevant parties, the Childbirth Accident Emergency Relief Act was deliberated and passed by the Legislative Yuan. The Act was promulgated by the President on December 30, 2015 and was taken into effect on June 30, 2016. The legislation of the national childbirth accident relief system helps improve doctor-patient relationship and thereby reduce childbirth complications for women, reaching another milestone in the development of the childbirth accident relief system.

I am proud to say that this Childbirth Accident Emergency Relief Act is the world's first Act that pertains to the handling of childbirth accidents. The intentions for its legislation is not only to encourage proactive and proper handling of childbirth accidents by medical care institutions so as to improve doctor-patient relationship and prevent unnecessary medical disputes or litigations, but to establish a complete reporting and debugging mechanism to reduce childbirth complications, improve medical practice environments, as well as improve patient safety and quality of health care.

Over the one-and-a-half-year period after the implementation of the Act in 2017, a total of 286 applications were accepted, and 98% of the applications received the relief fund. Applicant satisfaction surveys also indicated that both medical care institutions and the general public have a satisfaction rate of over 90% regarding this relief system and its application procedure. Therefore, I would like to take this opportunity to express my utmost respect and gratitude to the experts, officials, and individuals for their long-term dedication and promotion that made this remarkable system possible. Moreover, I would like to thank all the entrusted and co-organizing agencies for their efforts. Let us continue working on this path and create a reliable and harmonious health care environment for our people with the safest and highest quality childbirth services.

Shih-Chung Chen

Shih-Chung Chen
Minister of Health and Welfare

Abstract

In order to improve maternal and reproductive health, reduce childbirth complications, and overcome the challenges of improving obstetrics and gynecology practice settings and talent acquisition, the Ministry of Health and Welfare (hereinafter referred to as the Ministry), in cooperation with civil society organizations such as the Taiwan Association of Obstetrics and Gynecology and the Taiwan Women's Link, implemented the Birth-Related Dispute Incident Pilot Plan (hereinafter referred to as the pilot plan) in 2012. As the pilot plan proved to be effective in reducing childbirth-related medical disputes as well as raising the recruitment rate of obstetricians and gynecologists, the Legislative Yuan deliberated and passed the Childbirth Accident Emergency Relief Act in December 2015, and the Act took into effect on June 30, 2016.

According to Article 23 of the Childbirth Accident Emergency Relief Act, "the competent authority shall perform statistical analyses and publish the results annually for the childbirth accident relief cases processed". From June 30, 2016 through December 31, 2017, the Ministry received a total of 286 childbirth accident relief applications, of which 22 for maternal mortality and 69 for major maternal injuries (including 4 for disabilities and 65 for hysterectomy); 126 for fetal mortality, 67 for neonatal mortality and 2 for major neonatal injuries. A total of 282 (98.6%) applications were approved, and a total of NTD 130.8 million relief fund was provided.

This report is the first statistical report for childbirth accident relief. Apart from the statistical analyses of types of cases, regional distribution and levels of medical care institution, the report includes statistical analyses of age of mothers at childbirth, gestational age, birth order, and possible causes of childbirth accidents for these applications after the implementation of the Childbirth Accident Emergency Relief Act, as well as the 494 applications of the pilot plan (childbirth accidents happened from Jan 1, 2012 through June 29, 2016) received before June 29, 2018 so as to get the whole picture of childbirth accidents in Taiwan in recent years. However, since the implementation and relief conditions were different between the pilot plan and the Act, and the duration of the two and the number of cases were also limited, it was difficult to evaluate the long-term trends against the international experiences. Still, through the promotion of the relief system and the collection and analysis of the data, we are able to continuously improve the environment of maternal care and thereby improve the maternal and reproductive health in Taiwan.

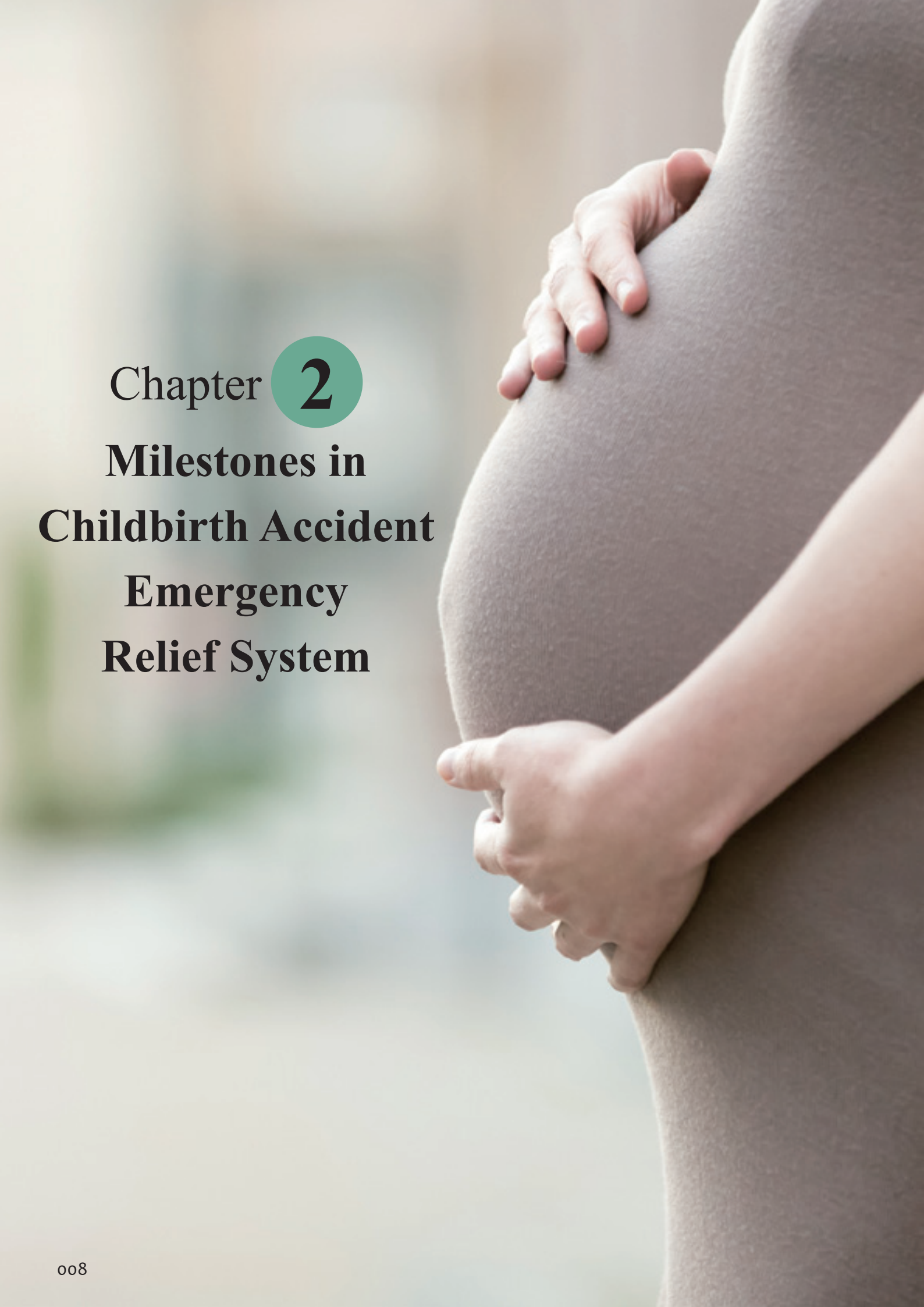
Contents

Chapter 1
Foreword

Medical disputes have long been one of the most critical issues concerned by the general public. Not only does it cause the deterioration of doctor-patient relationship, but it also leads to problems such as defensive medical practice and medical staff shortage in acute and critical care settings. The 1994 MacKay Memorial Hospital shoulder dystocia incidence resulted in a vigorous debate between medical and legal professions over whether liability without fault applies to medical disputes. In order to settle the dispute and clarify the responsibilities, the competent health authority (the then Department of Health) amended Article 82 of the Medical Care Act in 2004, which stipulates that "[t]hose conducting medical practices shall exercise due care in carrying out a medical procedure. Medical care institutions and their medical personnel shall be liable for compensation only for such harm that causes to patients, whether deliberately or negligently". However, any adverse outcomes from medical procedures is in nature different to other accidental injuries. Medical behaviors, which aim to resolve the harm to life or the body of the patient, possess a certain level of necessity and compulsion as well as invasiveness and uncertainty, and therefore are often difficult to determine the causal relationship between the adverse outcomes and the medical behaviors, as well as to define between deliberate and negligent liabilities. According to the medical dispute cases, which were entrusted by prosecutorial or judicial inquiries, analyzed by the Ministry's Committee of Medical Care Dispute Assessment, less than 20 percent of the assessment results were confirmed negligence or possible negligence. However, as the litigation between patients and doctors usually span many years and at times derive irrational conflicts that worsen the doctor-patient relationship, it results in uncountable cost to the overall society. In light of this, it is imperative that we establish a medical dispute resolution model different to the traditional litigation procedure, which on the one hand, compensates for the adverse outcomes experienced by patients, and on the other, upholds the principles of mutual aid and social justice, allowing robust development of a comprehensive health care system that leads to a win-win path for a harmonious doctor-patient relationship.

In view of other developed countries, some countries resolve doctor-patient disputes and litigation through the promotion of a medical relief system, such as the no-fault compensation system of Sweden, the Japan Obstetric Compensation System for Cerebral Palsy, and the Virginia Birth-Related Neurological Injury Compensation Program of the United States. However, since the socio-cultural background and litigation systems vary greatly between countries, whether Taiwan can use these examples and create a medical compensation and relief system that is suitable for Taiwan have become an important issue. Therefore, the Department of Health (now the Ministry of Health and Welfare) started to deliberate and address this issue in 2000 through the implementation of the childbirth accident relief system to resolve the gradually intensifying doctor-patient relationship, and based on that foundation, to promote such a system to other medical divisions and fields. In 2011, the Ministry, through joint efforts with the Taiwan Association of Obstetrics and Gynecology, proposed the Birth-Related Dispute Incident Pilot Plan to the Executive Yuan, which was later implemented on October 1, 2012. As the pilot plan proved to be effective in reducing up to 70% of childbirth-related medical litigations, and at the same time contributing to the recruitment of obstetricians and gynecologists, under the supports of majority of the legislators and medical professions, the Legislative Yuan passed the Childbirth Accident Emergency Relief Act on December 11, 2015, which was taken into effect on June 30, 2016. It is the first legal reference for medical accident relief system in Taiwan and also the first legislation for childbirth accident relief in Asia.

The Childbirth Accident Emergency Relief Act is a medical relief mechanism established by the government to reduce childbirth complications of women, which clearly stipulates the protection of women, fetuses and newborns during labor and delivery process to receive just-in-time relief in case of unforeseen accidents, including the inability to reach the hospital for childbirth. Through outreach, reporting and other related measures, the Act promotes a harmonious relationship between pregnant women and medical personnel, reducing medical disputes and litigations and improving health and safety protection of women at childbirth.



Chapter 2

Milestones in Childbirth Accident Emergency Relief System

Time	Milestones
May 28, 2004	Chairwoman Sue-ying Huang of the Taiwan Women's Link proposed the concept of childbirth relief fund to the Taiwan Association of Obstetrics and Gynecology and recommended to establish a national fund to reduce women's risk at childbirth. In the 7th Meeting of Action for Women's Health, Chairwoman Sue-ying Huang also declared the actions to "creating an environment for friendly delivery" and advocated the establishment of a childbirth relief fund for the protection of women.
2006	Minister Sheng-mou Hou of the Department of Health (now the Ministry of Health and Welfare) expressed his support of the no-fault compensation plan for division of obstetrics, which was proposed at the Meeting of Action for Women's Health, and at the same time considered expanding such a compensation plan for divisions such as anesthesia and cardiovascular surgery.
April–June 2009	The Department of Health planned the no-fault compensation system to provide compensation or relief to major injuries or deaths during medical procedures (e.g. childbirth, surgery and anesthesia). Through expert meetings and deliberation by all levels of competent health authorities, and representatives from the fields of medicine and academia, the draft of Medical Injury Relief Act was completed that included 7 chapters and 34 articles.
2010	The Department of Health and the Taiwan Association of Obstetrics and Gynecology jointly planned to promote childbirth accident relief pilot plan.
May 2011	The Office of Legislator Sue-ying Huang proposed the draft of Childbirth Relief Act.
July 4, 2011	The Department of Health drafted the Birth-Related Dispute Incident Pilot Plan and convened for deliberation.
September 15, 2011	Aligned with the Birth-Related Dispute Incident Pilot Plan, the Department of Health proposed the Quality Improvement Plan of Obstetrics and Gynecology Clinics.

2012	Legislator Yi-chen Wu proposed the draft of Childbirth Relief Act.
July 2012	President James Ching-hung Hsieh of the Taiwan Association of Obstetrics and Gynecology, Director Chung-liang Shih of the Department of Medical Affairs, and Chief Prosecutor Chao-ming Chu of the Ministry of Justice visited Deputy Justice Minister Ming-tang Chen and Minister without Portfolio Ying-shay Luo in succession to solicit support for the Birth-Related Dispute Incident Pilot Plan.
July 5, 2012	The Executive Yuan approved the Birth-Related Dispute Incident Pilot Plan for a period of two years, targeting hospitals, clinics and midwifery clinics with licensed obstetrics and gynecology department.
August 28, 2012	The Department of Health established the Committee of Childbirth Accident Relief Assessment and convened its first meeting to establish a common review procedure.
October 1, 2012	The Birth-Related Dispute Incident Pilot Plan was open for applications, and applicant eligibility can be backtracked to the childbirth accidents dating from January 1, 2012.
September 20, 2014	Announced the extension of the Birth-Related Dispute Incident Pilot Plan for two more years and extended the scope to include surgical and anesthesia accidents.
2014-2015	The Taiwan Women's Link and the Taiwan Association of Obstetrics and Gynecology jointly lobbied with Legislator Shu-fen Lin, Legislator Chiu-chin Tien, Legislator Chao-shun Huang, and Legislator Ching-chuan Su, and proposed the draft of Childbirth Accident Emergency Relief Act.
November 18, 2015	Convener Yu-hsin Yang of the Social Welfare and Environmental Hygiene Committee of the Legislative Yuan arranged the review and approved the Childbirth Accident Emergency Relief Act.
December 11, 2015	The Legislative Yuan passed the Childbirth Accident Emergency Relief Act.
December 30, 2015	The President promulgated the passing of Childbirth Accident Emergency Relief Act.

June 30, 2016

The Childbirth Accident Emergency Relief Act took into effect.

July 13, 2016

The Ministry of Health and Welfare promulgated the Regulations Governing the Childbirth Accident Relief, Regulations Governing the Establishment of the Childbirth Accident Relief Review Committee, and Regulations Governing the Reporting and Inspection of Childbirth Accidents.

August 26, 2016

The subsection for childbirth accident relief officially went live on the website of the Ministry of Health and Welfare.

September 20, 2016

The Committee of Childbirth Accident Relief Assessment convened its first meeting to establish a common review procedure.

September 22, 2016

Secretary General Ming-chao Huang of the Taiwan Association of Obstetrics and Gynecology delivered a speech on "No-fault childbirth accident relief mechanism of Taiwan" at the annual conference of the Korean Society of Obstetrics and Gynecology.

October 2016

The Ministry of Health and Welfare compiled and published the "Childbirth Accident Care Handbook". Meanwhile, the Taiwan Association of Obstetrics and Gynecology also published the "Special Issue of Childbirth Accident Relief".

September 26, 2017

The application form can be filled online at the subsection of Childbirth Accident Relief on the website of the Ministry of Health and Welfare.

November 6-8, 2017

Delegation from the Korea Medical Dispute Mediation and Arbitration Agency visited Taiwan for exchange on Taiwan's childbirth accident relief system and its operation. During the visit, they visited the Ministry of Health and Welfare, Taiwan Association of Obstetrics and Gynecology, the Foundation for Women's Health and Urogynecology of Taiwan, and MacKay Memorial Hospital.

Chapter 3

Birth-Related Incident Relief Pilot Plan and Implementation Results

Section 1 Birth-Related Incident Relief Pilot Plan

In October 2012, the Ministry of Health and Welfare initiated the Birth-Related Dispute Incident Pilot Plan (hereinafter referred to as the pilot plan) to ensure reasonable birth-related risk protection for pregnant women, to effectively resolve disputes arising from childbirth accidents, to avoid tension and confrontation in the doctor-patient relationship, and to improve practice settings for obstetricians and gynecologists. The plan's source of income was derived from the medical development fund, which included all the birth-related risks that pregnant women may face as its scope of relief, and at the same time served as the pioneering plan for the establishment of a medical risk relief system in Taiwan.

I. Plan Goals

i. Protect the rights of doctors and patients, and promote the harmony between doctor-patient relationships

The adverse outcomes of the birth process are in nature different from other general accidental injuries. The process of giving birth possesses a certain level of risk and uncertainty, and the determination of causality of the birth-related incidents has its difficulties. In addition, if disputes of a birth-related incident take place in the form of litigation, both doctor and patient must pay the cost of litigation and considerable amount of time, not to mention the physical and mental suffering during litigation. As a result, both sides would suffer without a doubt. Therefore, if reproductive institution or midwifery institution (hereinafter referred to as the institution), in the cases of disputes caused by birth-related incidents that are reconciled through full communication of both sides, agrees to give patient a monetary compensation or an assistance of care, under the requirements of the pilot plan, the government shall reward the institution for expediting the negotiation with patient or her family member to resolve the dispute, as well as to protect the patient's rights to receiving a reasonable compensation. Ultimately, this plan contributes to protecting the rights of patient and improving the doctor-patient relationship, at the same time reducing litigation and social costs.

ii. Resolve disputes quickly and achieve social justice

The pilot plan sets up a review committee that is responsible for the review of an incentive award case after the institution has reached an agreement with patient or her family member. Furthermore, depending on the nature of the case, the committee is to make a decision on the amount of the award, so as to encourage the institution to handle the adverse medical outcomes of the mother and the baby through quick negotiations. Compared with the litigation procedures in the past, this system is conducive to the timely resolution of disputes and protect the interests of all parties.

iii. Promote patient safety and improve quality of health care services

By the review of childbirth-related medical disputes and guidelines of medical management regulations, we are able to spur re-examination of internal medical quality and safety management systems in the institutions with childbirth accidents to correct the shortcomings in time and prevent the recurrence of adverse incidents. At the same time, through the evaluation of, or visit to the participating institutions as well as the requirement of proactive reporting, the plan could establish a mechanism of supervision that drives continuous improvement by institutions so as to achieve the goals of patient safety and medical quality.

iv. Improve obstetrics and gynecology practice settings, and implementation results of the plan can serve as a reference for medical accident relief

There is still a lack of systematic data collection or empirical research on medical disputes or medical accidents in Taiwan. Therefore, we proposed to set the scope of the pilot plan for accidents during childbirth as the pilot plan could serve as the pioneering plan for future legislation and implementation of medical accident relief expansion. This way, we can respond to the suggestions of women's rights groups and the Taiwan Association of Obstetrics and Gynecology regarding the improvement in the obstetrics and gynecology practice settings and provide one more layer of protection for pregnant women.

II. Plan Execution

Incentive reward conditions of the pilot plan: During the period of childbirth and midwifery, if the institution has delivered necessary diagnosis, treatment or midwifery measures according to professional benchmarks, and birth-related incidents of maternal mortality, neonatal and fetal mortality, or moderate to severe disabilities (as defined in the Person with Disabilities Rights Protection Act) still occur. An agreement between the institution and the patient should be reached within two years from the date of the incident, and an application for the relief fund is submitted to the Ministry of Health and Welfare within 60 days from the date of the agreement.

i. Exclusion criteria of childbirth accident relief

1. The adverse outcome suffered by the pregnant woman and the fetus is caused by miscarriage.
2. Fetal death (including stillbirth) or adverse outcomes on a newborn caused by premature birth, severe congenital malformation or gene defect at less than 36 weeks' gestation.
3. Psychological or psychiatric disorders suffered by the pregnant woman are caused by pregnancy or childbirth.
4. A childbirth accident that can be fully attributed to the institution or the patient.
5. Patient who is involved in human experiment during pregnancy.

ii. Eligibility criteria of relief benefit: For eligible applications, the amount of benefit will be reviewed based on the facts of the case with the upper limits as follows:

1. Maternal mortality: within NTD 2 million.
2. Fetal and neonatal mortality: within NTD 300 thousand.
3. Pregnant woman or newborn with profound disability: within NTD 1.5 million per person.
4. Pregnant woman or newborn with severe disability: within NTD 1.3 million per person.
5. Pregnant woman or newborn with moderate disability: within NTD 1.1 million per person.

The original implementation period of the pilot plan was from October 1, 2012 to December 31, 2014, but in view of the effective results of the pilot plan, which did contribute to substantive resolution of the dispute over childbirth-related medical disputes, the Ministry announced an extension of the pilot plan for 2 more years to the end of 2016 on September 20, 2014. On the basis of the experience gained from the pilot plan, the legislation of the Childbirth Accident Emergency Relief Act was expedited to give effect to the protection of women's safety at childbirth as well as the continuous improvement of the quality and safety of childbirth. On December 30, 2015, the President promulgated the Childbirth Accident Emergency Relief Act, which was taken into effect on June 30, 2016. For a seamless transition from the pilot plan to the implementation of the Act, on March 28, 2017, the Ministry announced an application extension of the pilot plan to June 29, 2018.

Section 2 Analysis of Applications

Since the start of the pilot plan on October 1, 2012, about 300 hospitals, clinics and midwifery clinics have participated in the plan, accounting for 90% of the medical care institutions with obstetrics and gynecology practice registration and delivery services. The admissible cases were childbirth accidents that occurred between January 1, 2012 and June 29, 2016. The statistical analysis covered all the cases before June 29, 2018, with a total of 494 applications (excluding the 12 returns/withdrawals) and 21 reconsiderations. A total of 41 review meetings were held to complete the review of 494 applications, and a total of 427 applications were approved (an approval rate of 86.4%), with a total amount of approximately NTD 415.51 million subsidized.

According to the annual distribution of the childbirth accident applications, the highest number of cases occurred in 2015, with 113 cases and less in 2016, with only 76 cases, as shown in Figure 3-1. The main reason being that only the childbirth accident applications occurred before June 29, 2016 were accepted, and the following childbirth accidents were considered as the relief target in the Childbirth Accident Emergency Relief Act. The analysis of levels of medical care

Figure 3-1

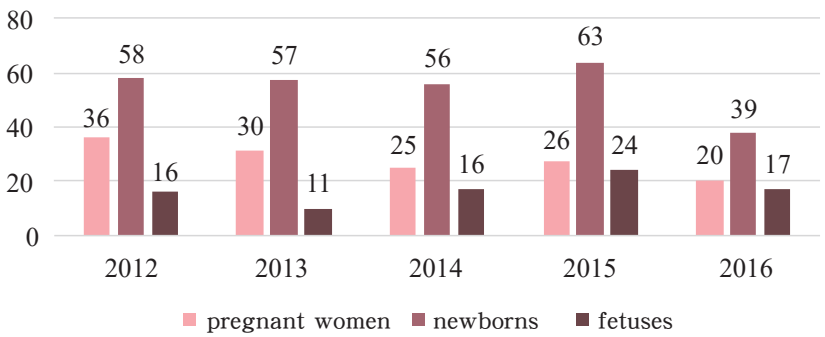


Figure 3-1. Distribution of childbirth accident applications (by year of the accident occurred)

Note: Childbirth accident applications from before June 29, 2016.

institution, regional distribution, and results of the application review were as follows:

I. Levels of medical care institution

According to the second point stipulated by the Standards and Operational Procedures for Childbirth Accident Relief Review, childbirth accident relief should be applied by the hospitals and clinics with the Ministry or the agency, institution or organization entrusted by the Ministry. Statistics showed that 309 medical care institutions participated in the pilot plan from 2012 to 2014, and 294 medical care institutions participated from 2015 to 2018. Out of a total of 494 accepted applications, 157 of the applications were applied by clinics, accounting for 31.8%, the majority of applications; 104 applications from local hospitals, accounting for 21.0%; 147 applications from regional hospitals, accounting for 29.8%; and 86 applications from medical centers, accounting for 17.4%. The number of applications from the various levels of medical care institutions, compared to the number of reported births to the National Health Insurance Administration (hereinafter referred to as the NHIA) in the same period, the highest numbers being the clinics and regional hospitals, both at the ratio of 0.58; next being the medical centers at 0.52; and local hospitals at 0.43, as shown respectively in Table 3-1 and Figures 3-2 and 3-3.

