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# Neonatal Resuscitation Online Registry in Shenzhen: protocol for a prospective, multicentre, open, observational cohort study

Hanni Lin ,[1] Jing Han,[2] Ping Jiang,[1] Zhangbin Yu,[3] Ping Zhou,[4] Hong Tang,[5] Lu Ding,[3] Jiebo Liu[1]

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HL and JH contributed equally.

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For numbered affiliations see end of article.

**Correspondence to**
Dr Jiebo Liu;
446107008@qq.com

## ABSTRACT

**Introduction** Preterm birth complications and neonatal asphyxia are the leading causes of neonatal mortality worldwide. Surviving preterm and asphyxiated newborns can develop neurological sequelae; therefore, timely and appropriate neonatal resuscitation is important to decrease neonatal mortality and disability rates. There are very few systematic studies on neonatal resuscitation in China, and its prognosis remains unclear. We established an online registry for neonatal resuscitation in Shenzhen based on Utstein's model and designed a prospective, multicentre, open, observational cohort study to address many of the limitations of existing studies. The aim of this study is to explore the implementation and management, risk factors and outcomes of neonatal resuscitation in Shenzhen.

**Methods and analysis** This prospective, multicentre, open, observational cohort study will be conducted between January 2024 and December 2026 and will include >1500 newborns resuscitated at birth by positive pressure ventilation at five hospitals in Shenzhen, located in the south-central coastal area of Guangdong province, China. Maternal and infant information, resuscitation information, hospitalisation information and follow-up information will be collected. Maternal and infant information, resuscitation information and hospitalisation information will be collected from the clinical records of the patients. Follow-up information will include the results of follow-up examinations and outcomes, which will be recorded using the WeChat applet 'Resuscitation Follow-up'. These data will be provided by the neonatal guardians through the applet on their mobile phones. This study will provide a more comprehensive understanding of the implementation and management, risk factors and outcomes of neonatal resuscitation in Shenzhen; the findings will ultimately contribute to the reduction of neonatal mortality and disability rates in Shenzhen.

**Ethics and dissemination** Our protocol has been approved by the Medical Ethics Committee of Shenzhen Luohu People's Hospital (2023-LHQRMYY-KYLL-048). We will present the study results at academic conferences and peer-reviewed paediatrics journals.

**Trial registration number** ChiCTR2300077368.

## STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This prospective cohort study will establish a multicentre online registry of cases involving neonatal resuscitation for efficient data management.
⇒ The study will conduct follow-up for newborns resuscitated at birth for up to 2 years.
⇒ The study will comprehensively evaluate various aspects of the prognosis of neonates resuscitated at birth, including survival, recent major illness and long-term neurodevelopmental outcomes.
⇒ The study will investigate the implementation of resuscitation measures in neonates in an actual clinical setting.
⇒ Because this is an observational study, loss to follow-up will be inevitable.

## INTRODUCTION

Globally, approximately 2.44 million newborns die each year, 36.1% die of preterm birth complications and 23.9% die of birth asphyxia.[1] In China, preterm birth complications and delivery-related complications (birth asphyxia/trauma) rank first and second, respectively, among the leading causes of neonatal deaths.[2] Preterm neonates often have poor respiratory ability at birth and are unable to establish spontaneous breathing.[3] Moreover, survivors of preterm birth carry a high risk of neurological and developmental disabilities.[4] Neonatal asphyxia is caused by various factors that prevent neonates from establishing spontaneous respiration at birth,[5 6] and up to 25% survivors remain with permanent neurological deficits.[7] According to the WHO, many of the causes of neonatal mortality can be avoided by simple, practical and inexpensive techniques such as neonatal resuscitation.[8]

Following the establishment of the neonatal resuscitation programme by the American Academy of Pediatrics and the American Heart Association in 1987, guidelines for neonatal

resuscitation were developed and have been revised every 5 years on the basis of evidence-based medicine.[9] Clinical research in the field of neonatal resuscitation has evolved rapidly in recent decades.[10] Approximately 10% of newborns receive resuscitation for successful transition at birth.[11] With the development of perinatal medicine and the continuous promotion of neonatal resuscitation training programmes, the incidence of neonatal asphyxia in China has decreased from 6.23% in 2003 to 1.67% in 2014 and the morbidity and mortality rates have decreased from 7.55% to 1.39%.[12] Correct and standardised resuscitation measures can effectively decrease neonatal mortality and disability rates.