II. Regional Distribution

All childbirth accident applications were analyzed according to the regions demarcated by the NHIA, with 160

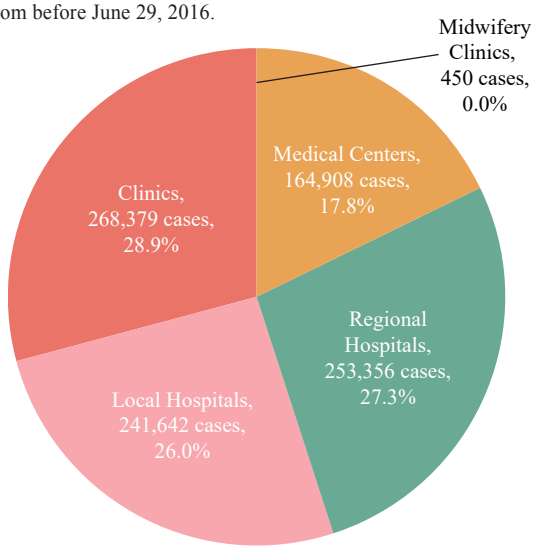


Figure 3-2. Distribution of the number of NHIA reported births by levels of medical care institution

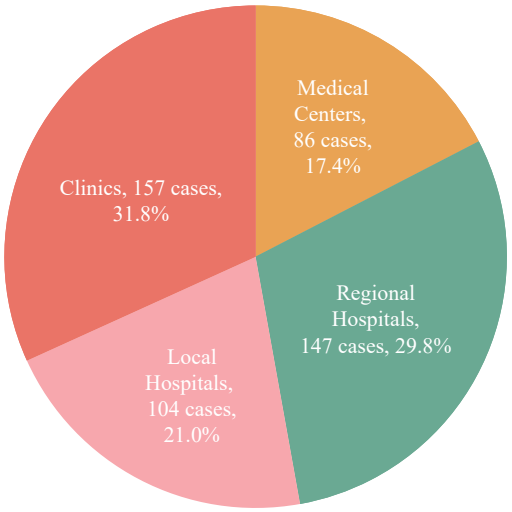


Figure 3-3: Distribution of the number of applications by levels of medical care institution (N=494)

Table 3-1. Distribution of the number of applications and reported births by levels of medical care institution

Levels of Medical Care Institution	Reported Births (A)		Applications (B)		Ratio (B/A)
	Number of Births	Percentage	Number of Cases	Percentage	Cases/ Reported Births
Medical Centers	164,980	17.8%	86	17.40%	0.52‰
Regional Hospitals	253,356	27.3%	147	29.80%	0.58‰
Local Hospitals	241,642	26.0%	104	21.1.%	0.43‰
Clinics	268,379	28.9%	157	31.8.%	0.58‰
Midwifery Clinics	450	0.0%	-	-	-
Total	928,807	100.0%	494	100.0%	0.53‰

Note: 1.Application through the pilot plan must have reached an agreement between the medical institution and the patient. The institution agrees to provide the patient with reasonable or appropriate assistance before submitting the application to the Ministry of Health and Welfare. Since participation and application to the pilot plan is voluntary for institutions, it is unable to represent or estimate the number of childbirth accidents occurred.

2.According to the Instructions for Application for the Birth-Related Dispute Incident Pilot Plan of the Ministry of Health and Welfare, applications of childbirth accidents at midwifery clinic are submitted through the medical care institution of which it has a medical assistance contract with.

(Source of number of births: National Health Insurance Administration, statistics from January 1, 2012 to June 29, 2016)

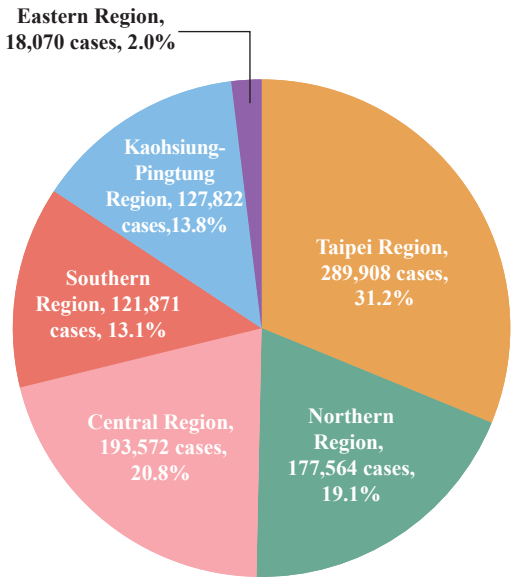


Figure 3-4. Distribution of the number of NHIA reported births by region

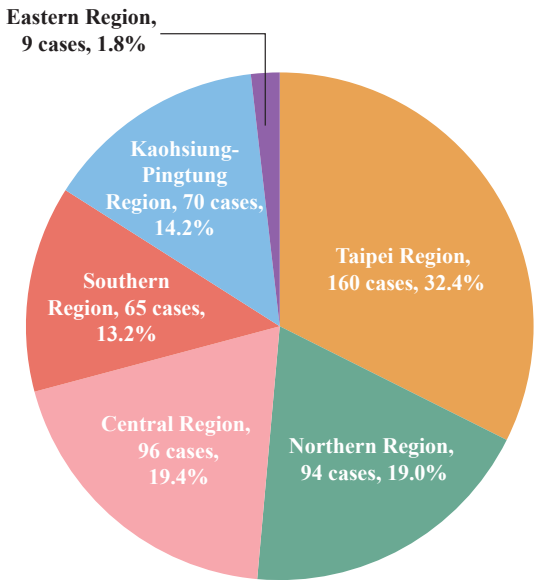


Figure 3-5. Distribution of the number of applications by region

Table 3-2. Distribution of the number of applications and reported births by region

NHIA Demarcated Regions	Reported Births (A)		Applications (B)		Ratio (B/A)
	Number of Births	Percentage	Number of Cases	Percentage	Cases/ Reported Births
Taipei Region	289,908	31.2%	160	32.4%	0.55‰
Northern Region	177,564	19.1%	94	19.0%	0.53‰
Central Region	193,572	20.8%	96	19.4%	0.50‰
Southern Region	121,871	13.1%	65	13.2%	0.53‰
Kaohsiung-Pingtung Region	127,822	13.8%	70	14.2%	0.55‰
Eastern Region	18,070	2.0%	9	1.8%	0.50‰
Total	928,807	100.0%	494	100.0%	0.53‰

Note:1.Application through the pilot plan must have reached an agreement between the medical care institution and the patient. The institution agrees to provide the patient with reasonable or appropriate assistance before submitting the application to the Ministry of Health and Welfare. Since participation and application to the pilot plan is voluntary for institutions, it is unable to represent or estimate the number of childbirth accidents occurred.

2.Regions demarcated by the NHIA are as follows: [Taipei Region] Taipei City, New Taipei City, Keelung City, Yilan County, Kinmen County, Lienchiang County; [Northern Region] Taoyuan City, Hsinchu City, Hsinchu County, Miaoli County; [Central Region] Taichung City, Changhua County, Nantou County; [Southern Region] Yunlin County, Chiayi City, Chiayi County, Tainan City; [Kaohsiung-Pingtung Region] Kaohsiung City, Pingtung County, Penghu County; [Eastern Region] Hualien County, Taitung County.

applications in the Taipei region, accounting for 32.4% of applications; 94 applications in the northern region, accounting for 19.0%; 96 applications in the central region, accounting for 19.4%; 65 applications in the southern region, accounting for 13.2%; 70 applications in the Kaohsiung-Pingtung region, accounting for 14.2%; and 9 applications in the eastern region, accounting for 1.8%. The ratio of childbirth accident applications in each region compared to the number of births in each district during the same period was between 0.50 and 0.55, as shown in Table 3-2 and Figures 3-4 and 3-5.

III. Sex ratio of newborns and fetuses

There were a total of 357 applications involving newborns and fetuses, of which 273 applications involved newborns (162 male applications, accounting for 59.3% of applications and 111 female applications, accounting for 40.7%), and 84 applications involved fetuses (42 applications for both male and female, 50% each), as shown in Table 3-3.

IV. Results of the application review

Out of a total of 494 reviewed applications, 427 applications were approved, with a total amount of NTD 415.51 million subsidized. Among the approved applications, 123 applications were for pregnant women, with a total amount of NTD 228 million subsidized (including 99 deaths for a total amount of NTD 196.3 million with an average subsidy of NTD 198.3 million; 24 major injuries for a total amount of NTD 31.7 million with an average subsidy of NTD 1.321 million); 228 applications for newborns,

Table 3-3. Gender analysis of newborn and fetal applications

Gender	Newborns		Fetuses	
	No. of Cases	Percentage	No. of Cases	Percentage
Male	162	59.3%	42	50.0%
Female	111	40.7%	42	50.0%
Total	273	100.0%	84	100.0%

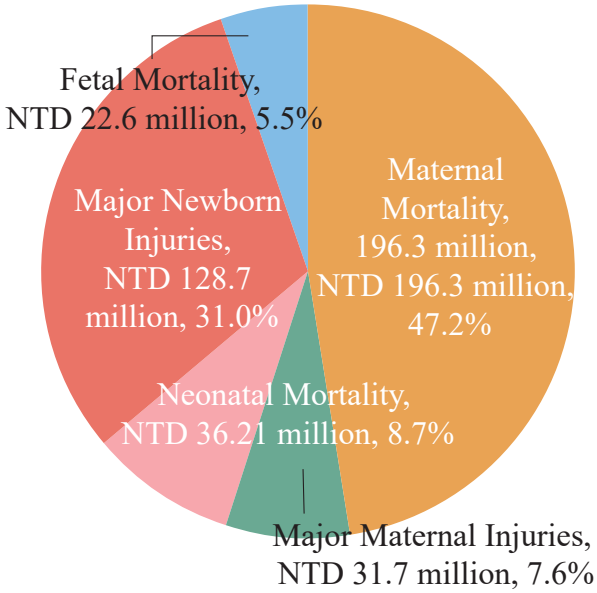


Figure 3-6. Distribution of the amount of relief granted by type of application

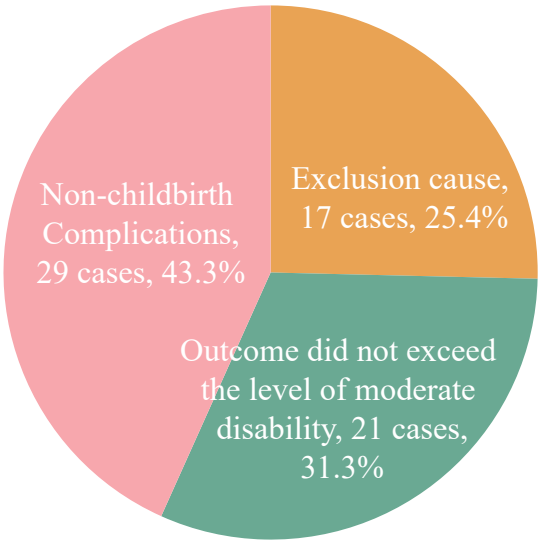


Figure 3-7. Analysis of reasons for disapproval

Note: According to Section 4-1-2 "Exclusion criteria of childbirth accident relief" of the Instructions for Application for the Birth-Related Dispute Incident Pilot Plan, the following circumstances should be excluded:

1. The outcome suffered by the pregnant woman and fetus is caused by miscarriage.
2. Fetal death (including stillbirth) or adverse outcomes on a newborn caused by premature birth, severe congenital malformation or gene defect at less than 36 weeks' gestation.
3. Psychological or psychiatric disorders suffered by the pregnant woman are caused by pregnancy or childbirth.
4. A childbirth accident that can be fully attributed to the institution or the patient.
5. Patient who is involved in human experiment during pregnancy.

Table 3-4. Analysis of the relief applications granted (in NTD 10 thousand)

Accident victim	Pregnant Woman		Newborn		Fetus	Total
Result of accident	Death	Major Injury (Moderate to severe disability)	Death	Major Injury (Moderate to severe disability)	Death	
Number of case granted relief	99	24	123	105	76	427
Average Amount	98.3	132.1	29.4	122.6	29.7	97.3
Median amount	200	150	30	130	30	-
Minimum amount	150	20	10.2	30	10	-
Maximum amount	200	150	30	150	30	-
Total amount	19,630	3,170	3,621	12,870	2,260	41,551

with a total amount of NTD 164.91 million (including 123 deaths for a total amount of NTD 36.21 million with an average subsidy of NTD 294 thousand; 105 major injuries for a total amount of NTD 128.7 million with an average subsidy of NTD 1.226 million); 76 applications were for fetuses, with a total amount of NTD 22.6 million and an average subsidy of NTD 297 thousand, as shown in Table 3-4 and Figure 3-6.

V. Analysis of reasons for disapproval

Out of a total of 494 reviewed applications, there were 67 disapproved applications, and the major reason being that most of these applications (29 applications, or 43%) were related to non-childbirth complications. Next reason being that the accidental outcome did not exceed the level of moderate disability (21 applications, or 31.3%). Last were the applications with exclusion cause (17 applications, or 25.4%), as shown in Figure 3-7.

Section 3 Analysis of Maternal Incidents

I. Analysis of maternal mortality

A total of 99 maternal mortality cases were granted. The analysis for these cases by levels of medical care institution, regional distribution, gestational age, birth order, age of mother at childbirth, and causes of childbirth accidents were as follows:

i. Levels of medical care institution

Analysis of maternal mortality by levels of medical care institution: 40 cases were applied by clinics, accounting for 40.4% of applications; 16 cases from local hospitals, accounting for 16.2%; 26 cases from regional hospitals, accounting for 26.2 %; and 17 cases from medical centers, accounting for 17.2%, as shown in Figure 3-8.

ii. Regional distribution

Regional distribution of the maternal mortality cases by NHIA demarcated regions: 39 cases in the Taipei region, accounting for 39.4% of applications; 19 cases in the northern region, accounting for 19.2%; 17 cases in the central region, accounting for 17,2%; 4 cases in the southern region, accounting for 4.0%; 19 cases in the Kaohsiung-Pingtung region, accounting for 19.2%; and 1 case in the eastern region, accounting for 1.0%, as shown in Figure 3-9.

iii. Gestational age

Analysis of maternal mortality by gestational age: a total of 82 births were given at or after 37 weeks of gestation, accounting for 82.8% of applications; and a total of 17 births were given at or before 36 weeks, accounting for 17.2%, as shown in Figure 3-10.

iv. Birth order

Analysis of maternal mortality by birth order: first birth was the highest in number with 31 cases, accounting for 31.3% of applications; followed by second and third birth with 26 cases each, each accounting for 26.3%, as shown in Figure 3-11.

v. Age of mother at childbirth

Analysis of maternal mortality by age of mother at childbirth: age group of 31-35 years was the highest in number with 43 cases, accounting for 43.4% of application; followed by age group of 36-40 years with 28 cases, accounting for 28.3%; and age group of 41-45 years with 11 cases, accounting for 11.1%, as shown in Figure 3-12.

vi. Causes of childbirth accident

Table 3-5. Analysis of causes of maternal mortality

Causes of Mortality	No. of cases	Percentage
Amniotic embolism	63	63.6%
Postpartum hemorrhage	9	9.1%
Vascular embolization	6	6.1%
HELLP syndrome	4	4.0%
Preeclampsia	3	3.0%
Placental complications	3	3.0%
Others	3	3.0%
Heart disease	3	3.0%
Poor uterine contraction	2	1.9%
Intracranial hemorrhage	1	1.1%
Uterine rupture	1	1.1%
Infection	1	1.1%
Total	99	100.0%

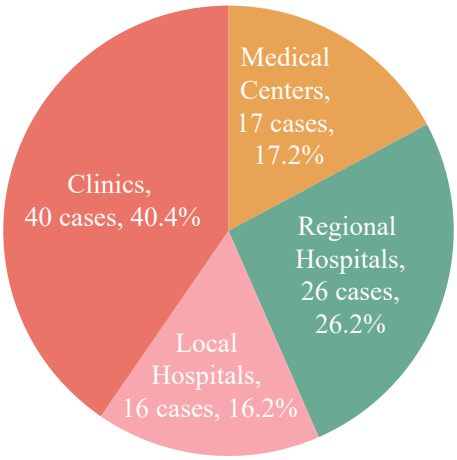


Figure 3-8. Distribution of maternal mortality by levels of medical care institution

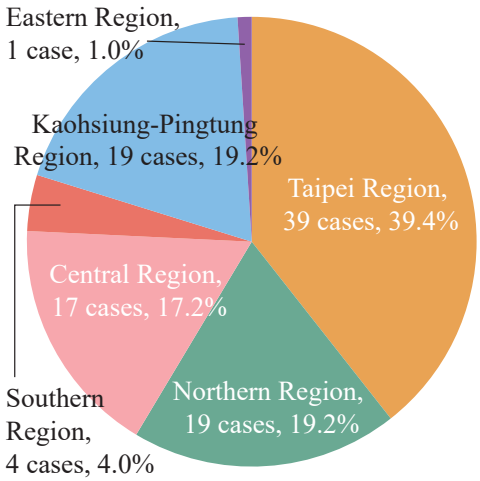


Figure 3-9. Distribution of maternal mortality by region

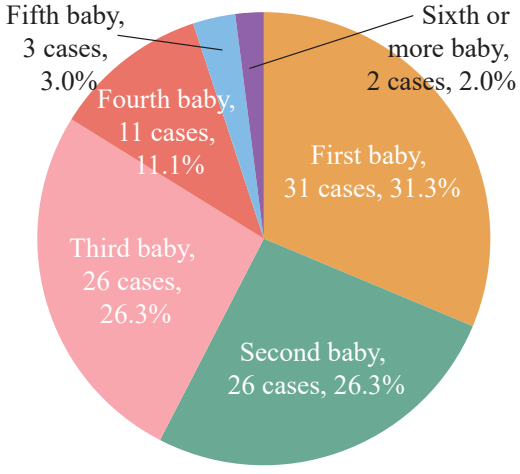


Figure 3-11. Distribution of maternal mortality by birth order

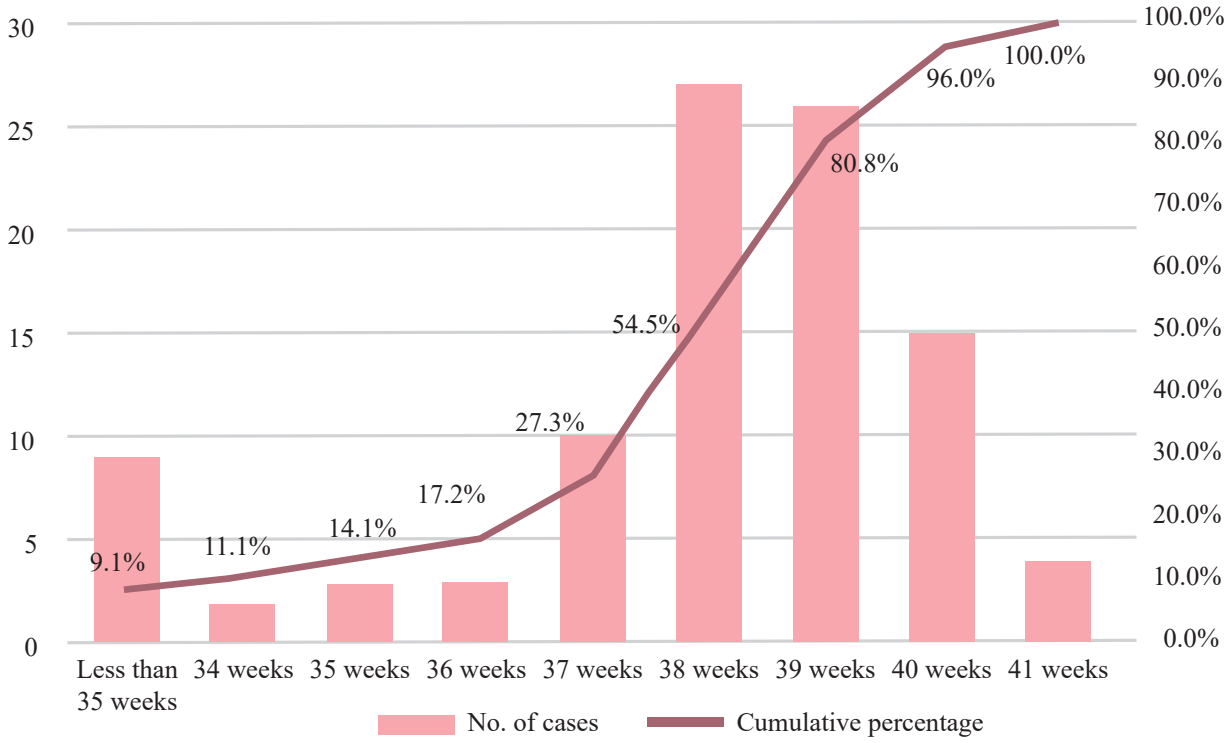


Figure 3-10. Distribution of maternal mortality by gestational age

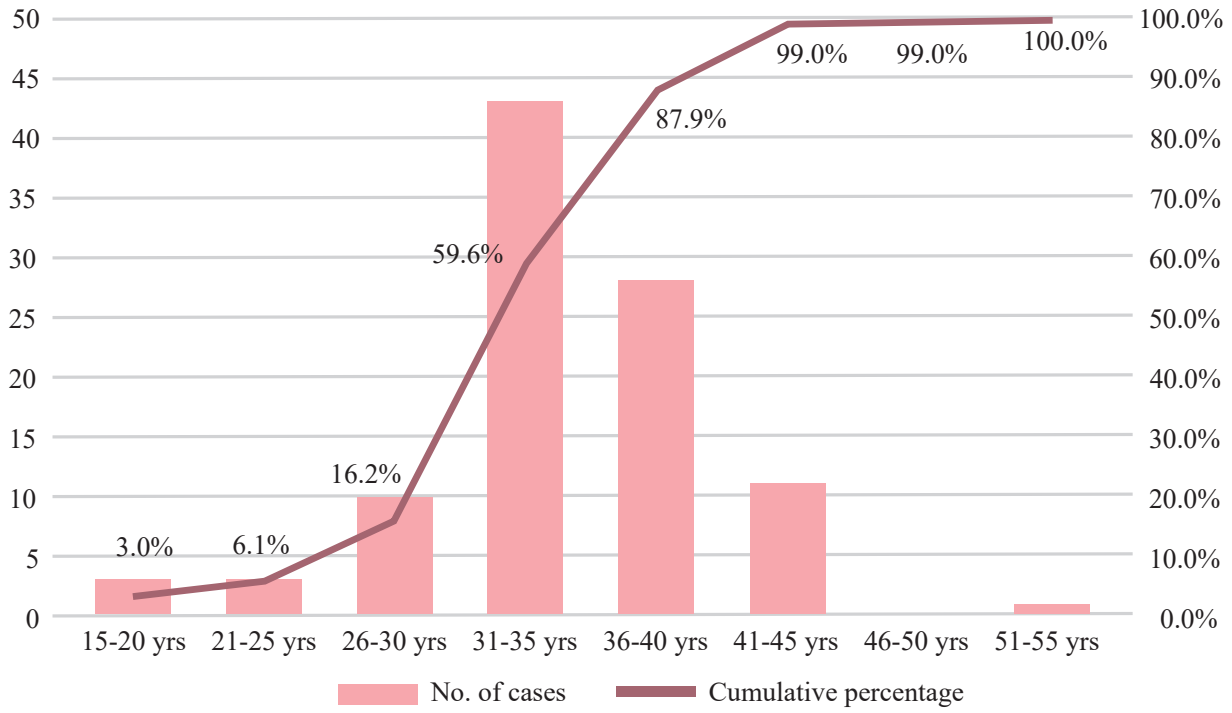


Figure 3-12. Distribution of maternal mortality by age of mother at childbirth

Analysis of causes of childbirth accidents relating to maternal mortality: 63 cases of amniotic embolism with the highest number of applications, accounting for 63.3% of applications; followed by 9 cases of postpartum hemorrhage, accounting for 9.1%, and 6 cases of vascular embolization, accounting for 6.1%, as shown in Table 3-5.