Many countries have realised the importance of neonatal resuscitation. The American Heart Association has established the Get with the Guidelines-Resuscitation Registry, the only national registry for inpatient cardiac arrest in North America; it is a prospective, quality-improvement registry of in-hospital cardiac arrest and resuscitation data, including studies of the characteristics and outcomes of neonates who survived cardiopulmonary resuscitation in the delivery room.[13–15] Furthermore, the National Institute of Child Health and Human Development (NICHD) Global Network for Women's and Children's Health initiated and registered interventional studies of neonatal resuscitation, which concluded that the perinatal mortality rate was decreased following enhanced training of birth attendants.[16 17]

In China, there are very few systematic studies on neonatal resuscitation. A retrospective study reported the short-term outcomes of delivery room resuscitation for very preterm and very low birth weight infants in 33 neonatal intensive care units (NICUs) in five provinces and cities in North China, although it did not provide information regarding post-discharge follow-up and outcomes of the infants.[18] Another retrospective study published in 2021 reported the clinical features of preterm infants with a birth weight of <1500 g who received resuscitation of different intensities in NICUs of 20 hospitals in Jiangsu province,[19] while yet another retrospective study published in 2023 reported the correlation between the intensity of delivery room resuscitation of preterm infants with a gestational age (GA) of $24^{+0}$–$31^{+6}$ weeks and their short-term outcomes from the Chinese Neonatal Network[20]; however, both these studies provided incomplete information for some cases.

Our study group established an online registry for neonatal resuscitation in Shenzhen on the basis of Utstein's model[11] and designed a prospective, multicentre, open, observational cohort study to address many of the limitations of existing studies. Here we describe the protocol for this study.

The primary objective of the study will be to investigate the comprehensive prognosis of newborns resuscitated at birth in Shenzhen.

The secondary objective will be to provide baseline information for improvement of the quality of neonatal resuscitation, enhancement of the resuscitation skills of neonatologists and achievement of a further decrease in neonatal mortality and disability rates in Shenzhen.

## METHODS AND ANALYSIS

### Study design

This multicentre, prospective, open, observational cohort study will be conducted from January 2024 to December 2026. More than 1500 newborns requiring resuscitation at birth by positive pressure ventilation (PPV) will be recruited from five hospitals in Shenzhen, located in the south-central coastal area of Guangdong province, China. All enrolled newborns will be followed-up to 2 years. The proposal has been approved by the medical ethics committees of the initiating hospital, and the other four hospitals have signed the multicentre collaboration agreements. Each hospital will be required to resuscitate the infant according to China neonatal resuscitation guideline (revised in 2021).[8] The protocol has been drafted in accordance with the Standardised Protocol Items: Recommendations for Observational Studies statement (online supplemental file 1).

Shenzhen Luohu People's Hospital, which is the affiliation of the promoter (JL) and primary investigator (HL), designed and initiated this study. Shenzhen People's Hospital is the coordinating hospital and the affiliation of the coordinators (LD and ZY). Several data recorders (neonatologists) and a data checker (neonatologist) have been appointed at each participating hospital. This is an open study, and we will welcome more eligible hospitals to participate. The flowchart of the study process is shown in online supplemental file 2.

### Patient and public involvement

The guardians of newborns and the public did not participate in the study design. The newborns will participate in the recruitment stage, and participation is entirely voluntary. WeChat groups will be established and guardians will be invited to join. The study results will be disseminated to guardians and the public by means of health brochures and academic conferences.

### Participants

Five hospitals in Shenzhen have formed a collaborative group for this multicentre study. Basic information about each hospital is shown in table 1. All newborns born and requiring resuscitation at birth by PPV in these hospitals between 1 January 2024 and 31 December 2026 will be included. Clinical practice of newborns will not be affected by their guardian's refusal to participate or withdrawal from the study.

### Informed consent

This study follows the Declaration of Helsinki, and written informed consent will be obtained from the guardians of all included newborns.

### Criteria

Inclusion criteria are as follows:

Table 1 Basic information and responsibilities for the five participating hospitals

| Hospital name | Responsibility | Number of infants delivered in 2022 |
|---|---|---|
| Shenzhen Luohu People's Hospital | Initiating hospital | 2079 |
| Shenzhen People's Hospital | Coordinating hospital | 5400 |
| Shenzhen Yantian District People's Hospital (Group) | Participating hospital | 1363 |
| Shenzhen Baoan Women's and Children's Hospital | Participating hospital | 18107 |
| Longgang District Maternity & Child Healthcare Hospital of Shenzhen City | Participating hospital | 12424 |

Newborn resuscitated at birth by PPV.