II. Analysis of major maternal injury

A total of 24 applications were approved relating to major maternal injuries. The analysis for these applications by levels of medical care institution, regional distribution, gestational age, birth order, age of mother at childbirth, and causes of childbirth accidents were as follows:

i. Levels of medical care institution

Analysis of major maternal injuries by levels of medical care institution: 9 cases were applied by clinics, accounting for 37.5% of applications; 6 cases from local hospitals, accounting for 25.0%; 5 cases from regional hospitals, accounting for 20.8%; and 4 cases from medical centers, accounting for 16.7%, as shown in Figure 3-13.

ii. Regional distribution

Regional distribution of the major maternal injuries by NHIA demarcated regions: 5 cases in the Taipei region, accounting for 20.8% of applications; 3 cases in the northern region, accounting for 12.5%; 6 cases in the central region, accounting for 25.0%; 6 cases in the southern region, accounting for 25.0%; 3 cases in the Kaohsiung-Pingtung region, accounting for 12.5%; and 1 case in the eastern region, accounting for 4.2%, as shown in Figure 3-14.

iii. Gestational age

Analysis of major maternal injuries by gestational age: a total of 15 births were given at or after 37 weeks of gestation, accounting for 62.5% of applications; and a total of 9 births were given at or before 36 weeks, accounting for 37.5%, as shown in Figure 3-15.

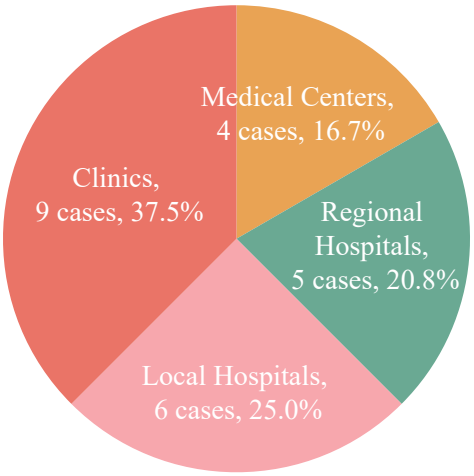


Figure 3-13. Distribution of major maternal injury by levels of medical care institution

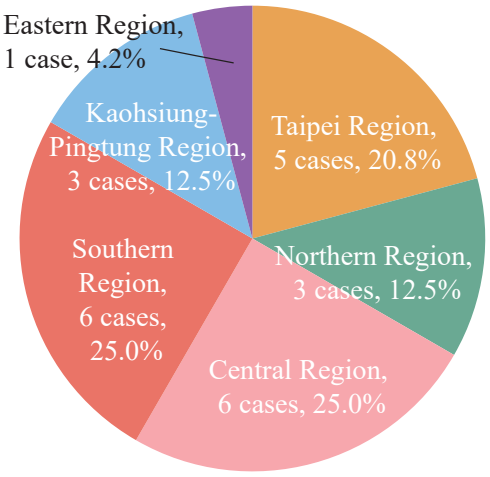


Figure 3-14. Distribution of major maternal injury by region

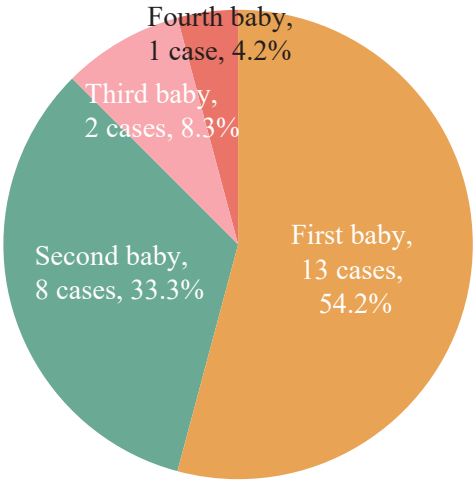


Figure 3-16. Distribution of major maternal injury by birth order

iv. Birth order

Analysis of major maternal injuries by birth order: first birth was the highest in number with 13 cases, accounting for 54.2% of applications; followed by second birth with 8 cases, accounting for 33.3%; and third birth with 2 cases, accounting for 8.3%, as shown in Figure 3-16.

v. Age of mother at childbirth

Analysis of major maternal injuries by age of mother at childbirth: age group of 31-35 years was the highest in number with 15 cases, accounting for 62.5% of applications; followed by age group of 36-40 years with 5 cases, accounting for 20.8%; and age group of 26-30 years with 3 cases, accounting for 12.5%, as

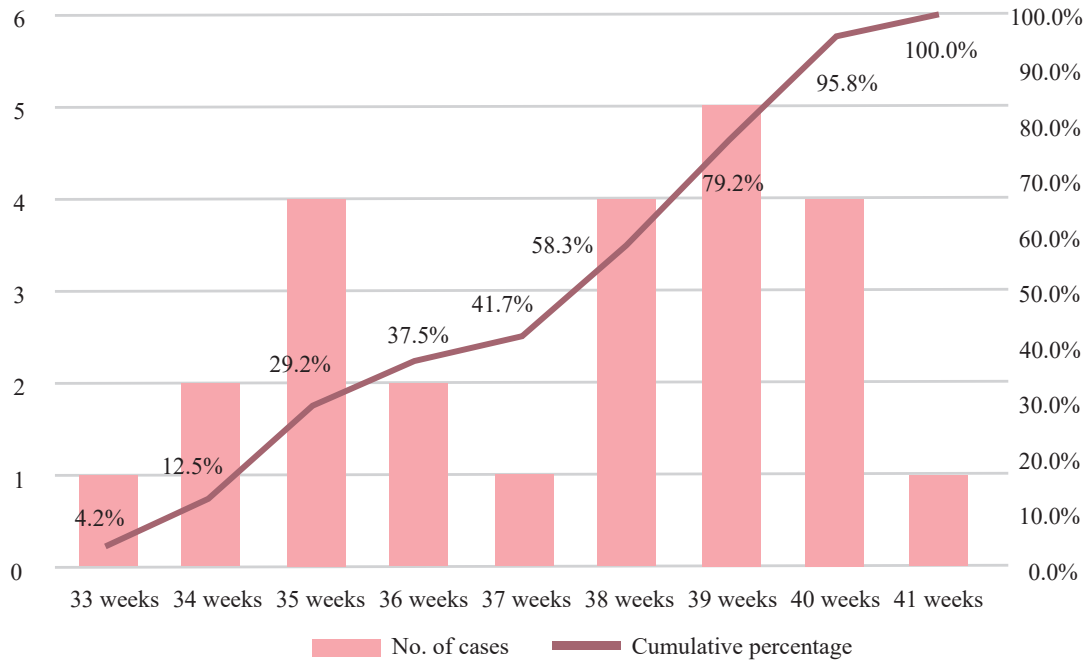


Figure 3-15. Distribution of major maternal injury by gestational age

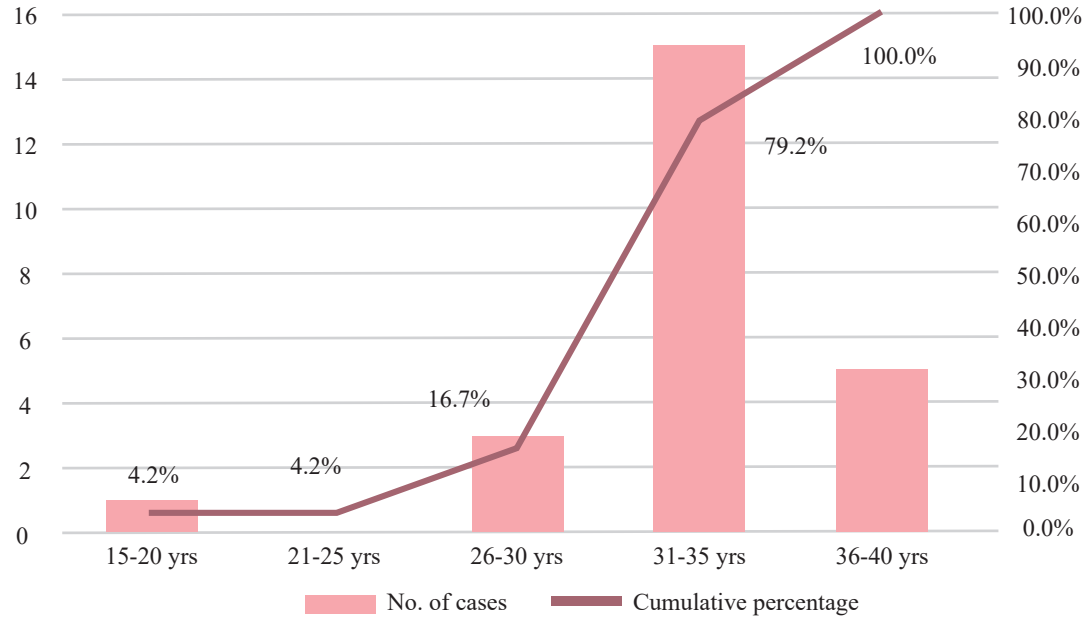


Figure 3-17. Distribution of major maternal injury by age

Table 3-6. Analysis of causes of major maternal injury

Causes of injury	No. of cases	Percentage
Intracranial hemorrhage	7	29.0%
Amniotic embolism	3	12.5%
Preeclampsia	3	12.5%
Vascular embolization	3	12.5%
Others	3	12.5%
Postpartum hemorrhage	1	4.2%
HELLP syndrome	1	4.2%
Placental complications	1	4.2%
Poor uterine contraction	1	4.2%
Infection	1	4.2%
Total	24	100.0%

shown in Figure 3-17.

vi. Causes of childbirth accident

Analysis of causes of childbirth accidents relating to major maternal injuries: 7 cases of intracranial hemorrhage with the highest number of applications, accounting for 29.0% of applications; followed by 3 cases each for amniotic embolism, preeclampsia and vascular embolization, each accounting for 12.5%, as shown in Table 3-6.

Section 4 Analysis of Neonatal and Fetal Incidents

I. Analysis of neonatal mortality and major injury

A total of 228 cases of neonatal mortality and major injuries were granted. The analysis by levels of medical care institution, regional distribution, gestational age, birth order, age of mother at childbirth, and causes of childbirth accidents relating to neonatal mortality and major injuries were as follows:

i. Levels of medical care institution

Analysis of neonatal mortality and major injuries by levels of medical care institution: 58 cases were applied by clinics, accounting for 25.5% of applications; 60 cases from local hospitals, accounting for 26.3%; 71 cases from regional hospitals, accounting for 31.1%; and 39 cases from medical centers, accounting for 17.1%, as shown in Figure 3-18.

ii. Regional distribution

Regional distribution of the neonatal mortality and major injuries by NHIA demarcated regions: 67 cases in the Taipei region, accounting for 29.4% of applications; 41 cases in the northern region, accounting for 18.0%; 54 cases in the central region, accounting for 23.7%; 31 cases in the southern region, accounting for 13.6%; 30 cases in the Kaohsiung-Pingtung region, accounting for 13.1%; and 5 cases in the eastern region, accounting for 2.2%, as shown in Figure 3-19.

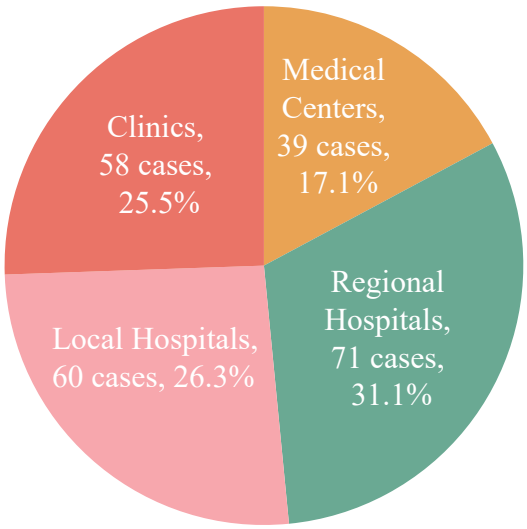


Figure 3-18. Distribution of neonatal mortality and major injury by levels of medical care institution

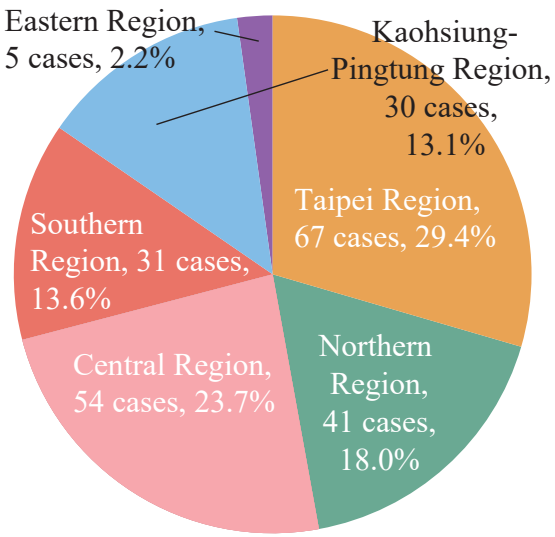


Figure 3-19. Distribution of neonatal mortality and major injury by region

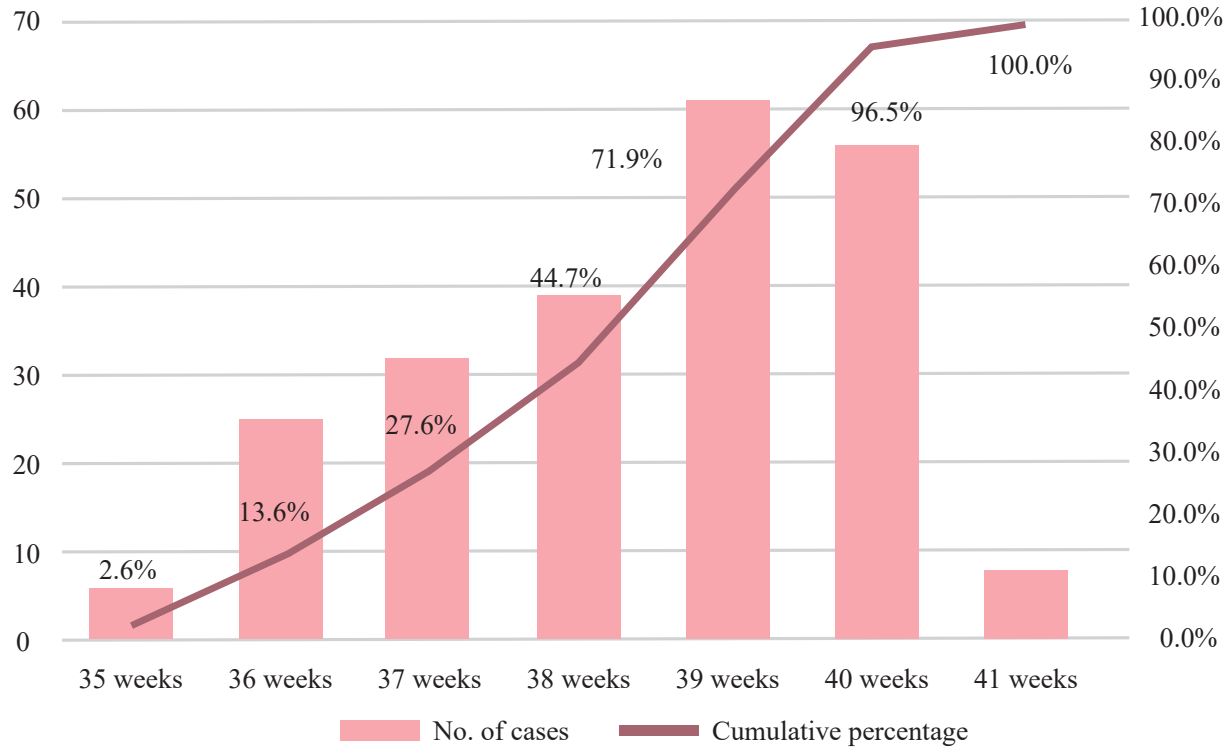


Figure 3-20. Distribution of neonatal mortality and major injury by gestational age

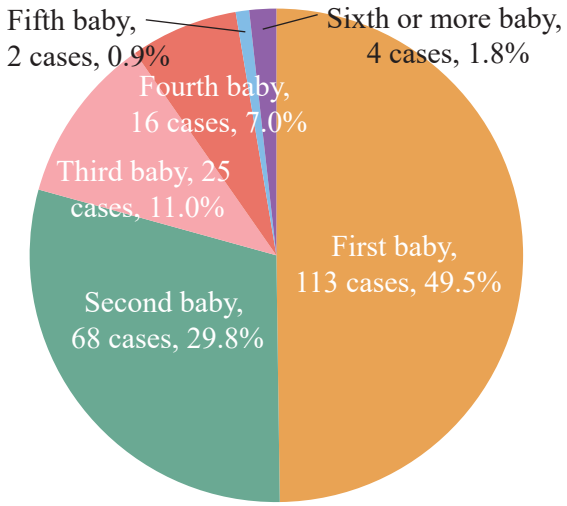


Figure 3-21. Distribution of neonatal mortality and major injury by birth order

iii. Gestational age

Analysis of neonatal mortality and major injuries by gestational age at the time of labor and delivery: a total of 197 births were given at or after 37 weeks of gestation, accounting for 86.4% of applications; and a total of 31 births were given at or before 36 weeks, accounting for 13.6%, as shown in Figure 3-20.

iv. Birth order

Analysis of neonatal mortality and major injuries by birth order: first birth was the highest in number with 113 cases, accounting for 49.5% of applications; followed by second birth with 68 cases, accounting for 29.8%; and third birth with 25 cases, accounting for 11.0%, as shown in Figure 3-21.

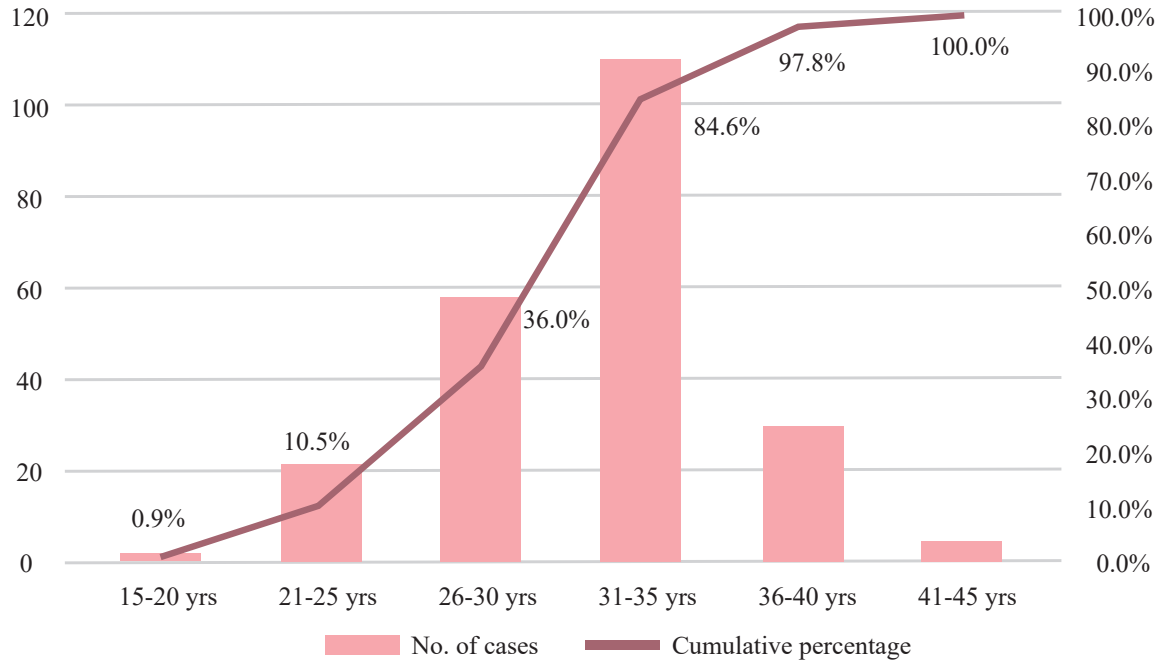


Figure 3-22. Distribution of neonatal mortality and major injury by age

Table 3-7. Analysis of causes of neonatal mortality and major injury

Causes	Mortality		Major injury		Total	
	No. of cases	Percentage	No. of cases	Percentage	No. of cases	Percentage
Fetal distress	29	23.6%	15	14.3%	44	19.3%
Perinatal hypoxia	10	8.1%	30	28.6%	40	17.5%
Placental complications	25	20.3%	9	8.6%	34	14.9%
Shoulder dystocia & brachial plexus injury	2	1.6%	18	17.1%	20	8.8%
Respiratory distress	15	12.2%	3	2.9%	18	7.9%
Cause unknown or undetermined	7	5.7%	10	9.5%	17	7.5%
Umbilical cord complications	8	6.5%	8	7.6%	16	7.0%
Meconium aspiration syndrome	10	8.1%	2	1.9%	12	5.3%
Infection	3	2.4%	8	7.6%	11	4.8%
Others	4	3.3%	2	1.9%	6	2.6%
Uterine rupture	5	4.1%	0	0.0%	5	2.2%
Intracranial hemorrhage	5	4.1%	0	0.0%	5	2.2%
Total	123	100.0%	105	100.0%	228	100.0%

v. Age of mother at childbirth

Analysis of neonatal mortality and major injuries by age of mother at childbirth: age group of 31-35 years was the highest in number with 111 cases, accounting for 48.6% of applications; followed by age group of 26-30 years with 58 cases, accounting for 25.5%; and age group of 36-40 years with 30 cases, accounting for 13.2%, as shown in Figure 3-22.

vi. Causes of childbirth accident

Analysis of causes of childbirth accidents relating to neonatal mortality and major injuries: the top 3 causes of neonatal mortality were fetal distress (29 cases, or 23.6%); placenta complications (25 cases, or 20.3%); and respiratory distress (15 cases, or 12.2%). Top 3 causes of major neonatal injuries were perinatal hypoxia (30 cases, or 28.6%); shoulder dystocia and brachial plexus injury (18 cases, or 17.1%); and fetal distress (15 cases, or 14.3%), as shown in Table 3-7.

II. Analysis of fetal mortality

A total of 76 fetal mortality cases were granted. The analysis by levels of medical care institution, regional distribution, gestational age, birth order, age of mother at childbirth, and causes of childbirth accident relating to fetal mortality were as follows:

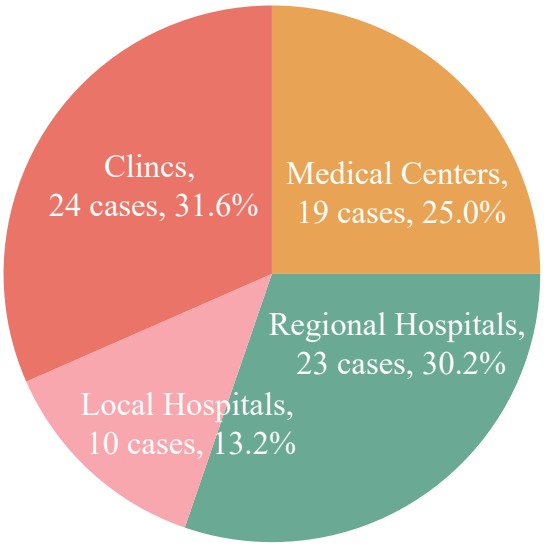


Figure 3-23. Distribution of fetal mortality by levels of medical care institution

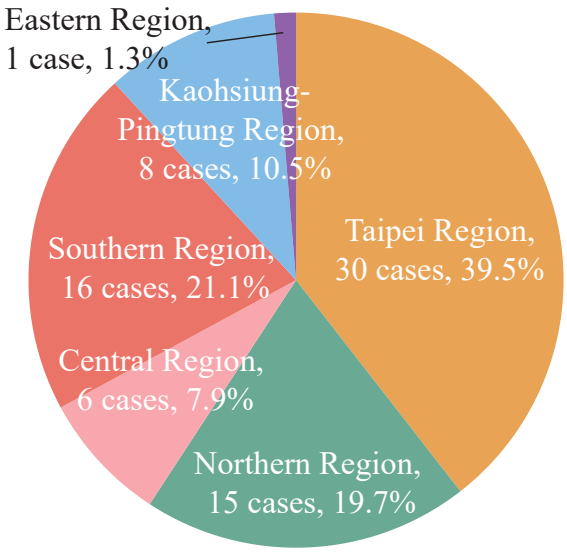


Figure 3-24. Distribution of fetal mortality by region

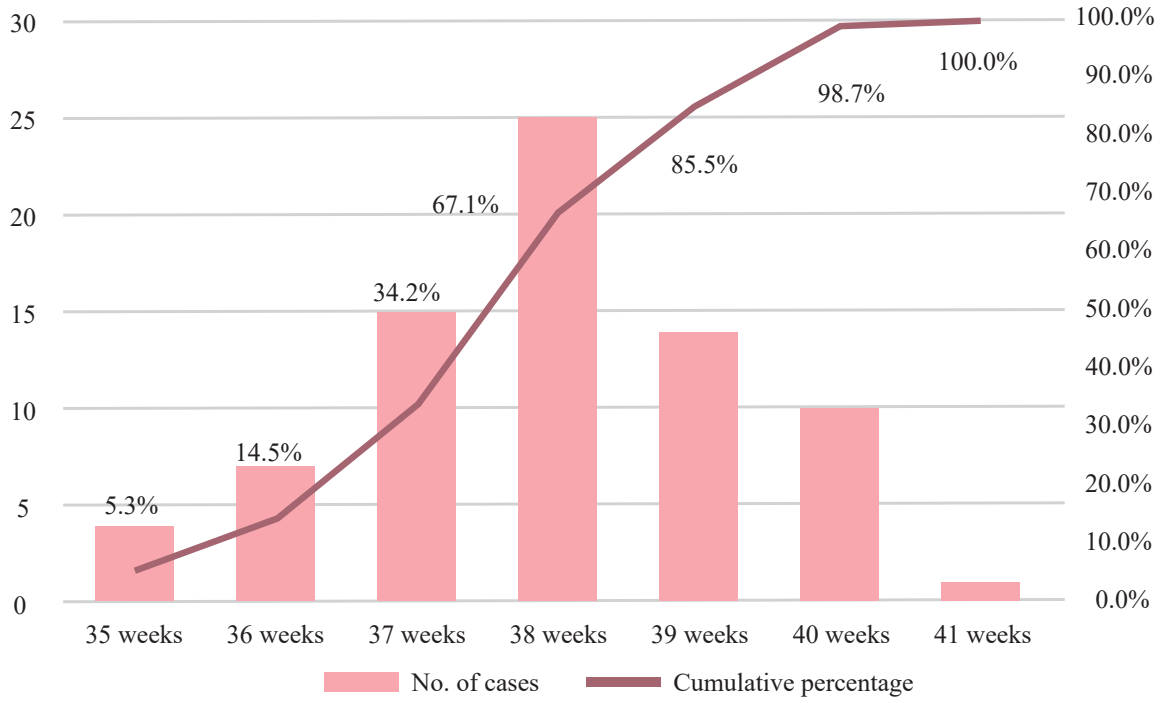


Figure 3-25. Distribution of fetal mortality by gestational age

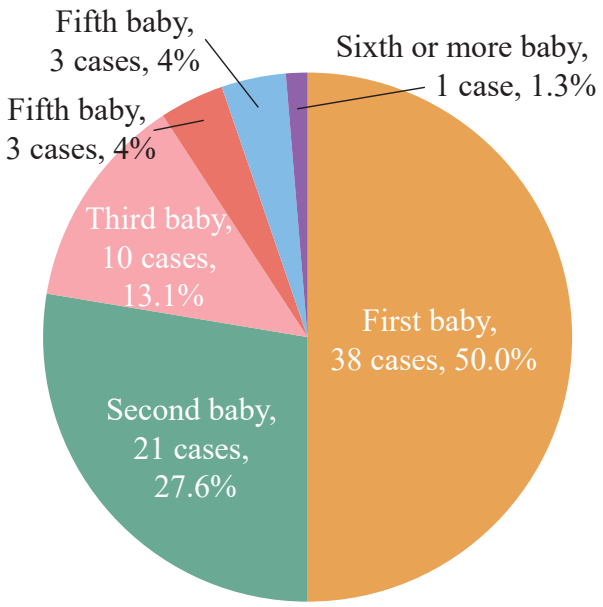


Figure 3-26. Distribution of fetal mortality by birth order

i. Levels of medical care institution

Analysis of fetal mortality by levels of medical care institution: 24 cases were applied by clinics, accounting for 31.6% of applications; 10 cases from local hospitals, accounting for 13.2%; 23 cases from regional hospitals, accounting for 30.2%; and 19 cases from medical centers, accounting for 25.0%, as shown in Figure 3-23.

ii. Regional distribution

Regional distribution of the fetal mortality cases by NHIA demarcated regions: 30 cases in the Taipei region, accounting for 39.5% of applications; 15 cases in the northern region, accounting for 19.7%; 6 cases in the central region, accounting for 7.9%; 16 cases in the southern region, accounting for 21.1%; 8 cases in the Kaohsiung-Pingtung region, accounting for 10.5%; and 1 case in the eastern region, accounting for 1.3 %, as shown in Figure 3-24.

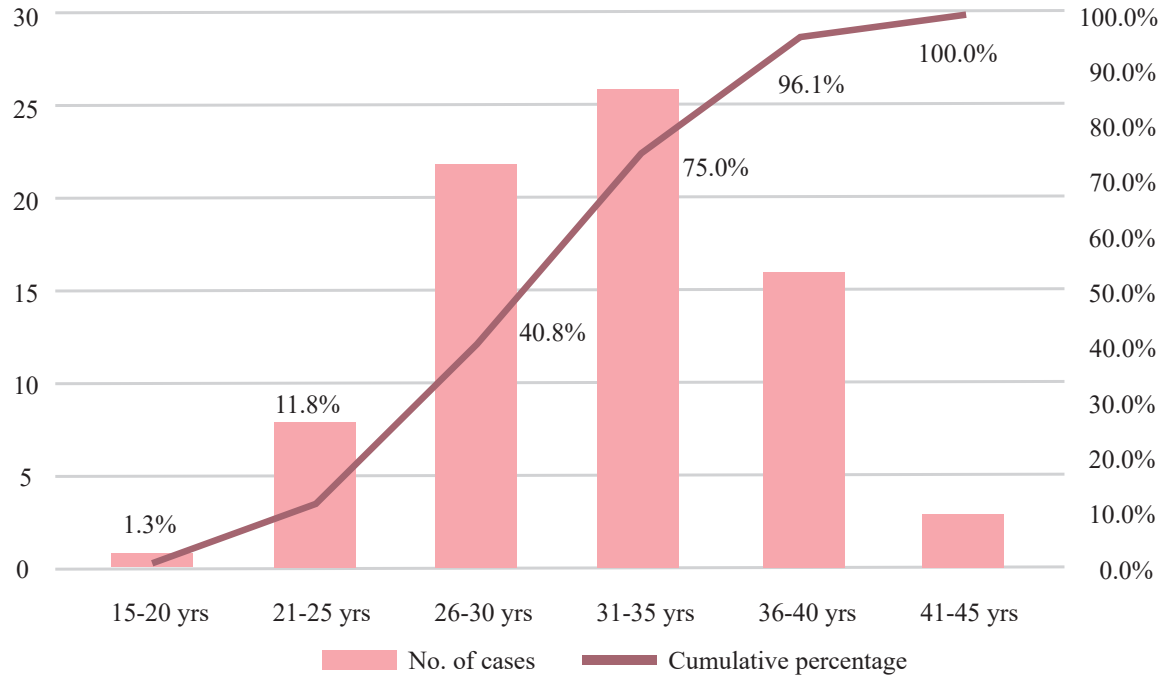


Figure 3-27. Distribution of fetal mortality by age of mother at childbirth

iii. Gestational age

Analysis of fetal mortality by gestational age at the time of labor and delivery: a total of 65 births were given at or after 37 weeks of gestation, accounting for 85.5% of applications; and a total of 11 births were given at or before 36 weeks, accounting 14.5%, as shown in Figure 3-25.

Table 3-8. Analysis of causes of fetal mortality

Causes of mortality	No. of cases	Percentage
Placental complications	20	26.3%
Umbilical cord complications	19	25.0%
Unexplained stillbirth	16	21.1%
Fetal distress	13	17.1%
Meconium aspiration syndrome	3	3.9%
Amniotic embolism	2	2.7%
Severe maternal infection	1	1.3%
Infection of amniotic sac and fetal membrane	1	1.3%
HELLP syndrome	1	1.3%
Total	76	100.0%

iv. Birth order

Analysis of fetal mortality by birth order: first birth was the highest in number with 38 cases, accounting for 50.0% of applications; followed by second birth with 21 cases, accounting for 27.6%; and third birth with 10 cases, accounting for 13.1%, as shown in Figure 3-26.

v. Age of mother at childbirth

Analysis of fetal mortality by age of mother at childbirth: age group of 31-35 years was the highest in number with 26 cases, accounting for 34.2% of applications; followed by age group of 26-30 years with 22 cases, accounting for 29.0%; and age group of 36-40 years with 16 cases, accounting for 21.1%, as shown in Figure 3-27.

vi. Causes of childbirth accident

Analysis of causes of childbirth accidents for fetal mortality: the top 3 causes were placenta complications (20 cases, or 26.3%); umbilical cord complications (19 cases, or 25.0%); and unknown causes (16 cases, or 21.1%), as shown in Table 3-8.

Section 5 Quality Improvement Plan of Childbirth Accident Relief for Medical Care InstitutionsInstitutions

I. Status of execution

Since 2012, the Department of Health (now the Ministry of Health and Welfare) initiated the Birth-Related Dispute Incident Pilot Plan to protect doctors' and patients' rights, as well as to promote a harmonious doctor-patient relationship and at the same time enhance the quality of medical services and improve practice settings. While implementing the policy, the participating institutions should bear the responsibility for reducing all the possible risks during childbirth and ensure maternal and newborn safety. Therefore, the participating institutions should pass the review and site visit within one year of joining the pilot plan, where results of the site visit will be announced to the public as a source of reference for medical choice.

II. Key results

The site visit benchmark includes two parts, namely "organizational operation, professional competence, and equipment management" and "professional and safe medical practice" (see Table 3-9 for benchmark classification). A total of 423 site visits and documentary review were completed during the pilot plan. Pertaining to institutions that have applied for more than 2 cases, experts were arranged to advise the

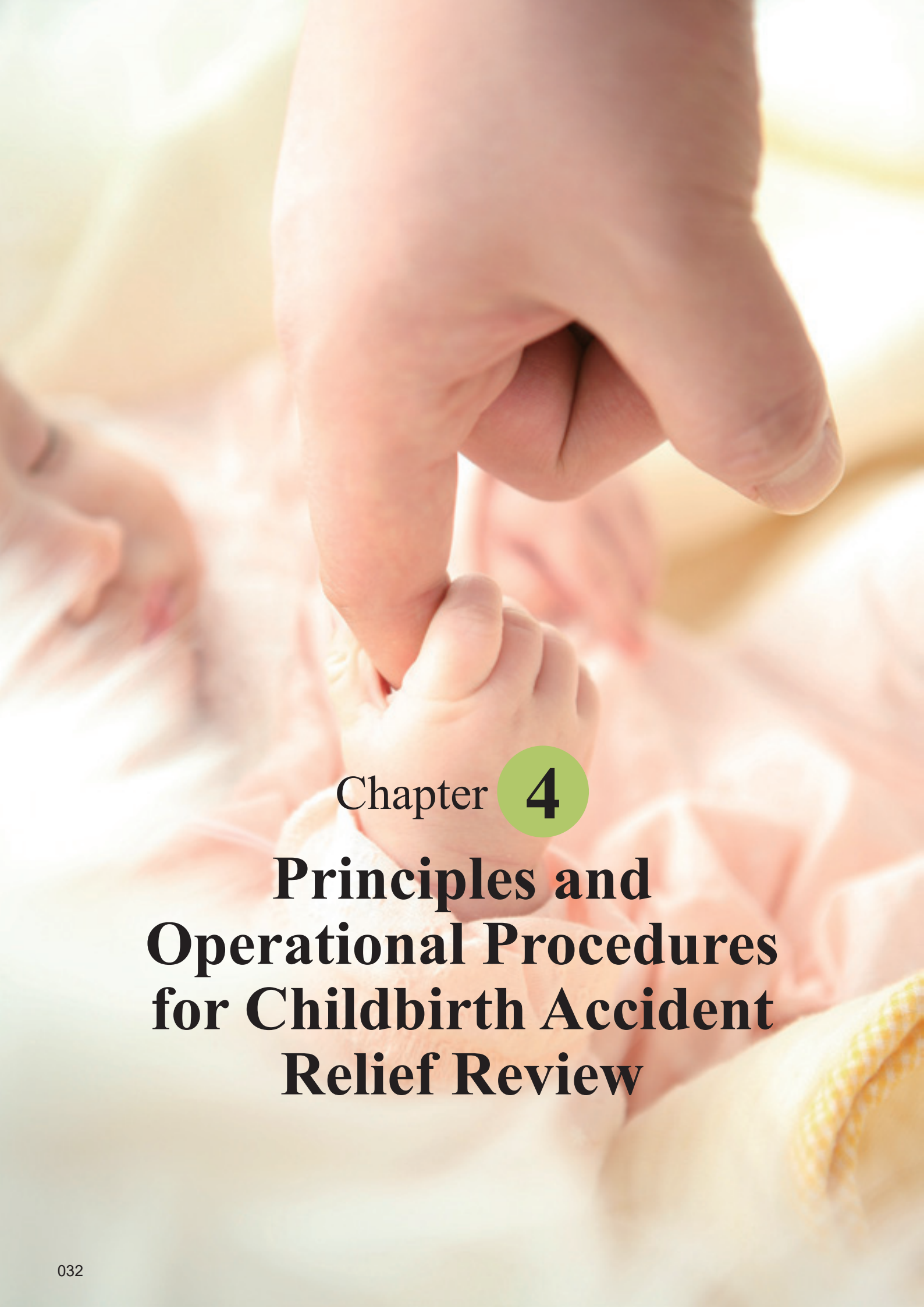
institution during their site visit, assisting the institution in self-examination of the degree of improvement in the childbirth care provided. In addition, we continuously track the performance of implementation and improvement of the institution. Especially in 2016, we focused on the institutions with a score less than 80 in the previous site visit and arranged follow-up visit with advising. The results showed that 84% of the institutions performed better than before with a higher score, with items "preparation for medical treatment" and "implementation of safe medical treatment" showing the most progress.

III. Quality improvement

This pilot plan analyzed common problems in childbirth care through site visit and implementation reports from institutions, such as emergency referral of premature birth, method of medical dispute resolution, interpretation and treatment during fetal monitoring, establishment of network and emergency treatment of high-risk pregnancy, newborn resuscitation, and basic concept and risk control of Root Cause Analysis (RCA). Furthermore, 4 conferences on the quality improvement of maternal care were held to improve the consistency of relevant medical measures among all participating institutions so as to achieve the goal of patient safety, and thereby directing focus from emergency response to error prevention.

Table 3-9. Site Visit Benchmark of Medical Care (Midwifery) Institutions in Obstetrics and Gynecology

Chapter 1 Organizational operation, Professional competence and equipment management	
1.1	Have a well-functioning organization and clearly defined services
1.2	Health care personnels have relevant professional skills for care, and registered with local competent authorities
1.3	Implement infection control measures
1.4	Implement environmental safety measures
1.5	Instruments and equipment provide accurate data and are regularly maintained
Chapter 2 Professional and safe medical practice	
2.1	Implement a sound assessment of the basic health information of the patient
2.2	Complete preparation for medical treatment
2.3	Implement safe medical treatment
2.4	Safe drug administration
2.5	Effective response to the emergency situations of the patient



Chapter 4

Principles and Operational Procedures for Childbirth Accident Relief Review

Section 1 Childbirth Accident Relief Target Applicants to Be Granted

In accordance to Article 3 of the Childbirth Accident Emergency Relief Act, “childbirth accident refers to serious harm or death of puerperae, fetuses, and newborns resulting from childbirth”. In addition, “the right to claim childbirth accident relief shall not be assigned, offset, confiscated, or provided for guarantee”. Target applicants to be granted relief are as follows: (1) death benefit: where the puerpera or newborn dies, the payment is made to the statutory heir. Where the fetus is stillborn, the payment is made to the mother. (2) Major injury benefit: The victim himself/herself.

Section 2 Childbirth Accident Relief Procedure of Application

In accordance to Article 14 of the Childbirth Accident Emergency Relief Act, “the right to claim childbirth accident relief expires in two years where no claim is made from the time when the eligible applicant becomes aware of the childbirth accident; the same applies to childbirth accidents that occurred over ten years ago”. Moreover, “R.O.C. nationals’ applications for childbirth accident relief are eligible only for childbirth accidents that occur within R.O.C. territory. Foreign spouses of R.O.C. nationals are eligible for making the aforesaid applications".

Applicants for childbirth accident relief should complete necessary application form and attach the following documentation and information to the central competent authority in accordance to Article 2 of the Regulations Governing the Childbirth Accident Relief:

(1) Maternal health booklet (including prenatal records); (2) medical records of the medical care institution or midwifery institution during the delivery and labor. Those involved with more than two medical care institutions or midwifery institutions should include medical records of both institutions; (3) any medical records relating to the diagnosis or treatment of chronic disease or childbirth-related diseases during the delivery or labor. Those involved with more than two medical care institutions should include medical records of both institutions; (4) proof of relationship for the applicant and the victim; (5) applicants of death benefit should include death certificate or stillbirth certificate; (6) applicants for major injury benefit should include a copy of disability card or certificate of diagnosis; (7) any other documentation or information designated by the central competent authority.

Section 3 Childbirth Accident Relief Review and Benefit

To implement the review of childbirth accident relief, the central competent authority should establish a committee of childbirth accident relief review that is formulated by medical experts, legal experts, women’s organization representatives, impartial parties in society, and institutional representatives. Furthermore, committee members of a single gender, legal experts, women’s organization representatives, and impartial parties in society must not constitute less than a third of the total number of members in the committee. For the review of applications, member’s voluntary recusal is required in the event of: (1) being the party concerned or the spouse, lineal relative, relative within the third degree of kinship, or relative by marriage of the party concerned; (2) being the representative of the party concerned; (3) working in the same medical care institution or midwifery agency as the party concerned or his/her representative.

For the processing of childbirth accident relief applications, the central competent authority should complete the review in three months, starting from the date of officially accepting the application. If necessary, the authority has a maximum of 3-month extension. After granting relief benefits, in any one of the following circumstances, in accordance to Article 12 of the Childbirth Accident Emergency Relief Act, “the central competent authority shall issue a written disciplinary measure to

order the beneficiary of the granted relief to return the benefit":

1. A concrete evidence shows that no relief should have been granted according to the provisions stated in Article 11 of the Act.

2. Private prosecution or charge for criminal case or a civil litigation is lodged after relief has been granted for the same childbirth incident.

The childbirth accident relief benefit is divided into death benefit and major injury benefit. Major injury refers to physically or mentally moderate to severe disability caused by delivery and labor, loss of reproductive function through hysterectomy, or any other physical or health injuries that are deemed untreatable or difficult to treat by the central competent authority. The degree of disability from the major injury shall be defined by the disability card issued by the municipality, county, or city government in accordance to the People with Disabilities Rights Protection Act. The amount of relief benefit is as follows:

1. Death benefit

(1) Women: maximum of NTD 2 million.

(2) Fetuses or newborns: maximum of NTD 300 thousand.

2. Major injury benefit

(1) Profound disability: maximum of NTD 1.5 million.

(2) Severe disability: maximum of NTD 1.3 million.

(3) Moderate disability: maximum of NTD 1.1 million.

(4) Loss of reproductive function from hysterectomy: depending on whether the family has children and the impact of reproductive function on the family—maximum of NTD 800 thousand.

(5) Physical or health injuries that are deemed untreatable or difficult to treat by the central competent authority—maximum of NTD $300 thousand.

According to the provisions stated in Article 11 of the Childbirth Accident Emergency Relief Act, "the childbirth accident relief is available only for cases that have causation with childbirth, or such causation cannot be excluded. However, no relief will be given in any one of the following circumstances:

1. The adverse outcome suffered by the pregnant woman or puerpera and the fetus is caused by termination of pregnancy for non-medical causes.

2. Fetal death (including stillbirth) or adverse outcomes on a newborn caused by severe congenital malformation, gene defect, or premature birth at less than 33 weeks' gestation.

3. Psychological or psychiatric disorders suffered by the pregnant woman or puerpera are caused by pregnancy or childbirth.

4. A childbirth accident for which a civil action, or private prosecution or accusation of a criminal case has already been filed. However, this does not apply to the following situations:

(1) The civil litigation is withdrawn before the conclusion of the court trial hearing in the first instance.

(2) For cases indictable only upon complaint, the accusation is withdrawn before the end of the investigation; or the private prosecution is withdrawn before the conclusion of the trial hearing in the first instance.

(3) For cases indictable not upon complaint, written intent of non-pursuit is submitted before the end of investigation.

5. Availability for cases to apply for relief pursuant to drug hazards, vaccinations and other laws.

6. Fake or fraudulent information used in the application for relief.

7. Childbirth accidents that occurred before the implementation of this Act".

Operational Procedures for Childbirth Accident Relief

Chapter 5

Analysis of Childbirth Accident Relief Applications

Since the implementation of the Childbirth Accident Emergency Relief Act on June 30, 2016, statistical data as of December 31, 2017 indicated that a total of 286 applications were received, with a total amount of NTD 130.8 million subsidized. The following analysis includes source of application, levels of medical care institution, childbirth accident by region of occurrence, sex ratio of newborns and fetuses, and results of the application review.

I. Source of application

Out of the 286 applications, 89 (or 31.1%) were applications from victims, 197 (or 68.9%) were applications from institutions as requested by the victims (see Figure 5-1).

II. Levels of medical care institution

Analysis of childbirth accident by levels of medical care institution: 71 incidents (24.8%) were occurred in clinics, 72 incidents (25.2%) in local hospitals, 57 incidents (19.9%) in regional hospitals, 85 incidents (29.7%) in medical centers (including would-be medical centers), with one home birth assisted by midwifery clinic (see Figure 5-2).

Compared to the number of reported births to NHIA in various levels of medical care institution, the distribution was shown in Table 5-1 and Figure 5-2.

III. Regional distribution

Analysis of childbirth accident by NHIA demarcated regions: 104 incidents (36.4%) in the Taipei region, 50 incidents (17.5%) in the northern region, 53 incidents (18.5%) in the central region, 38 incidents (13.3%) in the southern region, 36 incidents (12.6%) in the Kaohsiung-Pingtung region, and 5 incidents (1.7%) in the eastern region.

Compared to the number of reported births to NHIA in various regions, the distribution of the ratio was between 0.9‰ and 1.1‰, as shown in Table 5-2 and Figure 5-3.

IV. Sex ratio of newborns and fetuses

Analysis of childbirth accident by the sex ratio of newborns and fetuses: 69 incidents for newborns (male to female ratio of 2:1), and 126 incidents for fetuses (male to female ratio of 45:55), as shown in Table 5-3.

V. Results of the application review

The final number of relief cases granted was 282 (an approval rate of 98.6%), with a total amount of NTD 130.8 million subsidized, in which 90 incidents for pregnant women were subsidized a total amount of NTD 72 million (including 21 deaths for a total amount of NTD 42 million, and 69 major injuries for a total amount of NTD 30 million); 66 incidents for newborns were subsidized a total amount of NTD 21 million (including 64 deaths for a total amount of NTD 19.2 million, and 2 major injuries for a total amount of NTD 1.8 million); and 126 incidents for fetuses were subsidized a total amount of NTD 37.8 million (see Table 5-4 and Figure 5-4).