Informed consent has been obtained.

Exclusion criteria are as follows:

Severe congenital anomalies (eg, tetralogy of Fallot, complete transposition of the great arteries) and inherited metabolic disorders.

Forgo for resuscitation.

Less than one follow-up examination.

Refusal to consent.

## Standardisation of variable definitions

GA: GA is the number of completed weeks of gestation at birth.[21]

Corrected age: For each preterm infant, the corrected age is calculated by subtracting the number of weeks of preterm birth (40 weeks minus the actual week of gestation) from the calendar age at birth.[22]

Small for GA (SGA): SGA is defined as birth weight <10th percentile according to the Chinese neonatal birth weight values.[23]

Legal holidays: These are holidays uniformly stipulated by Chinese laws as breaks for celebrations and holidays, New Year's Day, Spring Festival, Qingming, Labour Day, Dragon Boat Festival, Mid-Autumn Festival, National Day, Women's Day, Youth Day, Children's Day and Army Day.

Assisted reproductive technology (ART): ART involves the use of hormones to downregulate pituitary function and stimulate the production of multiple oocytes, the manipulation of oocytes and sperm for in vitro fertilisation and intracytoplasmic monozoosperm injection procedures in vitro and cultivation of pre-implantation embryos in media and incubators prior to transfer to the uterus.[24]

Full course of antenatal steroids: This is defined as a course of four consecutive intramuscular injections of dexamethasone administered by the mother prior to delivery.

Antenatal steroid exposure: This is defined as less than four intramuscular injections of dexamethasone administered by the mother prior to delivery.

Prolongation of the second stage of labour: Without intrathecal analgesia, the second stage of labour exceeds 3 hours for primigravid women and 2 hours for transient women. If intrathecal analgesia is administered, the second stage of labour exceeds 4 hours for primigravid women and 3 hours for transient women.[25]

Mild asphyxia: Mild asphyxia is defined as an Apgar score of ≤7 for 1 min or ≤7 for 5 min at birth, with umbilical artery blood pH<7.2.[26]

Severe asphyxia: Severe asphyxia is defined as an Apgar score of ≤3 for 1 min or ≤5 for 5 min at birth, with umbilical artery blood pH<7.0.[26]

Low Apgar score: An Apgar score of ≤7 for 1 or 5 min without umbilical artery blood gas results is defined as a low Apgar score.[26]

Neonatal acidosis: A pH of <7.2 and/or base excess of <−12 mmol/L based on umbilical artery blood gas analysis is defined as neonatal acidosis.[27]

Bronchopulmonary dysplasia (BPD): According to the 2001 NICHD criteria, for infants born at a GA of <32 weeks, BPD is defined as having required supplemental oxygen (>21%) for at least the first 28 postnatal days and severity is evaluated at a postmenstrual age of 36 weeks or at discharge, whichever occurs first. For infants born at a GA of ≥32 weeks, BPD is defined as having required supplemental oxygen (>21%) for at least the first 28 postnatal days and severity is evaluated at a postnatal age of 56 days or at discharge, whichever occurs first. The severity is classified as follows: mild, no oxygen use; moderate, need for oxygen and a fraction of inspiration $O_2$ ($FiO_2$) of <30%; and severe, $FiO_2$ of ≥30% or the need for continuous positive airway pressure or mechanical ventilation.[28 29]

Persistent pulmonary hypertension of the newborn (PPHN): PPHN is diagnosed using ultrasound and defined as a pulmonary artery systolic pressure of >35 mm Hg or >2/3 of the body circulation systolic pressure or as the presence of right-to-left shunting at the level of the atria or arterial conduit.[30]

Symptomatic patent ductus arteriosus (sPDA): sPDA is defined as PDA with an internal diameter of >1.5 mm, a left atrial internal diameter/aortic internal diameter ratio of ≥1.4, or a left ventricular end-diastolic internal diameter/aortic internal diameter ratio of ≥2.1, accompanied by one of the following clinical manifestations: characteristic heart murmur, hyperdynamic precordial impulse, tachycardia, bounding pulses, widened pulse pressure and worsening respiratory status.[31]

Feeding intolerance (FI): FI is defined when >50% of the last meal remains in the stomach, accompanied by vomiting and/or bloating.[32]

Acute kidney injury (AKI): AKI is classified according to neonatal AKI Kidney Diseases: Improving Global Outcomes (KDIGO) criteria.[33]

Cystic periventricular leukomalacia (cPVL): cPVL is defined as the presence of periventricular cysts on cranial ultrasound or MRI.