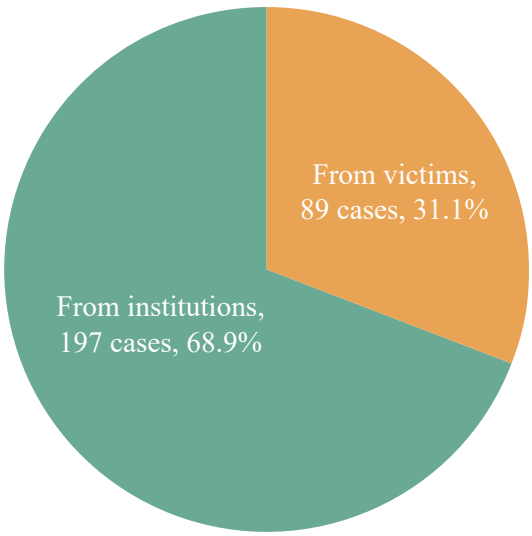


Figure 5-1. Source of Application

Table 5-1. Distribution of the number of applications and reported births by levels of medical care institution

Levels of Medical Care Institution	Reported Births (A)		Applications (B)		Ratio (B/A)
	No. of Births	Percentage	No. of Cases	Percentage	Cases/Reported Births
Medical Centers	51,951	17.7%	85	29.7%	1.6‰
Regional Hospitals	74,818	25.4%	57	19.9%	0.8‰
Local Hospitals	82,823	28.2%	72	25.2%	0.9‰
Clinics	84,048	28.6%	71	24.8%	0.8‰
Midwifery Clinics	177	0.1%	1	0.4%	5.6‰
Total	293,817	100.0%	286	100.0%	0.97‰

(Source of number of births: National Health Insurance Administration, statistics from June 30, 2016 to December 31, 2017)

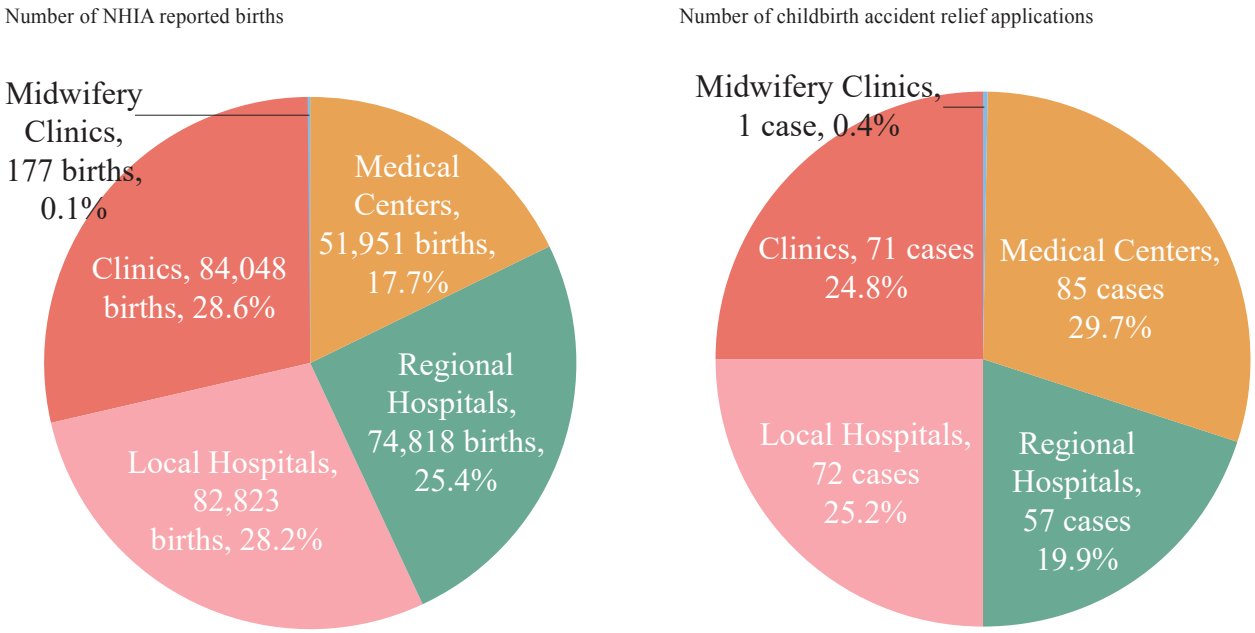
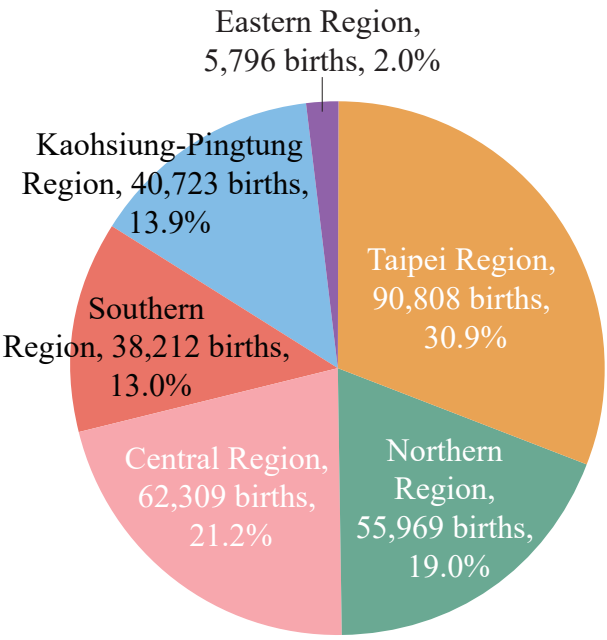


Figure 5-2. Distribution of the number of NHIA reported births and childbirth accident relief applications by levels of medical care institution

Table 5-2. Distribution of the number of applications and reported births by region

	Reported Births (A)		Applications (B)		Ratio (B/A)
NHIA Demarcated Regions	No. of Births	Percentage	No. of Cases	Percentage	Cases/Reported Births
Taipei Region	90,808	30.9%	104	36.4%	1.1‰
Northern Region	55,969	19.0%	50	17.5%	0.9‰
Central Region	62,309	21.2%	53	18.5%	0.9‰
Southern Region	38,212	13.0%	38	13.3%	1.0‰
Kaohsiung-Pingtung Region	40,723	13.9%	36	12.6%	0.9‰
Eastern Region	5,796	2.0%	5	1.7%	0.9‰
Total	293,817	100.0%	286	100.0%	0.97‰

Number of NHIA reported births



Number of childbirth accident relief applications

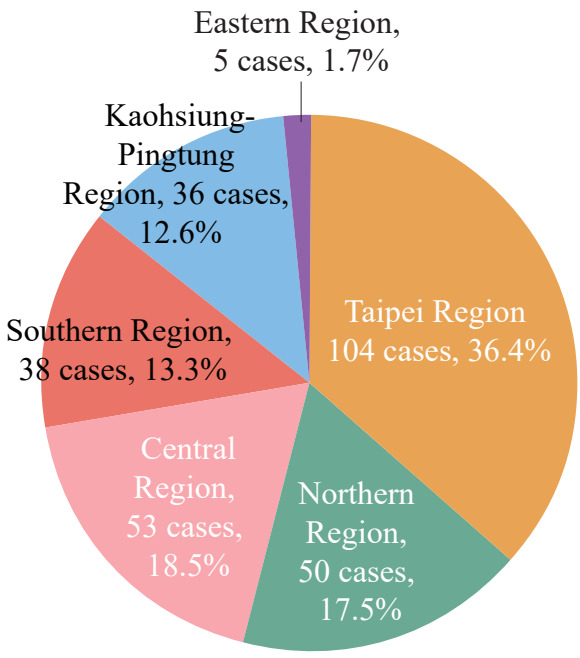


Figure 5-3. Distribution of the number of NHIA reported births and childbirth accident relief applications by region

Table 5-3. Gender analysis of newborn and fetal applications

Gender	Newborns	Fetuses
	No. of Cases（%）	No. of Cases（%）
Male	46（66.7%）	57（45.2%）
Female	23（33.3%）	69（54.8%）
Total	69（100.0%）	126（100.0%）

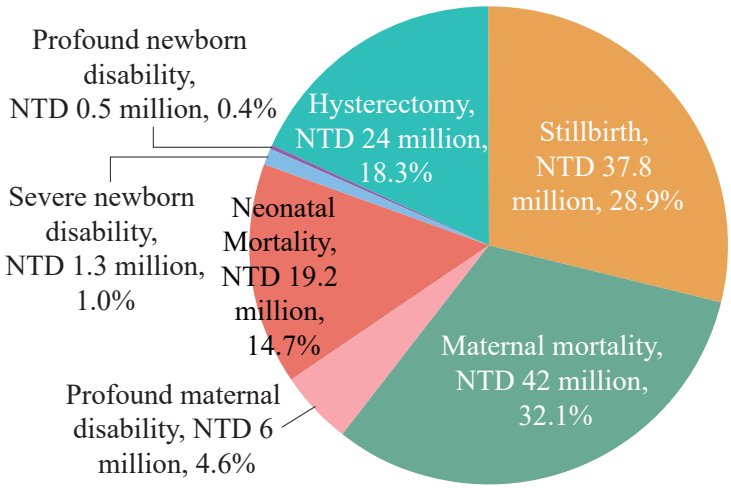


Figure 5-4. Distribution of the amount of relief granted by type of application

Table 5-4. Analysis of the relief applications granted (in NTD 10 thousand)

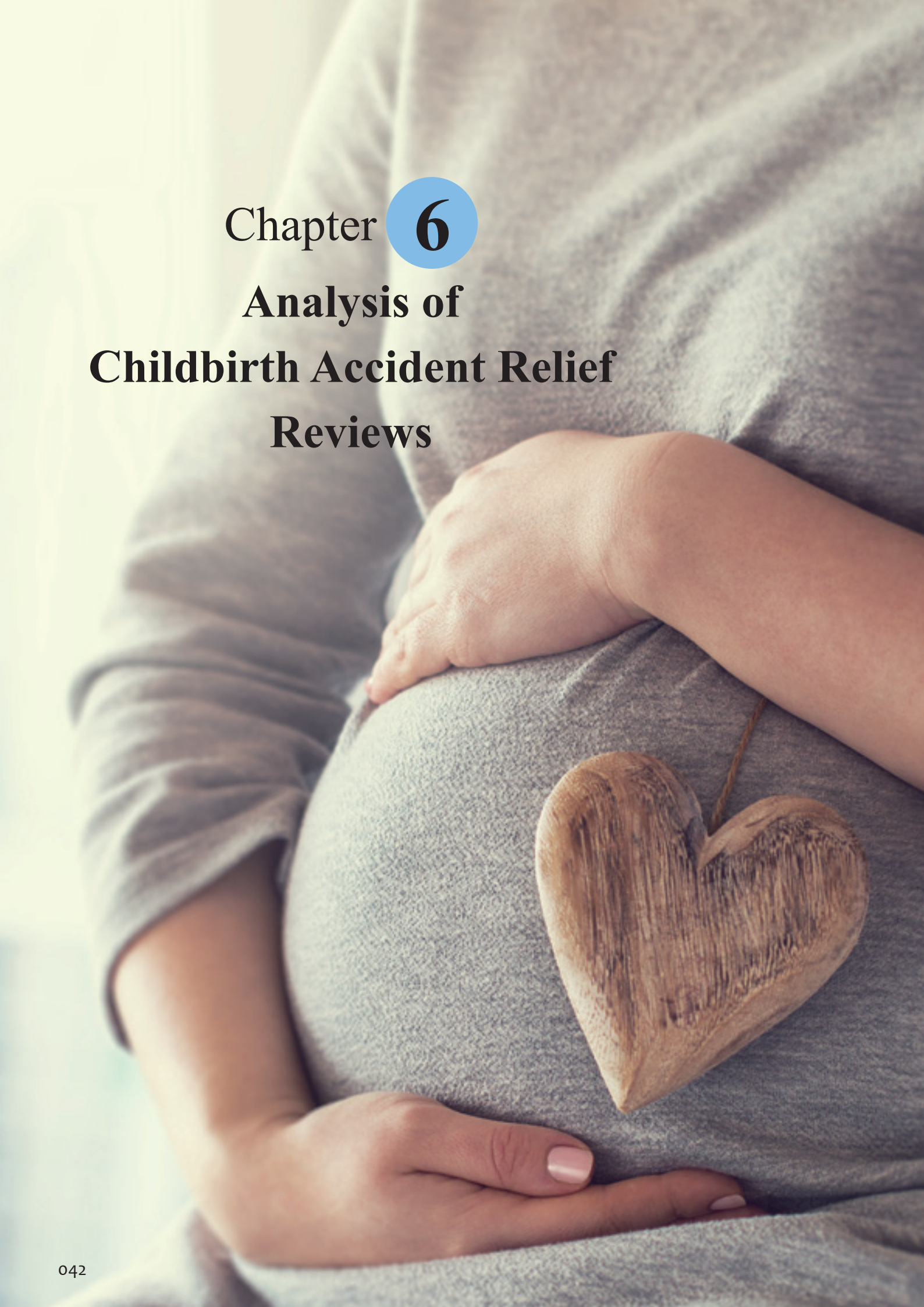
Accident victim	Pregnant Woman			Newborn		Fetus	Total
Result of accident	Death	Major injury		Death	Major injury (Moderate to severe disability)	Death	
		Moderate to severe disability	Hysterectomy				
Number of case granted relief	21	4	65	64	2	126	282
Average Amount	200	150	36.9	30	90	30	46.3
Median Amount	200	150	30	30	90	30	-
Minimum Amount	200	150	30	30	50	30	-
Maximum Amount	200	150	80	30	130	30	-
Total Amount	4,200	600	2,400	1,920	180	3,780	13,080

VI. Disapproved application

In accordance to Article 11 of the Childbirth Accident Emergency Relief Act, "the childbirth accident relief is available only for cases that have causation with childbirth or such causation cannot be excluded". Among the applications, four were deliberated and determined to have no causation with childbirth, and therefore were resolved as no relief granted. Incident diagnosis and the results were shown in Table 5-5.

Table 5-5. Analysis of the reasons for disapproval

	Date of Birth	Gestational Age	Main Diagnosis	Result	Reason for disapproval
Case 1	Dec 2016	38 weeks and 2 days	Unexplained encephalitis	Maternal death	No causation with childbirth
Case 2	Jan 2017	35 weeks	Congenital intestinal obstruction and sepsis	Neonatal death	No causation with childbirth
Case 3	April 2017	36 weeks and 1 day	Congenital heart disease	Neonatal death	No causation with childbirth
Case 4	May 2017	41 weeks and 2 days	Congenital heart disease	Neonatal death	No causation with childbirth



Chapter 6

Analysis of Childbirth Accident Relief Reviews

The Childbirth Accident Emergency Relief Act was implemented on June 30, 2016, which clearly stipulates "the right to claim childbirth accident relief expires in two years where no claim is made from the time when the eligible applicant becomes aware of the childbirth accident". This chapter analyzed the reviewed results of all applications eligible for childbirth accident relief from the date the Act taking into effect up to December 31, 2017. The following sections were divided into the different types of incidents covered by the scope of the Act, such as maternal mortality and major injury, newborn mortality and major injury, and fetal mortality.

Section 1 Analysis of Maternal Mortality

According to the World Health Organization (WHO), maternal mortality ratio is defined as "the death of a woman while pregnant or within 42 days of termination of pregnancy" per 100,000 live births in a year. In other words, any deaths of a pregnant woman related to or aggravated by pregnancy or its treatment, but not from accidental or incidental causes such as car accidents, suicide or murders, are defined as maternal mortality.

A WHO report showed that global maternal mortality ratio from 1990 to 2015 fell by nearly 44% to an estimated 216 maternal deaths per 100,000 live births in 2015. The goal is to reduce the global maternal mortality ratio to less than 70 per 100,000 live births by 2030 (see Table 6-1). However, a significant difference remains between countries around the world in quality of health care, definition of maternal mortality, and completeness of the death registration or reporting mechanism. As for the cause of maternal mortality, it is classified into direct and indirect causes of death as defined by the WHO. According to the statistical analysis between 2003 and 2009, the direct causes of maternal deaths were postpartum hemorrhage (27.1%), gestational hypertension (14.0%), infection and sepsis (10.7%), miscarriage (7.9%), and embolism (3.2%). Indirect causes of maternal deaths mostly relate to the women's existing diseases that resulted in pregnancy-related complications, such as cardiovascular disease (about 27.5%).

I. Current status in Taiwan

Taiwan's maternal mortality reached its peak in 1989 with a ratio of 12.7 (per 100,000 live births), and from there it has gradually fell. By 2010, the ratio stood at 4.2 (per 100,000 live

Table 6-1. Comparison of maternal mortality rates between 1990 and 2015 by country

Country / Year	R.O.C. (Taiwan)	UK	Canada	USA	Japan	S. Korea	Singapore	Finland
1990	12	10	7	12	14	21	12	6
1995	8	11	9	12	11	19	13	5
2000	8	12	9	12	10	16	18	5
2005	7	12	9	13	7	14	16	5
2010	4	10	8	14	6	15	11	3
2015	12	9	7	14	5	11	10	3

(Source: National Statistics R.O.C. (Taiwan) and WHO Global Health Observatory (GHO). The maternal mortality is calculated as number of people per 100,000 live births)

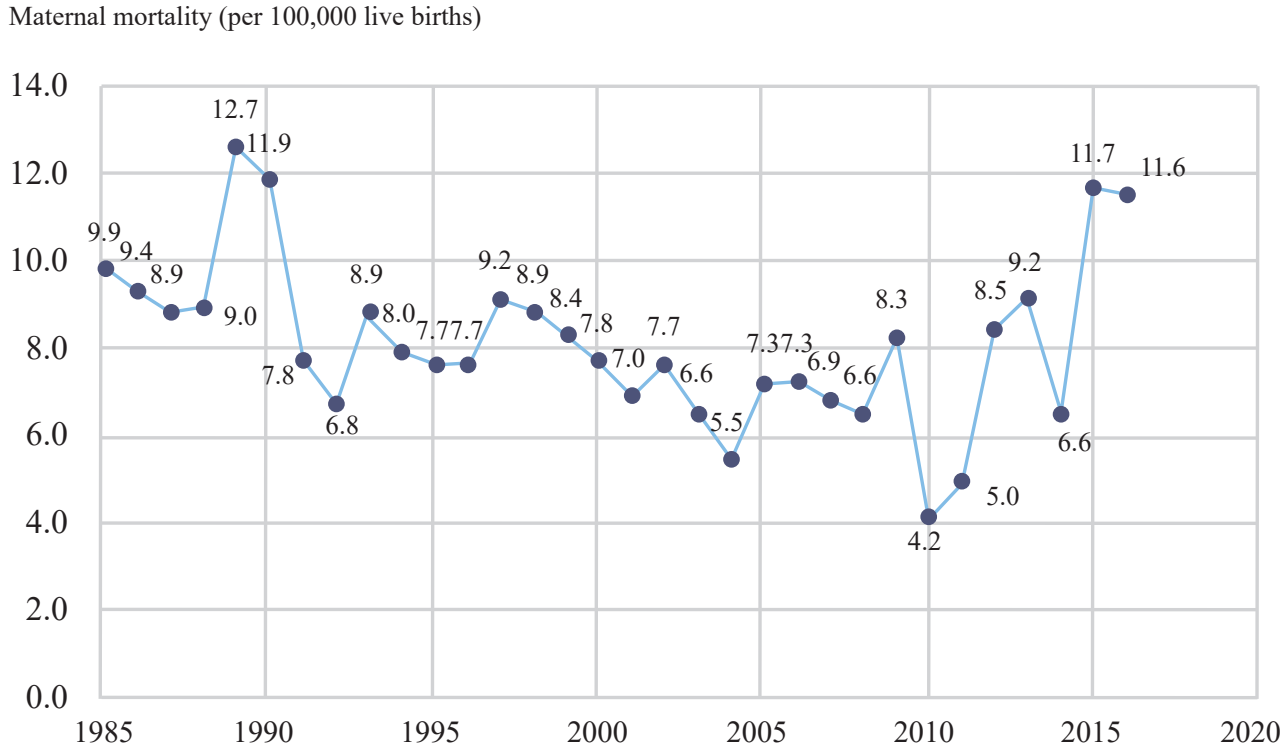


Figure 6-1. Changes in maternal mortality in R.O.C. (Taiwan) between 1985 and 2016

(Source: Department of Statistics, Ministry of Health and Welfare)

Note:

1. This table includes data from Kinmen County and Lienchiang County started from 1994.
2. The cause of death in this table has been classified as ICD-10 since 2008.
3. From 2015, the "pregnancy status" field in the death certificate is used to reconcile the statistics of maternal mortality.

births) as shown in Figure 6-1. However, to improve the accuracy of the registration data, the Ministry of Health and Welfare (MOHW) amended the national death certificate in 2015 to include “pregnancy status”, which adopted the definition by the WHO to include the death of a woman while pregnant or within 42 days of termination of pregnancy as part of the maternal mortality ratio. Although in the same year, Taiwan’s maternal mortality ratio rose to 11.7 (per 100,000 live births) and to 11.6 in 2016, the numbers were significantly lower than neighboring countries, such as China, Vietnam, and the Philippines. Taiwan was closer to Singapore and Korea in maternal mortality ratio, but slightly higher than Japan. However, since Japan defines their maternal mortality differently to international standards, it is difficult to be compared to other countries.

Moreover, the analysis of causes of maternal mortality by local scholars indicated that the most common direct causes of death between 2004 and 2011 were postpartum hemorrhage (43%), amniotic embolism (36%), and complications of gestational hypertension (12%). Indirect causes mostly were cardiovascular complications (20%) and stroke (43%).

II. Statistics and analysis of application

During the period of which the statistical data were analyzed, 22 cases of maternal mortality benefit applications were

received, and one had no causation with childbirth, so it was not granted relief benefit. Relief was granted to 21 of the cases with analysis as follows:

i. Levels of medical care institution

According to the distribution of childbirth accidents by levels of medical care institution, 7 cases were occurred in clinics (33.3%), 5 cases in local hospitals (23.8%), 7 cases in regional hospitals (33.3%), and 2 cases in medical centers (9.6%) (see Figure 6-2).

ii. Regional distribution

According to the distribution of childbirth accidents by NHIA demarcated regions, 7 cases were occurred in the Taipei region (33.3%), 5 cases in the northern region (23.8%), 4 cases in the central region (19.0%), 1 case in the southern region (4.9%), 4 cases in the Kaohsiung-Pingtung region (19.0%), and none in the eastern region (see Figure 6-3).

iii. Gestational age

According to the distribution of childbirth accidents by gestational age, 18 cases of full-term births were given at or after 37 weeks of gestation (85.7%); 3 cases of premature births including 2 cases of births at 33 weeks (9.5%), and 1 case of birth at 28 weeks (see Figure 6-4).

iv. Birth order

According to the distribution of childbirth accidents by birth order, 12 cases were first birth (57.1%), 3 cases were second birth (14.3%), 4 cases were third birth (19.0%), and 1 case for fourth and sixth birth each (4.8% each) (see Figure 6-5).

v. Age of mother at childbirth

According to the distribution of childbirth accidents by age of mother at childbirth, 8 cases were in the age group of 36-40 years with the highest number of cases (38.2%), followed by 7 cases in the age group of 31-35 years (33.2%), 3 cases in the age group of 26-30 years (14.3%), 2 cases of 40 years and older (9.5%), and 1 case of younger than 25 years old (4.8%) (see Figure 6-6).

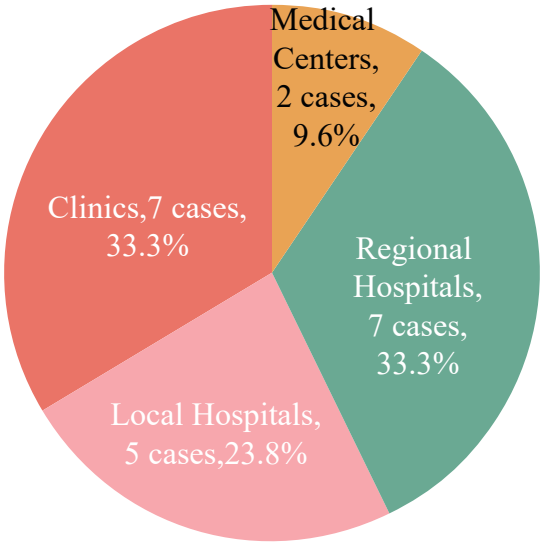


Figure 6-2. Distribution of maternal mortality by levels of medical care institution

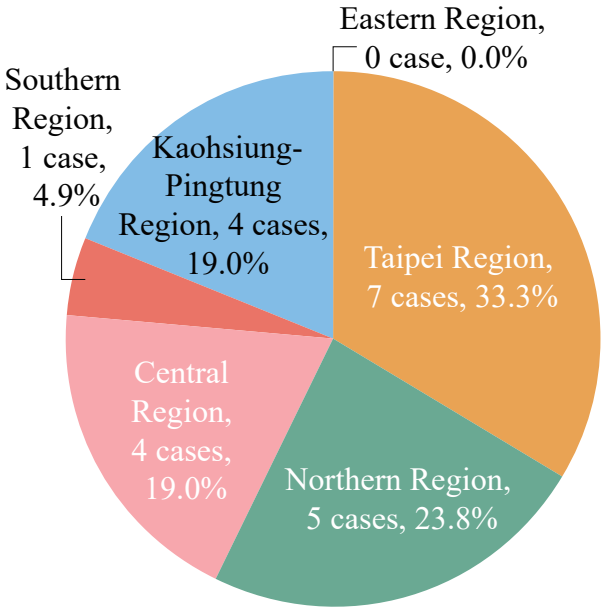


Figure 6-3. Distribution of maternal mortality by region

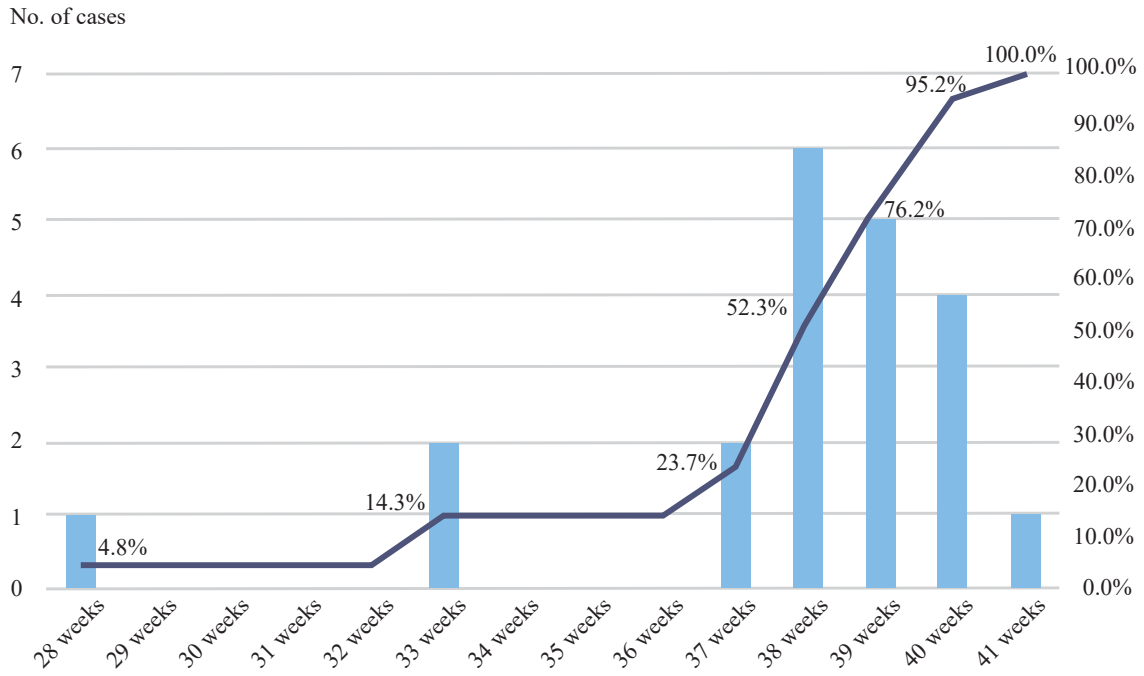


Figure 6-4. Distribution of maternal mortality by gestational age

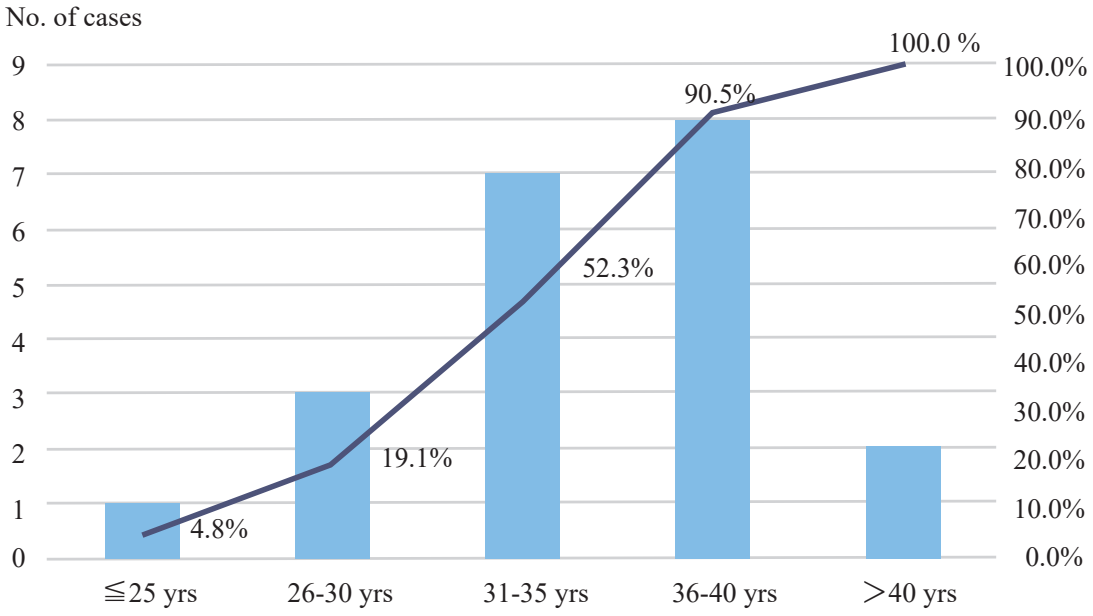


Figure 6-6. Distribution of maternal mortality by age of mother at childbirth

vi. Delivery method

According to the distribution of childbirth accidents by delivery method, 7 cases were vaginal delivery, 4 cases were planned caesarean section, and 10 cases were unplanned emergency caesarean section.

vii. Causes of childbirth accident

Analyzing the causes of maternal mortality, there were 18 cases by direct causes and 3 by indirect causes, elaborated as follows: 9 cases of suspected or confirmed amniotic embolism, 7 cases of antepartum or postpartum hemorrhage, 4 cases of pulmonary embolism, 1 case of cerebral infarction. There were 1 case of Onset Still's Disease and 1 case of acute myocardial infarction, where 2 cases occurred amniotic embolism and postpartum hemorrhage simultaneously.

If we observed the timing of the incident, 2 cases were antepartal, 4 cases were intrapartal, and 15 cases were postpartal.

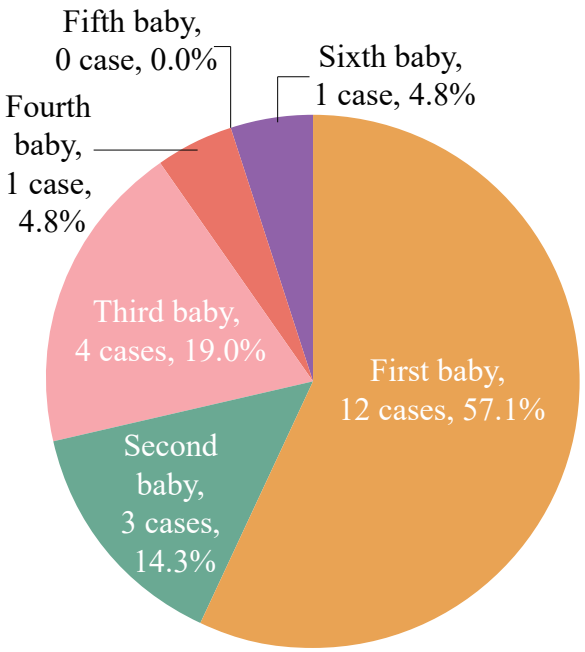


Figure 6-5. Distribution of maternal mortality by birth order

Section 2 Analysis of major maternal injury

WHO defines maternal near-miss as a woman who nearly died but survived a life-threatening complication that occurred during pregnancy, childbirth or within 42 days of termination of pregnancy in 2011. The aforementioned complications can arise from the dysfunction or loss of cardiovascular, respiratory, renal, liver, neural, coagulation and uterus function. As the maternal complications outnumbers maternal mortality, collection and analysis of such data will not only provide key information to understanding severe obstetric complications and demonstrating results of medical treatment, but also serve as a quality indicator for maternal care.

Postpartum hemorrhage has always been one of the top causes of maternal mortality. When medical treatments cannot effectively stop the bleeding, physician may resort to emergency hysterectomy. So, in order to reduce the chance of emergency hysterectomy, we would need to approach the root cause of postpartum hemorrhage. The most common reason for postpartum hemorrhage is poor uterine contraction that accounts for more than 80% of cases of postpartum hemorrhage, with other reasons including birth injury and coagulation disorders. Hemorrhage derived from birth injury could possibly come from obstetric laceration of cervix or vagina, surgical wound, or uterine rupture. Coagulation disorders could play the role in both the cause and the effect when postpartum hemorrhaging occurs.

According to statistics, the incidence of emergency hysterectomy is 0.24-8.7 per 1,000 deliveries, and it occurs more frequently in caesarean section than in vaginal birth. Common reasons for emergency hysterectomy are placenta previa or placenta accreta, followed by poor uterine contraction and uterine rupture. Risk factors include advanced maternal age (≥35 years of age), obesity, multiple pregnancy, birth after caesarean section, scarred uterus, and major hemorrhage.

I. Current status in Taiwan

According to a retrospective study on single fetal pregnancy using the statistics of National Health Insurance

Research Database of Taiwan in 2002, the method of delivery by Taiwanese citizens were vaginal birth (66.5%), cesarean section (33.2%), and vaginal birth after c-section (0.3%). Out of the 214,237 samples of single fetal pregnancy from this study, 287 patients received postpartum hysterectomy (incidence of 1.34 per 1,000 deliveries). Looking at the age analysis, the lowest incidence rate was in the age group of 20-24 years, slightly higher in the age group of over 30 years, and the highest in the age group of over 35 years. Furthermore, hysterectomy cases were significantly more among medical centers, regional hospitals, and local hospitals than among clinics, perhaps related to the medical referral and evacuation of patient with high-risk pregnancy.

II. Statistics and analysis of application

During the period of which the statistical data were analyzed, 69 cases of maternal injury benefit applications were received, with 4 cases of moderate to severe disability and 65 cases of hysterectomy. All the cases were granted relief benefit, and the analysis was as follows:

i. Levels of medical care institution

According to the distribution of childbirth accidents by levels of medical care institution, 11 cases were occurred in clinics (15.9%), 14 cases in local hospitals (20.3%), 21 cases in regional hospitals (30.4%), and 23 cases in medical centers (33.4%) (see Figure 6-7).

ii. Regional distribution

According to the distribution of childbirth accidents by NHIA demarcated regions, 25 cases were occurred in the Taipei region (36.2%), 15 cases in the northern region (21.7%), 18 cases in the central region (26.1%), 5 cases in the southern region (7.3%), 5 cases in the Kaohsiung-Pingtung region (7.3%), and 1 case in the eastern region (1.4%) (see Figure 6-8).

iii. Gestational age

According to the distribution of childbirth accidents by gestational age, 49 cases of full-term birth were given at or after 37 weeks of gestation (71.0%) and 20 cases of premature births (29.0%) (see Figure 6-9).

iv. Birth order

According to the distribution of childbirth accidents by birth order, 26 cases were first birth (37.7%), 22 cases were second birth (31.9%), 15 cases were third birth (21.7%), 5 cases were fourth birth (7.2%), and 1 case were fifth birth (1.5%) (see Figure 6-10).

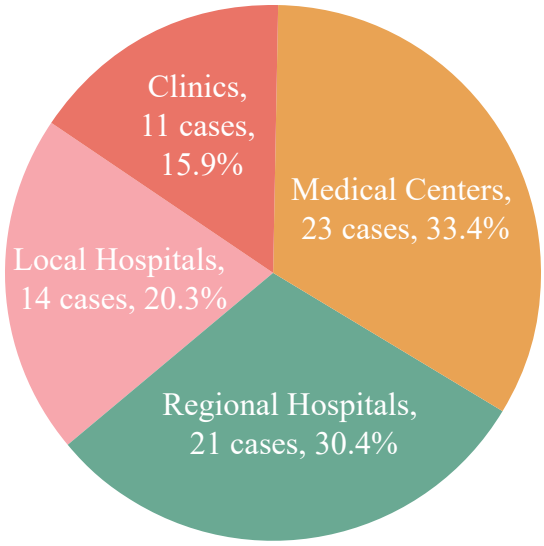


Figure 6-7. Distribution of major maternal injury by levels of medical care institution

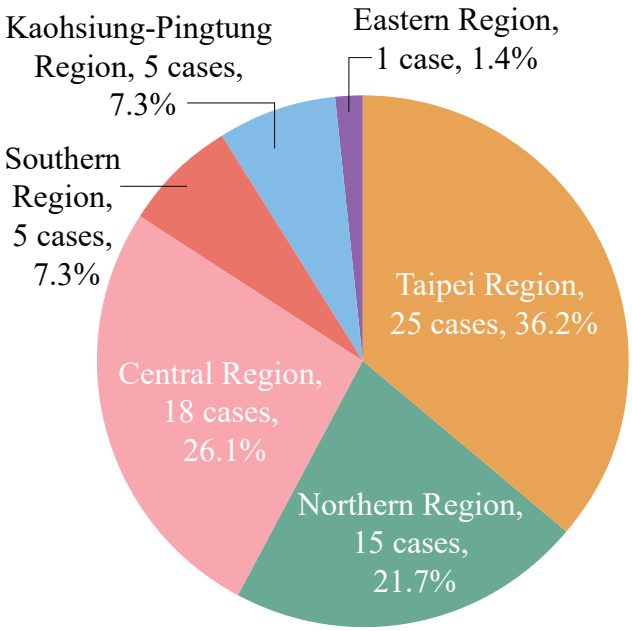


Figure 6-8. Distribution of major maternal injury by region

v. Age of mother at childbirth

According to the distribution of childbirth accidents by age of mother at childbirth, 31 cases were in the age group of 36-40 years with the highest number of cases (44.9%), followed by 27 cases in the age group of 31-35 years (39.1%), 4 cases in the age group of 26-30 years (5.8%), 6 cases of 40 years and older (8.7%), and 1 case of younger than 25 years old (1.5%) (see Figure 6-11).

vi. Delivery method

According to the distribution of childbirth accidents by delivery method, out of the 65 cases of hysterectomy, 21 were vaginal delivery (32.3%), 28 were planned caesarean section (43.1%), and 16 were unplanned emergency caesarean section (24.6%). Out of the 4 cases with moderate to severe disability, 3 were caesarean section and 1 was vaginal birth.

vii. Causes of childbirth accident

Analyzing the causes of major maternal injury, there were 4 cases of disabilities, in which 2 cases were suspected amniotic embolism the day after delivery, 1 case of postpartum HELLP syndrome, and 1 case of suspected anesthesia complications after caesarean section.

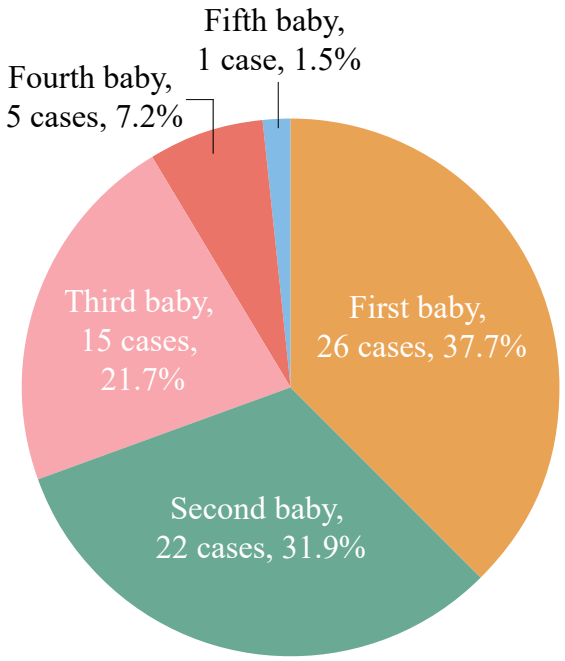


Figure 6-10. Distribution of major maternal injury by birth order

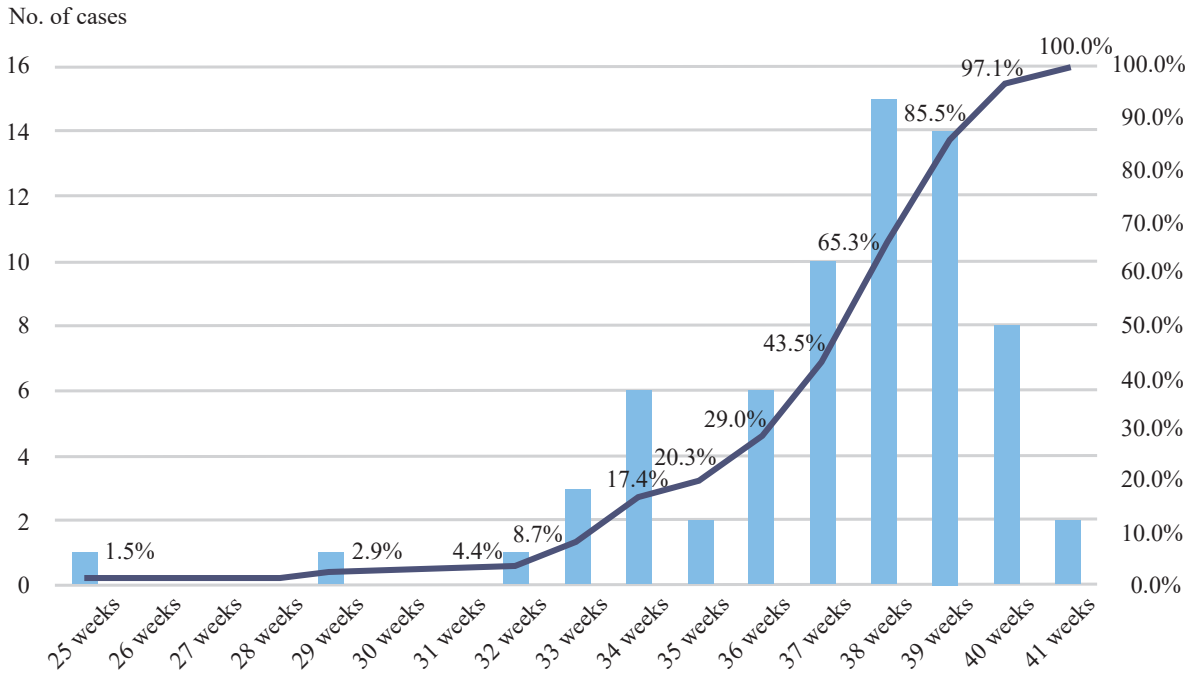


Figure 6-9. Distribution of major maternal injury by gestational age

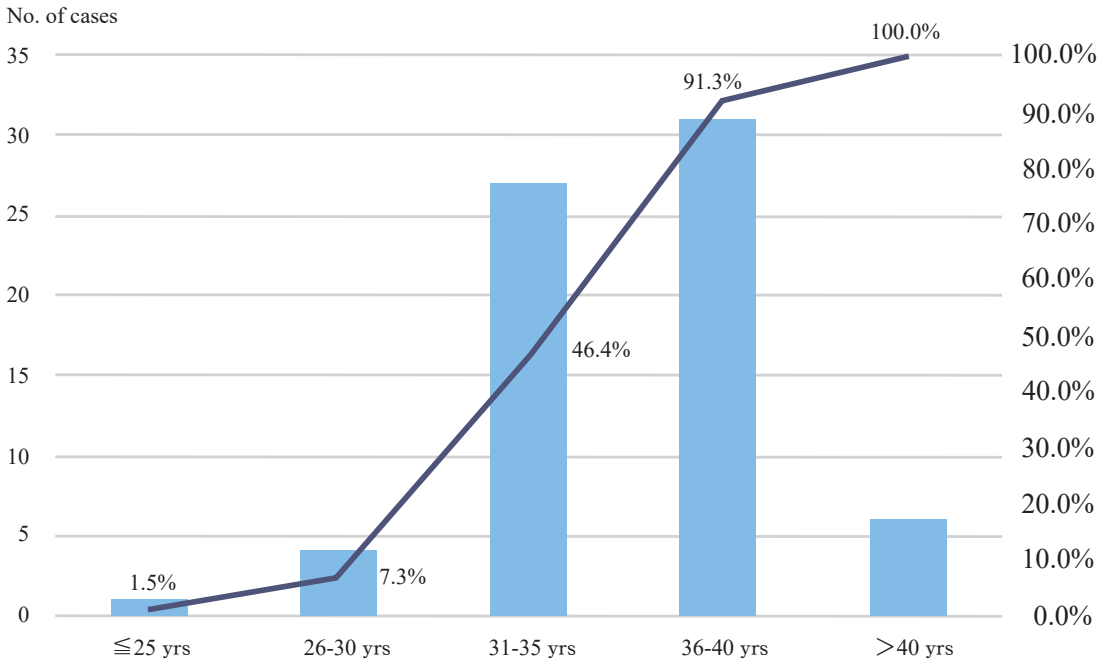


Figure 6-11. Distribution of major maternal injury by age

Analyzing the causes of the 65 cases of hysterectomy (see Table 6-2), each case may have more than one single cause, but most cases experienced postpartum hemorrhage (57 cases, or 87.7%), and the causes of the hemorrhage include poor uterine contraction and disseminated intravascular coagulation (DIC). Further analyzing the cases of postpartum hemorrhage that resulted in hysterectomy, 23 cases were combined with placenta-related factors, accounting for 40.4% of the cases (see Table 6-3). Analyzing the type of hysterectomy, 26 cases were total hysterectomy (40.0%) and 39 cases were subtotal hysterectomy (60.0%).

Table 6-2. Analysis of causes of hysterectomy

Causes	No. of cases（%）
Postpartum hemorrhage	57（87.7%）
Placenta accreta	2（3.1%）
Placenta previa and placenta accreta	4（6.1%）
Bladder/fallopian tube rupture	2（3.1%）
Total	65（100%）

Table 6-3. Analysis of causes of hysterectomy caused by postpartum hemorrhage

Causes	No. of cases (%)
Not combined with other factors	27（47.4%）
Placenta accreta	9（15.8%）
Placenta previa	5（8.8%）
Placenta previa and placenta accreta	3（5.3%）
Retained placenta	2（3.5%）
Abruptio placenta	3（5.3%）
Abruptio placenta and Uterine laceration	1（1.7%）
Uterine/Ovarian laceration	5（8.8%）
Uterine fibroids and internal bleeding	1（1.7%）
Intrauterine infection	1（1.7%）
Total	57（100%）

Section 3 Analysis of Neonatal Mortality and Major Injury

According to the WHO data, global neonatal mortality in the first 28 days of life shows gradual downward trend each year. In 2000, the neonatal mortality rate stood at 30.7 deaths per 1,000 live births, dropped to 22.5 deaths per 1,000 live births in 2010, and by 2016, the neonatal mortality rate was at 18.6 deaths per 1,000 live births. The statistical data of the United States show a similar trend. Since 1960, the U.S. neonatal mortality rate has dropped sharply, and by the 1970s, it was lower than 15 deaths per 1,000 live births. Post 1990, the neonatal mortality rate of the U.S. maintained below 5 deaths per 1,000 live births (4.6 by 2000, 4.1 by 2010, and 3.7 by 2016). The major causes of neonatal mortality include infection (36%), premature birth (28%), and fetal asphyxia (23%). However, the causes and rate of neonatal mortality are greatly different from country to country and are dependent on the health care system provided. For countries with abundant medical care resources, neonatal mortality is mostly related to premature births, congenital abnormality, and perinatal issues.

I. Current status in Taiwan

Regarding the total number of newborns in Taiwan, according to the statistics of birth reporting system of the Ministry of Health and Welfare, in 2016, the total number of births was 210,269, among which 1.16% were stillbirths and 98.84% were live births. According to the analysis of the place of birth delivery, 150,408 births were in hospitals (71.53%), 59,466 births in clinics (28.28%), and 395 births in midwifery clinics, home, or any other place (0.19%). Birth weight statistics for newborns were as follows: 185,949 births weighed between 2,500-3,999 grams (88.43%), and 2,621 births weighed ≧ 4,000 grams (1.25%). According to the week of pregnancy, 93,981 women (44.7%) delivered in 37-38 weeks of gestation, 90,160 women (42.88%) delivered in 39-40 weeks, and 22,562 women (10.73%) delivered before 37 weeks.