## Data collection

Patients will be prospectively recruited, and the recruitment phase is expected to end in 2026. Data will be collected in two parts. The data of maternal and infant information, resuscitation information and hospitalisation information will be collected on the basis of the Neonatal Resuscitation Online Registry using the Perinatal Cloud Database (https://www.perinatalcloud.com/) established by the coordinator (ZY). Each hospital will select several neonatologists as data recorders, who will be trained and assessed by the coordinating hospital before they start data collection. To ensure the accuracy of the data, we will record a video at the resuscitation site. We will standardise the use of 5G smartphones (Honor V.30 Pro mobile phones) as the video recording devices, integrating stopwatch features into the video recording functions, allowing the timing of events while simultaneously recording video (online supplemental file 3). At the resuscitation site, a mobile phone holder will be used to support the mobile phone on the top left or right of the infant radiation warming table to allow for an all-around video recording of the resuscitation process. Follow-up information will be collected by the WeChat applet 'Resuscitation Follow-up' (table 2). The applet is divided into a doctor's port and a guardian's port. The guardian can provide the results of follow-up examinations using the guardian's port on their mobile phones under the directions of the doctor. If the results are not available on the applet when the child is 2 years old, we will contact the guardian via WeChat or conduct a telephone interview.

The collected data will include the following (online supplemental file 4).

### Maternal and infant information

Infant information: name, birth hospital, hospitalisation number, sex, GA, birth weight, SGA, birth date, multiple births, congenital anomalies or hereditary syndromes and medical payment method.

Maternal information: name, age, ethnicity, mobile phone number, residential address, occupation, marital status, monthly family income, education level and medical payment method.

Antenatal information: maternal history, previous adverse pregnancy outcomes, mode of conception, antenatal care, antenatal intervention, antenatal body mass index, hypertension, diabetes, anaemia, cardiac disease, placenta praevia, placental abruptio placenta, antenatal haemorrhage, chorioamnionitis, premature rupture of membranes >18 hours, other pregnancy complications, antenatal steroid use, antenatal magnesium sulphate use, antenatal anaesthesia or analgesia, antenatal fetal monitoring anomalies, obstructed labour, emergency labour, type of labour initiation, prolonged second stage of labour, weak contractions.

Intrapartum information: mode of delivery, fetal position, amniotic fluid volume, nature of amniotic fluid, umbilical cord around the neck, umbilical cord prolapse, umbilical cord extrusion, delayed umbilical cord ligation, Apgar score (1 min, 5 min, 10 min), umbilical artery blood gas analysis and diagnosis.

### Resuscitation information

Resuscitation process: place of resuscitation; antenatal counselling; resuscitation team and division of labour; preparation of resuscitation items; warmth including the warming measure; suction or stimulation; suction device; oxygen administration, including start time, end time, duration, initial oxygen concentration and maximum oxygen concentration; use of PPV, including mode of ventilation, maximum peak inspiratory pressure, maximum positive end-expiratory pressure, start time, end time and duration; ventilation assessment; saturation of peripheral oxygen monitoring and start time; corrective ventilation steps; use of laryngeal mask airway, endotracheal tube insertion, including the number of intubations, intubation time and success of intubation; chest compression for ≥30 s, including the compression method, start time, end time and duration; electrocardiographic monitoring

**Table 2** Data collection by the WeChat applet 'Resuscitation Follow-up'

| Data | Hospitalisation period/term equivalent | Follow-up 1: corrected age, 3–6 months | Follow-up 2: corrected age, 1 year | Follow-up 3: corrected age, 2 years |
|---|---|---|---|---|
| Cranial MRI | √ | * | * | * |
| aEEG | √ | * | * | * |
| BAEP/AABR | √ | * | * | * |
| Physical examination | * | * | * | √ |
| GDS-C | | | * | √ |

√Required. *If applicable.
AABR, automatic auditory brainstem response; aEEG, amplitude-integrated electroencephalogram; BAEP, brainstem auditory-evoked potential; GDS-C, Griffiths Development Scales-Chinese; ROP, retinopathy of prematurity.

including the start time, and 100% oxygen concentration including the start time.

Resuscitation administration: umbilical vein cannulation, including the number of cannulations; epinephrine use and the number of administrations, time of administration, dose of administration and mode of administration; the type and total dose of fluid resuscitation; other interventions including the time of intervention.

Resuscitation summary: resuscitation end time, duration, resuscitation outcome (success, failure, forgo treatment), postnatal transition (transfer to neonatal ward, rooming in, transfer to another hospital, death in delivery room).