According to the annual birth weight analysis of live births, the birth weight of <2,500 grams was between 7.3% and 9.3% of the total reported, showing gradual increase every year. For live births with birth weight ≧ 4,000 grams, the number maintained between 1.2% and 2.4%, showing gradual decrease every year. Analyzing the annual gestational age of live births given, the number maintained between 8.4% and 9.8% for births given before 37 weeks with no significant changes. Live births given at or after 42 weeks maintained a number below 0.4% of the total reported, showing a trend of annual decrease.

According to the statistics of MOHW, neonatal mortality was 2.7 deaths per 1,000 live births in 2011, 2.3 deaths per 1,000 live births in 2012, 2.4 deaths per 1,000 live births in 2013, 2.2 deaths per 1,000 live births in 2014, 2.5 deaths per 1,000 live births in 2015, and 2.4 deaths per 1,000 live births in 2016. According to the statistical analysis of Taiwanese scholars, neonatal mortality (less than 28 days of life) between 2011 and 2013 was 2.4 deaths per 1,000 live births, which ranked 16th compared to the 33 Organization for Economic Co-operation and Development (OECD) countries.

II. Statistics and analysis of application

The childbirth accident relief targeted newborns with gestational age greater than 33 weeks. During the period of which the statistical data were analyzed, a total of 69 cases of neonatal mortality and major injury benefit applications were received, with 3 cases of deaths without any causation with childbirth that was not granted relief. The analysis of the 66 cases of neonatal mortality and major injury relief that were granted were as follows:

i. Levels of medical care institution

According to the distribution of childbirth accidents by levels of medical care institution, 24 cases were occurred in clinics (36.4%), 19 cases in local hospitals (28.8%), 11 cases in regional hospitals (16.7%), and 12 cases in medical centers (18.1%) (see Figure6-12).

ii. Regional Distribution

According to the distribution of childbirth accidents by NHIA demarcated regions, 24 cases were occurred in the Taipei region (36.4%), 8 cases in the northern region (12.1%), 10 cases in the central region (15.2%), 10 cases in the southern region (15.2%), 12 cases in the Kaohsiung-Pingtung region (18.1%), and 2 cases in the eastern region (3.0%) (see Figure 6-13).

iii. Gestational age

According to the distribution of childbirth accidents by gestational age, 53 cases of full-term births were given at or after 37 weeks of gestation (80.3%), and 13 cases of premature births (19.7%) (see Figure 6-14).

iv. Birth order

According to the distribution of childbirth accidents by birth order, 41 cases were first birth (62.1%), 18 cases were second birth (27.3%), 6 cases were third birth (9.1%), and 1 case was fourth birth (1.5%) (see Figure 6-15).

v. Age of mother at childbirth

According to the distribution of childbirth accidents by age of mother at childbirth, 26 cases were in the age group of 31-35 years with the highest number of cases (39.4%), followed by 14 cases each in the age groups of 26-30 years and 36-40 years (21.2% each), 5 cases of 40 years and older (7.6%), and 7 cases of younger than 25 years old (10.6%) (see Figure 6-16).

vi. Causes of childbirth accident

Analyzing the causes of neonatal mortality and major injuries, some of the cases exhibited a few risk factors before childbirth, for example, preeclampsia (5 cases), gestational diabetes (4 cases), and others, such as fetal growth retardation or gestational hypertension, premature birth, and premature rupture of membrane. However, there is usually no single cause that results in neonatal mortality or major injury, and it is often due to a combination

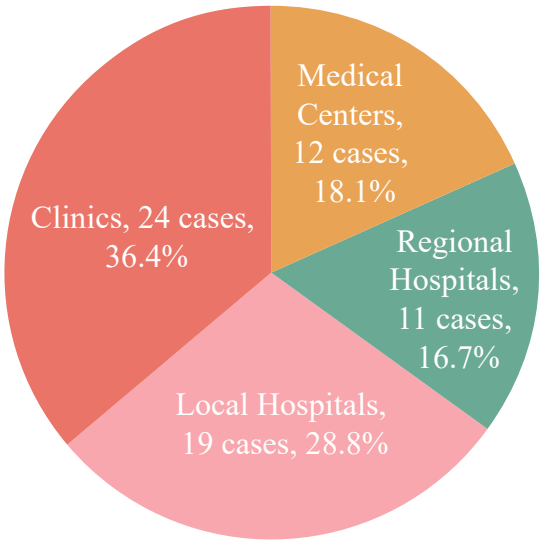


Figure 6-12. Distribution of neonatal mortality and major injury by levels of medical care institution

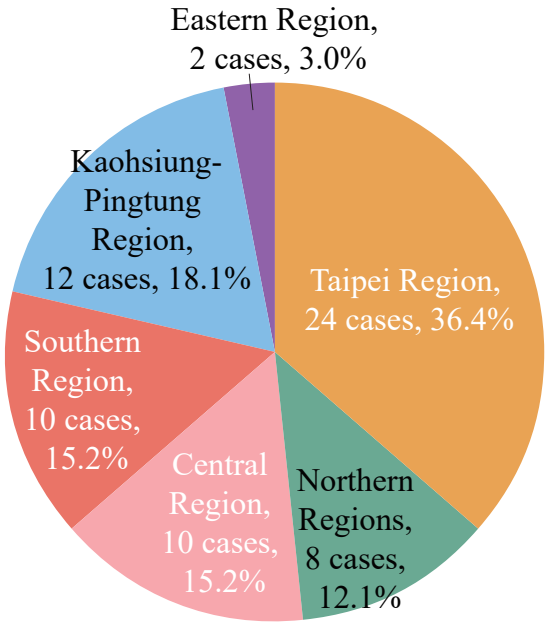


Figure 6-13. Distribution of neonatal mortality and major injury by region

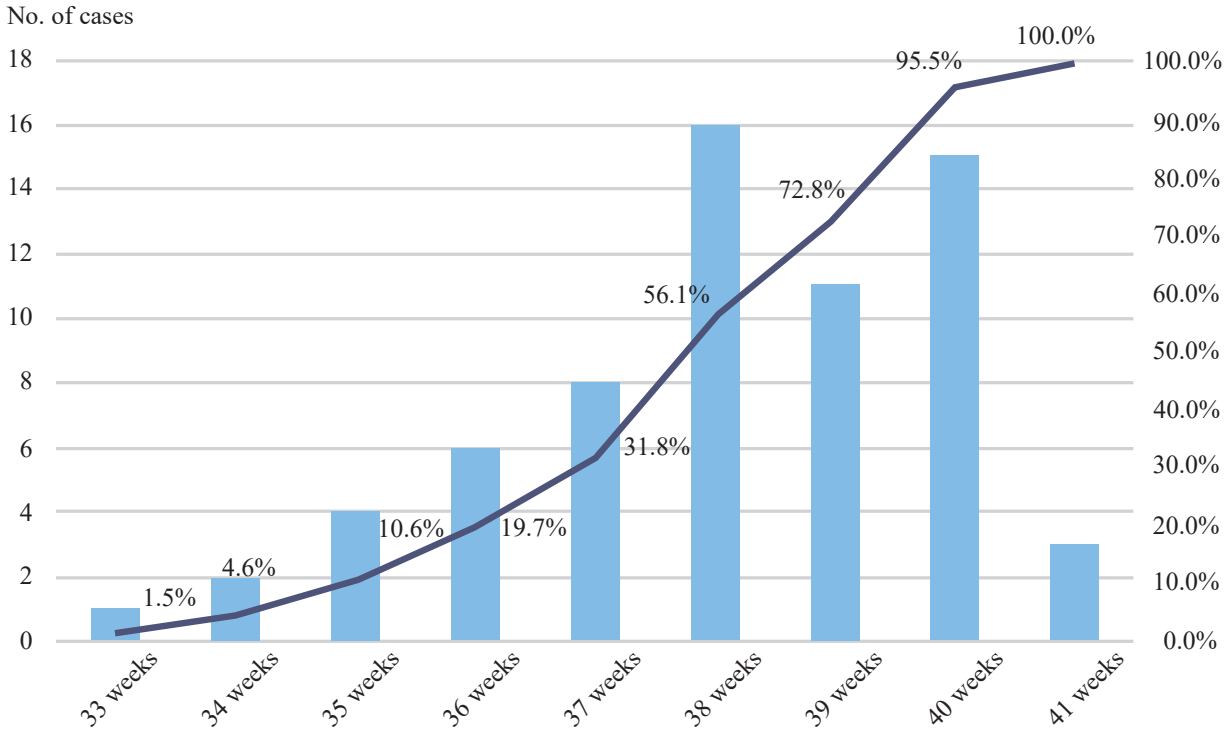


Figure 6-14. Distribution of neonatal mortality and major injury by gestational age

of multiple causes (see Table 6-4). Out of the 66 cases that were granted relief, the major causes in order were antepartal fetal distress, abruptio placenta, and meconium aspiration syndrome. However, among the cases involving antepartal fetal distress, it was found that many cases had a combination of abnormal or prolonged labor, and some cases had a combination of abruptio placenta, or a combination of nuchal cord, umbilical abnormality, or meconium aspiration syndrome.

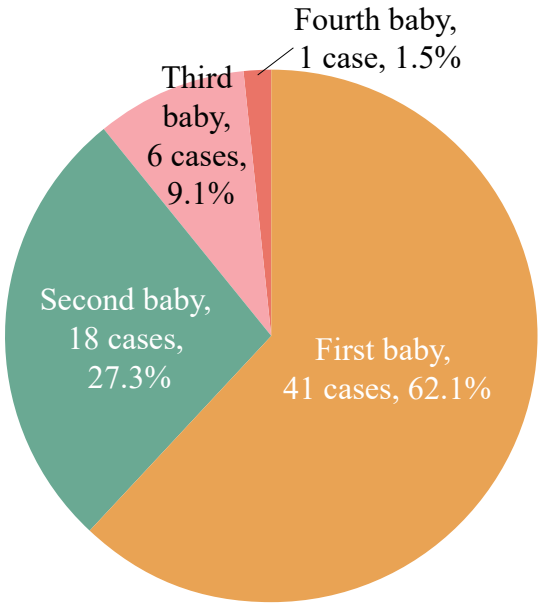


Figure 6-15. Distribution of neonatal mortality and major injury by birth order

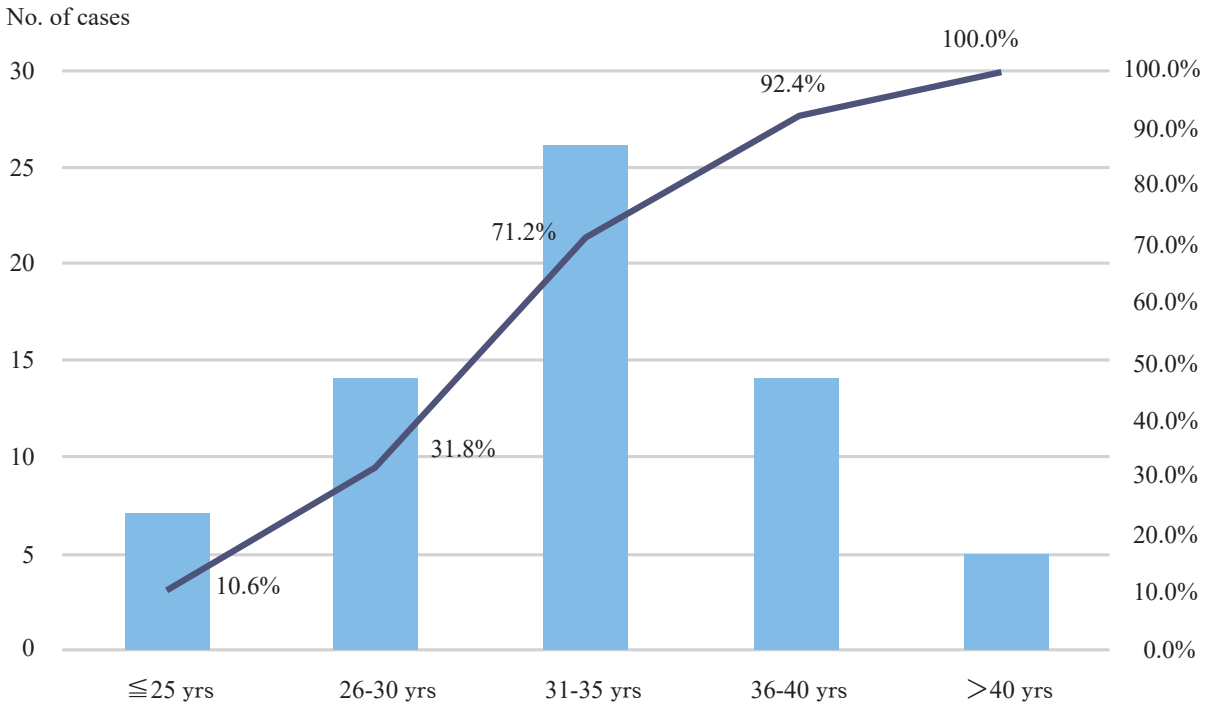


Figure 6-16. Distribution of neonatal mortality and major injury by age of mother at childbirth

Table 6-4. Analysis of causes of neonatal mortality and major injury

Causes	No. of cases（%）
Fetal distress	36（54.5%）
Abruptio placenta	14（21.2%）
Meconium aspiration syndrome, meconium stained liquor	14（21.2%）
Pulmonary hypertension, pneumorrhagia, respiratory distress	11（16.7%）
Nuchal cord, umbilical cord abnormalities, umbilical cord accidents	5（7.6%）
Cerebral hemorrhage, intracranial hemorrhage	5（7.6%）
Abnormal labor, prolonged labor	4（6.1%）
Shoulder dystocia, brachial plexus injury	3（6.1%）
Infection	3（4.5%）
Placental insufficiency	2（3.0%）
Neonatal anemia	1（1.5%）
Unknown causes	1（1.5%）

Section 4 Analysis of Fetal Mortality

In 2016, the WHO published the “Making every baby count: audit and review of stillbirths and neonatal deaths” in hopes of reducing stillbirths to 12 or fewer per 1,000 live births in all countries (including underdeveloped countries) by 2030. The report defined stillbirth as bodyweight ≥ 1000g, ≥ 28 completed weeks of gestation, or body length ≥ 35cm. However, the definition of stillbirth was updated by the US Centers for Disease Control and Prevention (CDC) in October 2017 as either early stillbirth (between 20 and 27 completed weeks of pregnancy), late stillbirth (between 28 and 36 completed pregnancy weeks), or term stillbirth (between 37 or more completed pregnancy weeks).

In a latest retrospective review of 85 national stillbirth reports across 50 countries with a total of 489,089 stillbirths between 2009 and 2016, published by the Royal Society of Medicine of the United Kingdom in 2017, a new disease classification system was used to engage in reclassification and analysis of cause, and the results showed that "unexplained" was the most common cause of death among these stillbirths regardless of high-, middle-, or low-income countries. However, in low-income countries, ratio of fetal asphyxia and infection was higher than other countries. Apart from unknown reasons, placenta-related factors were the major reasons for stillbirths in middle- and high-income countries.

I. Current status in Taiwan

There are many causes resulting in intrauterine fetal death, for reasons associated to the maternal body as follows: gestational diabetes, gestational hypertension, immune diseases, and postdatism in pregnancy. Causes of fetal death related to the fetal conditions include intrauterine fetal growth retardation, polyhydramnios or oligohydramnios, chromosomal abnormalities, congenital malformation, and hemolytic disease of the fetus. Causes of death related to placenta and umbilical cord include umbilical cord prolapse, kinking of umbilical cord, umbilical cord embolism, abruptio placenta, placental insufficiency, placenta previa, Twin to Twin Transfusion Syndrome (TTTS), and fetomaternal transfusion. Complications during childbirth include preterm labor, premature rupture of membrane, infection, fetal distress, and perinatal asphyxia; however, unknown reasons account for a large percentage of intrauterine fetal death.

The National Taiwan University Hospital conducted a statistical analysis on the causes of stillbirth in Taiwan between 2001 and 2004, and the data showed that there were 8,841 stillbirths out of the 932,497 total births, a ratio of 9 stillbirths per 1,000 live births. Stillbirths for multiple births was 3 to 6 times higher than average pregnancies, and woman younger than 20 or older than 40 years old also increased her chance of having stillbirth by two to three times. While mother suffered from diabetes, hypertension and other diseases increased the chance of stillbirth, Rh isoimmunization, polyhydramnios or oligohydramnios, and cervical incompetence would also increase the chance of stillbirth.

Additionally, according to local research data, from September 1999 to December 2011, there was a total of 121 stillbirths out of 12,290 total births, a fetal mortality rate of 9.8 per 1,000 live births. The top reason of stillbirth in the second trimester was unknown reasons (29.85%), followed by congenital abnormalities (19.4%) and abnormalities of the umbilical cord (16.42%). For stillbirth in the third trimester, the top cause was umbilical cord accidents (33.33%), followed by maternal diseases (24.07%) and unknown reasons (14.81%). Consolidating all causes of stillbirth in second and third trimesters, the top cause was abnormalities or accidents of the umbilical cord (23.97%), followed by unknown reasons (23.14%) and maternal diseases (14.05%).

II. Statistics and analysis of applications

The childbirth accident relief targeted newborns or fetuses with gestational age greater than 33 weeks. During the period of which the statistical data were analyzed, there were 126 cases of stillbirths, and the analysis was as follows:

i. Levels of medical care institution

According to the distribution of childbirth accidents by levels of medical care institution, 26 cases were occurred in clinics (20.6%), 34 cases in local hospitals (27.0%), 18 cases in regional hospitals (14.3%), 47 cases in medical centers (37.3%), and 1 case in midwifery institutions (0.8%) (see Figure6-17).

ii. Regional distribution

According to the distribution of childbirth accidents by NHIA demarcated regions, 46 cases were occurred in the Taipei region (36.5%), 22 cases in the northern region (17.5%), 21 cases in the central region (16.7%), 21 cases in the southern region (16.7%), 14 cases in the Kaohsiung-Pingtung region (11.1%), and 2 cases in the eastern region (1.5%) (see Figure 6-18).

iii. Gestational age

According to the distribution of childbirth accidents by gestational age, 79 cases of full-term birth were given at or after 37 weeks of gestation (62.7%) and 47 cases of premature births (37.3%) (see Figure 6-19).

iv. Birth order

According to the distribution of childbirth accidents by birth order, 76 cases were first birth (60.3%), 37 cases were second birth (29.4%), 11 cases were third birth (8.7%), 1 case was fourth birth (0.8%), and 1 case was sixth birth (0.8%) (see Figure 6-20).

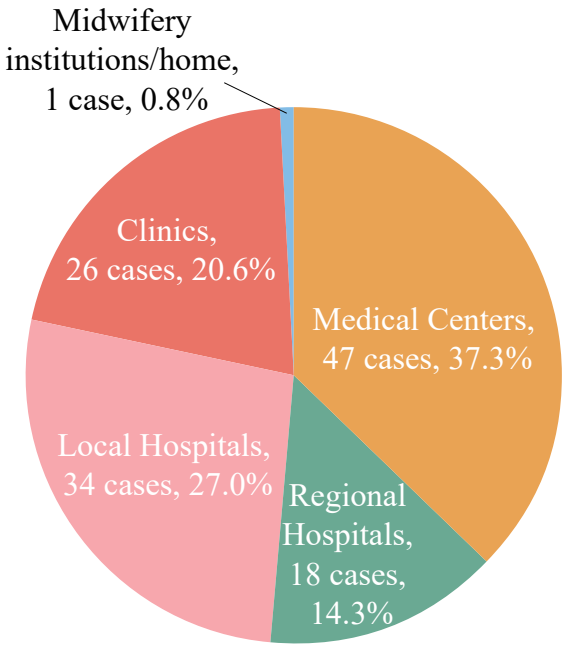


Figure 6-17. Distribution of fetal mortality by levels of medical care institution

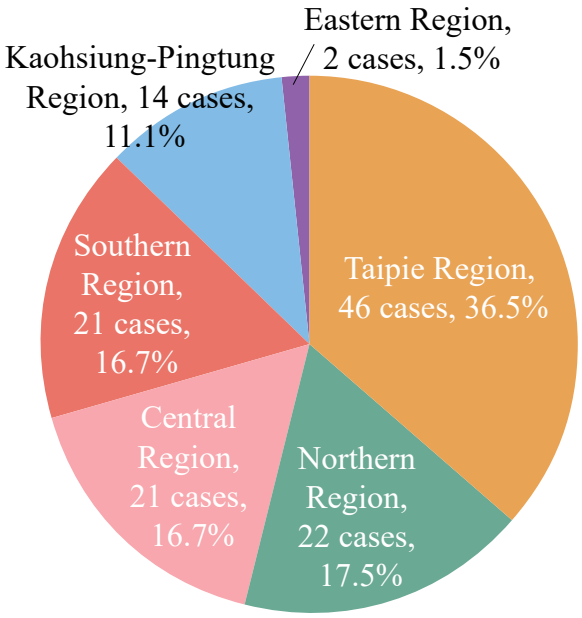


Figure 6-18. Distribution of fetal mortality by region

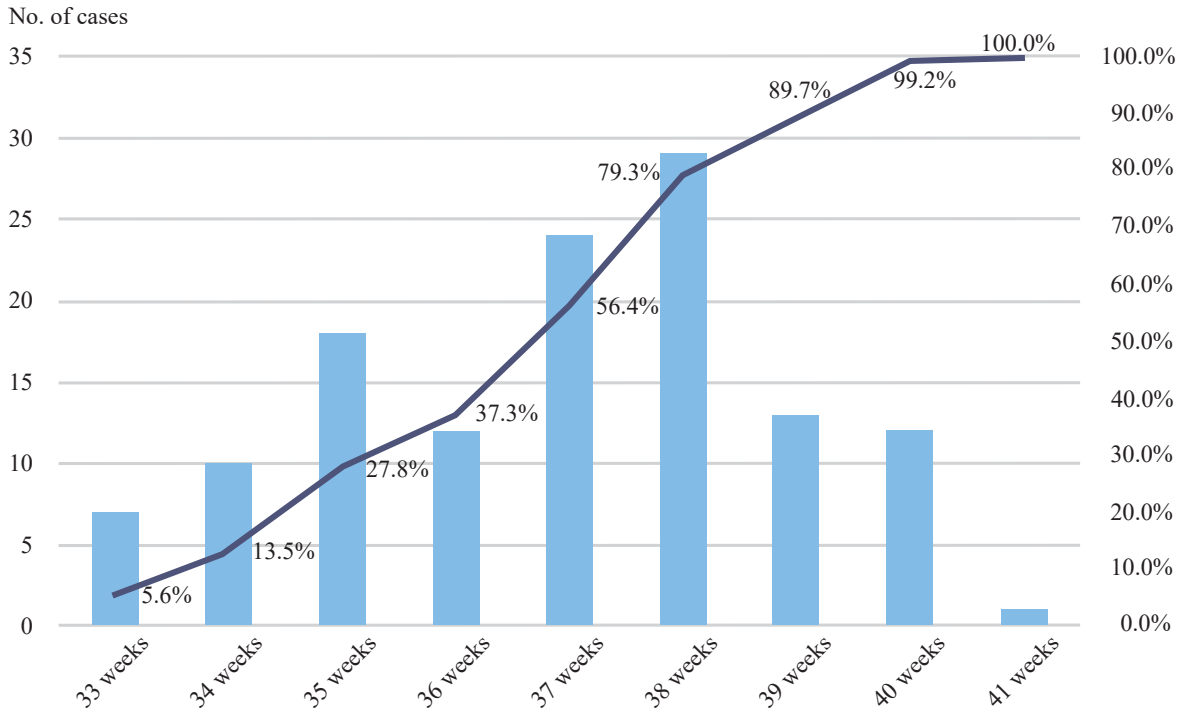


Figure 6-19. Distribution of fetal mortality by gestational age

v. Age of mother at childbirth

According to the distribution of childbirth accidents by age of mother at childbirth, 45 cases were in the age group of 31-35 years with the highest number of cases (35.7%), followed by 35 cases in the age group of 26-30 years (27.8%), 31 cases in the age group of 36-40 years (24.6%), 10 cases of younger than 25 years old (7.9%), and 5 cases of 40 years and older (4.0%) (see Figure 6-21).

vi. Causes of childbirth accident

Analyzing the causes of fetal mortality, most of the cases were of a combination of multiple causes (see Table6-5). However, the most common cause of stillbirth was unknown reasons with 70 cases (55.6%), with other causes include 22 cases of abruptio placenta (17.5%), 21 cases of nuchal cord, umbilical abnormality, or umbilical cord accidents (16.7%), 12 cases of fetal distress (9.5%), and 11 cases of placental insufficiency (8.7%).

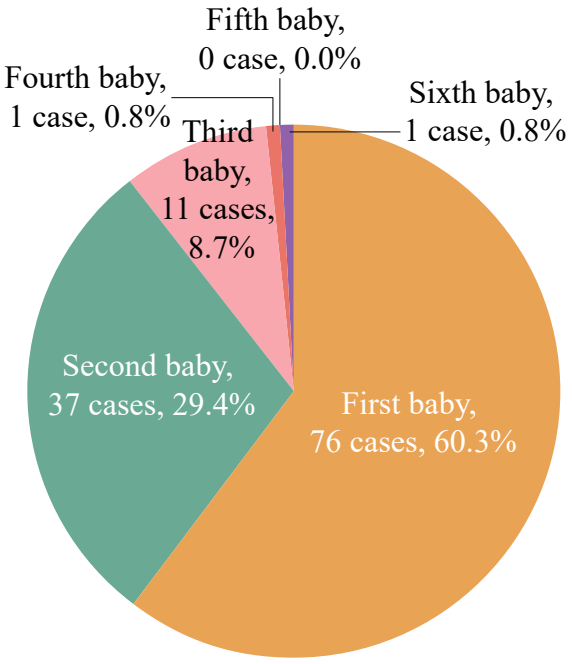


Figure 6-20. Distribution of fetal mortality by birth order

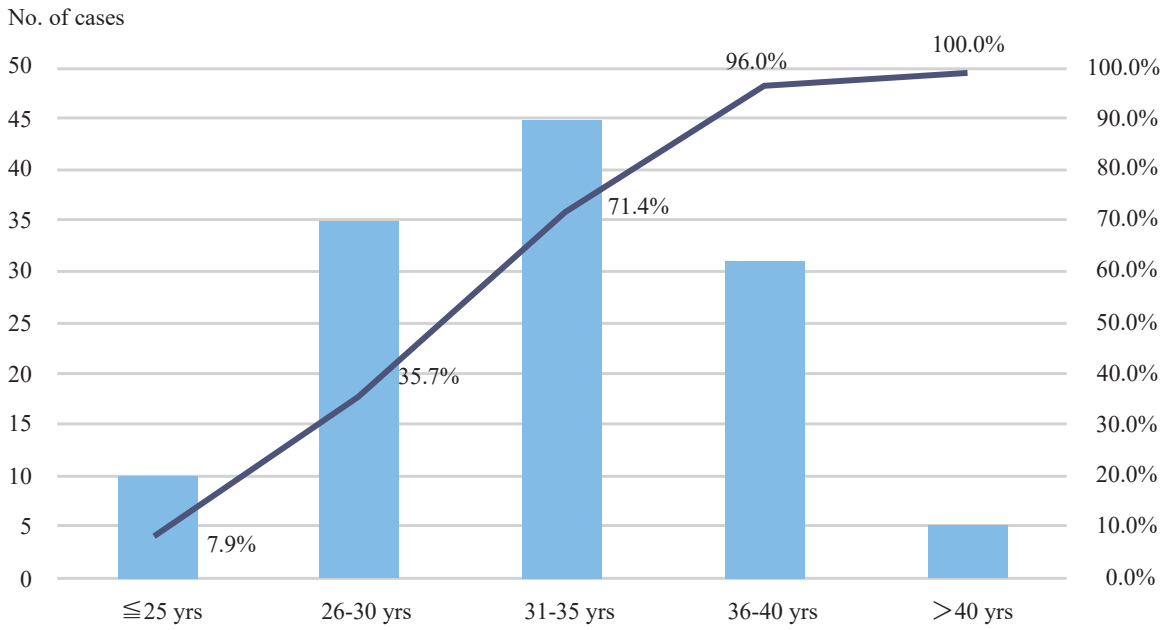


Figure 6-21. Distribution of fetal mortality by age of mother at childbirth

Table 6-5. Analysis of causes of fetal mortality

Causes	No. of cases（%）
Unknown causes	70（55.6%）
Abruptio placenta	22（17.5%）
Nuchal cord, umbilical cord abnormalities, umbilical cord accidents	21（16.7%）
Fetal distress	12（9.5%）
Placental insufficiency	11（8.7%）

Chapter 7
Review and Prospect

Children are the future of our country, not to mention that they are the foundation that affect national development and competitiveness. The health condition of women from pregnancy to childbirth is the most important key to the fetal growth and development, which in turn impacts the future growth and health of children. The birth of a new life brings happiness and content to the family, but the process of childbirth hides many unforeseen risks that may endanger the lives of the pregnant woman and her child or result in irreparable damage. Once the incident becomes a medical dispute, the long-drawn litigation process often brings suffering and inconvenience to both the doctor and the patient. Not to mention that in most cases, the result of the litigation does not ease the tension and emotions of both parties. As a result, over the long term, it reduces doctors' willingness to devote to high-risk specialties, or lead to defensive medical practices to avoid medical disputes that impacts the quality of health care, ultimately compromising patient rights and harmony in the doctor-patient relationship.

Since the implementation of the Birth-Related Dispute Incident Pilot Plan, its two major goals are to reduce disputes and litigations, as well as improve quality of health care. On the one hand, the authority guides hospitals to establish outreach teams to engage in proactive outreach and explanation with pregnant woman and her family in event of a childbirth accident and provide necessary assistance (including assisting the family in applying for childbirth accident relief). On the other hand, the authority requires the reporting of major childbirth accidents to review and investigate the causes as well as the possible improvements so as to provide the medical care institutions an opportunity to learn and improve their health care quality in childbirth. For incidents that involve systematic issues, the authority can establish mechanisms to prevent the occurrence of accidents or reduce damages through policy making. Although the Childbirth Accident Emergency Relief Act was only taken into effect on June 30, 2016 and would require long-term observation, the current results can still be reviewed to serve as future policy direction.

I. Proactive outreach is conducive to reducing litigations and promoting doctor-patient relationship

The promotion of a childbirth accident relief system is not only about providing economic support by the government to the family with childbirth accident, but also about stipulating that hospitals should establish childbirth accident outreach teams to proactively engage in explanation, communication and provision of assistance as well as outreach services to the family within two days of the childbirth accident. Most of the medical disputes are derived from ineffective communication between doctors and patients, and frankly speaking, the risk of litigation is often one of the most important barriers in the communication of major medical disputes. Therefore, the Act clearly stipulates that the medical personnel's or other representative's regret, apology, or similar statement in the explanation, communication, assistance provision and outreach process shall not be used as evidence or basis of judgment for the relevant litigation. The motivation of this Act is to encourage trust and communication to re-establish doctor-patient relationship that will ultimately reduce unnecessary dispute or litigation.

After the implementation of the Childbirth Accident Emergency Relief Act, the entrusted agency by the Ministry conducted an applicant satisfaction survey of all completed childbirth accident relief incidents by the end of December 2017. It was found that 66% of the surveyed received outreach services by the medical care institution within 5 days of the incident, with 80% of the surveyed being satisfied or very satisfied with the outreach services provided by the institution. The surveyed also reflected that 85% of the medical care institutions will assist in the application of childbirth accident relief benefits, out of which 95% of the incidents were not required for mediation by the local department of health. Furthermore, 85% of the surveyed believed that the outreach service mechanism by the medical care institutions can improve doctor-patient relationship.

As for disputes and litigation, the system has also achieved apparent improvements thereof. From 2011 to the end of 2017, out of the total of the litigation cases entrusted by the judicial or prosecutorial agencies to the Ministry's Committee of Medical Care Dispute Assessment, obstetric cases have been significantly reduced by 60% (see Table7-1 and Figure 7-1). Obstetric cases have reduced from 35 cases in 2011 to 15 cases in 2017. Out of the 15 childbirth litigations in 2017, only one met the conditions

of the Childbirth Accident Emergency Relief Act.

In summary of the above, the promotion of a childbirth accident relief system is conducive to the reduction of litigation associated with medical disputes, and the key success factor is attributed to the timely outreach and communication after an incident occurred. According to previous research, there were still 30% of the public that have not experienced the outreach services from the medical care institution after the childbirth incident has occurred. It will be one of the most important areas of work for our continuous improvement plans.

II. Establish a no-blame patient safety culture to improve overall health care quality

In terms of the analysis of the childbirth accident relief applications, another important spirit of the legislation of the Childbirth Accident Emergency Relief Act is to propose feasible improvement plans that could improve quality of childbirth. The Act stipulates that the medical care institutions shall develop in-house risk control and incident reporting mechanisms. They shall analyze the root causes of major childbirth accidents and make proposals for improvements. On the other hand, in order to

Table 7-1. Statistical analysis of the examined medical disputes relating to obstetrics and gynecology

Year	Total number of cases in obstetrics and gynecology	Total number of cases initially examined in obstetrics and gynecology	Number of initially examined cases in gynecology	Number of initially examined cases in obstetrics
2011	68	46	11	35
2012	62	42	12	30
2013	49	30	8	22
2014	52	37	13	24
2015	54	37	9	28
2016	35	27	6	21
2017	38	22	7	15

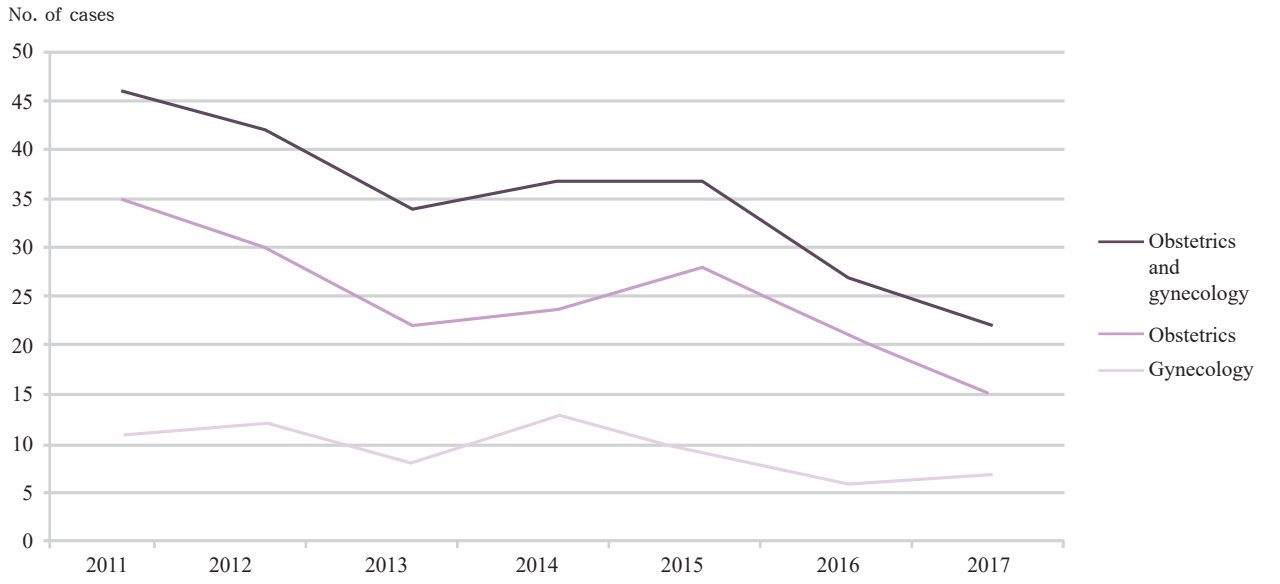


Figure 7-1. Trends of cases initially examined in obstetrics and gynecology

encourage the frontline personnel and institution to proactively report and disclose childbirth accidents so as to assist in the review and improve the quality of care, as well as serve as references to other institutions, the Act also stipulates that the content of the analysis for the root causes of major childbirth accidents shall not be used as evidence in judicial cases, that in part, build a no-blame patient safety culture.

In view of the report data, we compiled the following development recommendations.

i. In terms of maternal mortality, most of the causes were related to amniotic embolism and postpartum hemorrhage. Although these types of incidents cannot be prevented before childbirth, we can still continuously strengthen the emergency training and emergency response competency of clinical personnel as well as pre-establish a patient referral mechanism, or emergency incident processing and medical evacuation procedures for the effective risk management of high-risk pregnancies, so as to increase the chances of successful treatment.

ii. In terms of major maternal injuries, most of the incidents were hysterectomy as a result of postpartum hemorrhage. The prevention heavily relies on the detection of risk factors for postpartum hemorrhage, such as placenta previa or highly suspected placenta accreta, during prenatal examinations. Apart from delivering appropriate counselling and health education, we should ensure that the human resources, drugs, blood supplies and equipment are complete at childbirth for high-risk pregnancies. Furthermore, if the medical care institution is unable to provide adequate care after its self-assessment, prenatal referral should take place. For unforeseen postpartum hemorrhage, timely hysterectomy should be engaged in the premise of life-threatening situation, the related emergency treatment, blood supply (transfusion), and referral and evacuation procedures are indispensable.

iii. Neonatal mortality is one of the most important health care indicators. From our analysis, one could find that some of the women had been confirmed as high-risk pregnancies before childbirth. Therefore, the priority still lies with the strengthening of health education for high-risk pregnancies and prenatal referral. On top of that, enhancing the training for early identification and treatment of fetal distress and improving the proficiency of neonatal resuscitation program would be able to provide effective emergency treatment in face of high-risk pregnancy or unforeseen neonatal emergency situations that would minimize the damage to newborns.

iv. In terms of fetal mortality, we can see from the statistical analysis that, similar to overseas reports, more than half of the causes of stillbirths were due to unknown reasons. Since the causes are hard to prevent, the key point of the prenatal health education delivered is to educate the woman to monitor the changes in fetal movement. When the pregnant woman notices an apparent reduction in fetal movement, she should visit the doctor for further examination. Medical care institutions should also conduct fetal growth monitoring for woman with reduced fetal movement, such as measuring the size of the fetus and level of amniotic fluid through ultrasound and observing fetal movement through fetal monitors, so as to confirm the risk factors that could lead to stillbirth and conduct appropriate medical treatment. After termination of pregnancy, the medical care institution should also examine the risk factors of the woman, fetus and placenta, and correctly and completely record the causes of stillbirth to serve as reference strategy to reduce similar incidents in the future.

Since the implementation of the Act, we have completed a root cause analysis (RCA) and compiled a total of 10 case studies that is made available on “Taiwan Patient Safety Net” and “Childbirth Accident Relief Section” on the Ministry’s website as reference for all institutions. The case studies aim to meet the goals of achieving joint learning, improving quality of health care, and establishing a safe health care environment.

Furthermore, in order to establish a blood supply (transfusion) network in response to postpartum hemorrhage experienced in the clinics, in accordance to Paragraph 6, Article 2 of the Standards Governing the Establishment of Medical Laboratory, medical laboratory providing medical tests that include pre-transfusion testing and blood bank operations shall establish a blood supply center as per relevant regulations and cooperate with hospitals or clinics in the neighborhood to provide blood and blood tests and reduce the delivery time of the blood supply to patients in need. This measure will effectively improve the quality of blood supply and protect patient rights. As such, the Medical Laboratory’s Blood Supply Center Establishment Pilot Plan proposed by the

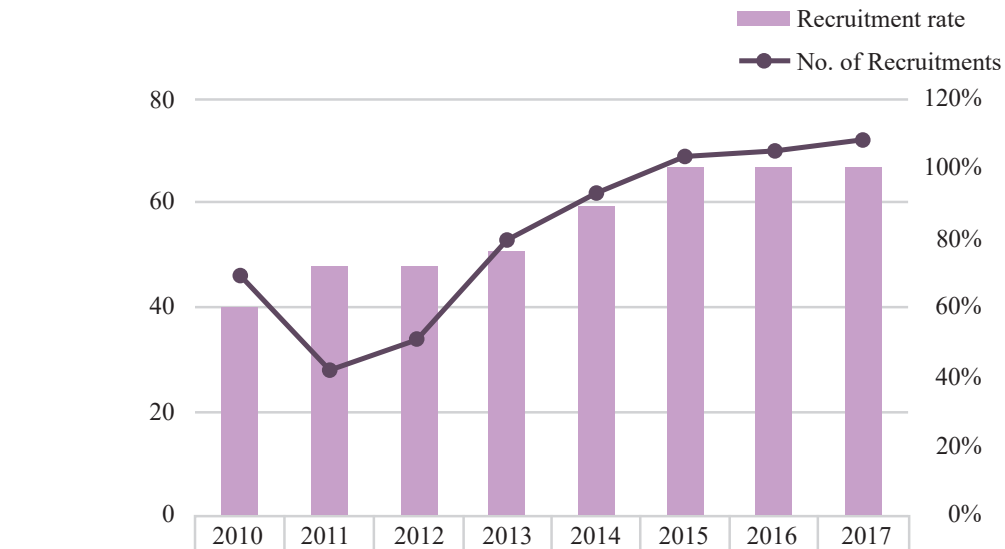
Tainan Association of Medical Technologists will be assessed after a year of implementation and gradually promoted throughout the country to ensure a safe and effective blood supply (transfusion) network.

III. Improve practice setting and attract the return of young doctors

According to the research of the coordinating agency for childbirth accident relief, 83% of the obstetricians and gynecologists agreed that the pilot plan can effectively improve the practice settings and reduce childbirth complications. Next, 97% of the physicians agreed that the pilot plan is the best solution for resolving medical disputes and recommend the pilot plan as a reference for the compensation for medical disputes of other medical divisions. The drop in medical disputes and litigations have improved the practice conditions for obstetrics and gynecology. It has also helped the number of recruitments and recruitment rate of obstetrics and gynecology residents, from 46 people in 2010 with 60% recruitment rate up to 72 people in 2017 with 100% recruitment rate (see Figure 7-2). It is evident that young physicians are gradually returning to serving in obstetrics and gynecology divisions, which will ultimately improve the maternal and child care environment and quality in the future.

IV. Mirror the successful experience of childbirth accident relief to promote the legislation of medical incident prevention and dispute resolution

Due to the successful experience in the promotion of the childbirth accident relief system, the Ministry is also proactively promoting to strengthen the medical dispute processing mechanism outside of litigation, such as pre-incident communication enhancement, proactive outreach when an incident occurs, and mediation before litigation. Additionally, since 2016, the Ministry has begun the promotion of Shared Decision Making (SDM) mechanism, organized outreach training and workshop, guided hospitals in establishing outreach teams, improved the mediation quality and performance of the department of health in handling medical disputes, initiated pilot plan of dual mediation by medical and judicial agencies, and provided third party expert's opinions. At the same time, in order to supplement the medical dispute resolution mechanism not regulated under the Childbirth Accident Emergency Relief Act, and extend the successful experience of the outreach and communication as well as improved reporting system to all other medical accidents, the Ministry has proposed the draft of Act for Prevention of Medical Accident and Settlement of Medical



	2010	2011	2012	2013	2014	2015	2016	2017
Recruitment rate	60%	72%	72%	76%	89%	100%	100%	100%
No. of Recruitments	46	28	34	53	62	69	70	72

Figure 7-2. Recruitment of obstetrics and gynecology residents between 2010 and 2017

Disputes (referred to as the Medical Accident Act below). The draft Act aims to legislate the proactive outreach for medical accidents, pretrial mediation for medical disputes, third party commentary and opinion, and debugging mechanism of no-blame system. Currently, the draft Act has been sent to the Legislative Yuan for review on April 13, 2018. The differences between the Medical Accident Act and Childbirth Accident Emergency Relief Act are outlined in the following paragraphs, and we hope that the new legislation can make the prevention and settlement of childbirth accident more complete.

i. Establish a fair third-party professional commentary for medical disputes

In order to efficiently clarify and provide a fair, objective and professional commentary and opinion about the issues in medical dispute, the central competent authority will entrust or establish a dedicated agency to accept applications from the party concerned or mediation committee, and provide professional commentary and opinion based on the medical records and related information to bring the gap of understanding between both parties closer and resolve the dispute efficiently leading to settlement.

ii. Levels of outreach mechanism for medical accident help actual operation

The Medical Accident Act is expanded to cover the outreach targets in all types of medical accidents other than childbirth incidents. It applies to nearly 500 hospitals and 20,000 clinics across the country, which is greatly different to the Childbirth Accident Emergency Relief Act that only covers the 163 hospitals and 178 clinics that provide childbirth services. Therefore, considering the difference in the scale and human resources of medical care institutions, the draft Act stipulates that hospitals, clinics and other medical care institutions with less than 99 beds can designate professional personnel or entrust professional institution or organization to provide explanation, communication and outreach services to protect the rights of patients and medical personnel.

iii. Legalize medical dispute settlement to drive mediation before litigation.

The local department of health should establish a medical dispute mediation committee. All litigations, regardless of civil or criminal medical litigations, shall be mediated first by the committee with a mediation period of three months as the limit. When necessary, the mediation can be extended by another three months, and the mediation outcome should be approved by the court for judicial effect in order to reduce caseload and social costs. For the dispute mediation procedure and related operational regulations, since the formulation of administrative rules and its execution detail should keep up with the times and adapt to local conditions, the draft stipulates related authorization to be aligned with the administrative procedure of the competent authority.

iv. Establish a no-blame culture of patient safety to strengthen system debugging mechanism and improve health care quality

Medical care institutions should establish a patient safety management system, so as to complete the no-blame patient safety reporting and risk management mechanism. As for the occurrence of major medical accident, the medical institution should proactively engage in root cause analysis, review and improve, as well as report to the competent authority. For cross-institutional, departmental, or regional major medical accidents, the central competent authority will establish an external investigation task force to investigate and report for further system debugging as well as prevent incident reccurrence. Additionally, in order for both doctor and patient to openly face the medical accident, sincerely settle and promote the improvement of the medical system, the draft Medical Accident Act stipulates that the regret or other statements of the party concerned in the outreach, communication and medication process for alleviating doctor-patient tension after the medical accident shall not be used as evidence or basis of judgment for the relevant litigation and administrative injunction. Furthermore, in-house incident reporting data and root cause analysis of major medical accidents of the medical care institutions are for the goals of proactive improvement, system debugging, and joint learning that cannot be used as evidence or basis of judgment in judicial litigation, allowing the Act to promote the safety and quality improvement of the health care system and benefit the health and welfare of all citizens.

Chapter 8
Conclusion

The Childbirth Accident Emergency Relief Act is the first medical accident related relief regulation of Taiwan, and it is also the first no-blame relief regulation in the world that covers all childbirth accidents. We hope that the protection provided by the nation would make women feel safe during their delivery and labor. At the same time, through the implementation of the childbirth accident relief system, we are able to drastically reduce medical disputes in obstetrics and gynecology, promote a harmonious doctor-patient relationship, and collect additional local data to continuously improve and enhance quality of childbirth. The successful experience gained from the development of the childbirth accident relief system will serve as reference for the future promotion of related regulations. By maintaining physician professionalism and protecting patient rights, we have successfully established the processing mechanism for medical disputes and steered towards the communication between doctors and patients instead of resolution through litigation. We look forward to encouraging an attitude of openness in the review of medical accidents to ultimately improve medical safety and quality under protection of the laws, and furthermore serve the purpose of preventing medical accidents, reducing medical brain drain in emergency and critical care for the sustainable development of our health care system.

2018 Annual Report of Childbirth Accident Relief

Publisher Shih-Chung Chen
Editor-in-chief Chung-Liang Shin
Editorial board
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Published by the Ministry of Health and Welfare, R.O.C. (Taiwan)
Address: No.488, Sec. 6, Zhongxiao E. Rd., Nangang Dist., Taipei City 11558
Website: https://www.mohw.gov.tw
Tel: +886-2-8590-6666
Fax: +886-2-8590-7088
Date of publication December 2018
First edition December 2018
Designed by Arteck Creative Consultants, Inc.
Price NTD 250

Distribution:
Government Publications Bookstore
Address: 1F, No.209, Sung Chiang Rd., Taipei City
Tel: +886-2-2518-0207
Wu-Nan Cultural Plaza Bookstore
Address: No.6, Zhongshan Rd., Taichung City
Tel: +886-4-2226-0330

ISBN 978-986-05-8346-5
GPN 1010702784

This report is also available at the website of the Ministry of Health and Welfare at https://www.mohw.gov.tw

Promoting the health and well-being of all citizens

Being the most trustworthy government agency

ISBN 978-986-05-8346-5

ISBN：978-986-05-8346-5
GPN：1010702784
Price：NT$ 250