### Hospitalisation information

Treatment information: temperature on admission; therapeutic hypothermia, including the cooling method, temperature control mode and start time; postnatal glucose monitoring; and minimum blood glucose measurement.

Auxiliary examination information: echocardiography, cranial ultrasound, cranial CT, cranial MRI, amplitude-integrated electroencephalogram (aEEG), brainstem auditory evoked potentials (BAEP) or automatic auditory brainstem response (AABR) and screening for retinopathy of prematurity (ROP).

Summary of hospitalisation: duration of hospitalisation, discharge outcome (cured or improved, transfer to another hospital, death before discharge, forgo treatment), complications (pneumothorax, meconium aspiration syndrome, BPD, PPHN, sPDA, necrotising enterocolitis, FI, AKI, ROP, hypoxic-ischaemic encephalopathy, intraventricular haemorrhage, cPVL).

### Follow-up information

Follow-up examination: cranial MRI, aEEG, BAEP or AABR at the corrected age of 3~6 months, 1 year and 2 years (if applicable); physical examination; and Griffiths Development Scales-Chinese at the corrected age of 2 years (table 2).

Follow-up outcome: normal, sequelae (cerebral palsy, mental retardation, epilepsy, cognitive impairment, hearing impairment, motor retardation, neurodevelopmental delay, attention deficit, learning difficulties, visual impairment, etc), death or loss to follow-up. These data need to be confirmed jointly by the paediatric neurologist, paediatric rehabilitation physician, ophthalmologist and otolaryngologist.

## Study outcomes

The primary outcomes of this study include survival and neurodevelopmental outcomes for newborns resuscitated at birth, and the secondary outcome includes recent major illnesses.

## Data management

Each hospital will designate an attending (or above) neonatologist as a data checker, who will be trained and assessed by the coordinating hospital and will be responsible for reviewing the data from that hospital after passing the assessment. The principal investigator and data checker from each hospital form the data monitoring committee, which will be responsible for the following: for conducting quarterly data quality control meetings and providing timely feedback on the results of the checks and supervising corrective actions; for holding regular quality control and analysis meetings to assess the progress of the study and determine any deviations from the plan; for ensuring the management and operation of the online registry, video recordings, WeChat groups and WeChat applet as well as the data security; and for overall sampling quality control; recruitment of other participating hospitals; organisation of training; provision of training materials; checking, collating and analysing data and publication of the study results. If changes to the study design are required, the committee should seek approval from the Medical Ethics Committee. The Ethics Committee, independent of the data checkers or any other entity that may influence its decisions, will audit the conduct of the study annually.

To protect privacy, each hospital and its patients will have a unique identification number, and this information and data will be analysed and published in an anonymous form.

## Data integrity or withdrawal from the trial

We will apply strict quality control procedures for data collection and management to ensure data integrity. If a subject's guardian requests to withdraw during or after the trial, we will fully respect the wish, withdraw informed consent, delete the relevant information and proceed to recruit new subjects.

## Sample size estimation

The primary objective will be to provide a comprehensive description of the composite prognosis of neonates requiring PPV at birth. Because this is an observational study, sample size estimation is not necessary. We will calculate the sample size used for the logistic regression analysis of risk factors for the requirement of PPV at birth at each hospital. We expect to test 6–10 variables as potential risk factors, each with an event count of at least 10, and we will need 100 neonates resuscitated at birth.[34 35] A previous study reported that approximately 4.4% of newborns require bag-mask ventilation each year,[36 37] and assuming a 20% loss-to-follow-up rate, a minimum sample size of 2810 newborns would be required per hospital. The minimum number of neonatal deliveries in 2022 at participating hospitals was 1363, and we will prospectively collect data for 3 years so each hospital can meet the minimum sample size requirement. We expect to recruit >1500 neonates.

## Statistical analysis

Because of variations in the need for resuscitation, outcomes of neonates with different GAs and implementation of resuscitation at different hospitals, enrolled

newborns will be stratified and analysed according to the GA or hospital and standardised morbidity and survival rates will be calculated. The study will prospectively focus on enrolled neonates to investigate the prognosis as well as risk factors for neonates with different resuscitation intensities. Given the low incidence of high-intensity resuscitation, a nested case–control study design will be used to eliminate its effects. Statistical analysis will be performed using SPSS V.27.0. Data will be presented as mean (SD) or median (range) and analysed using the Student's t-test or Mann-Whitney U test. Counts will be presented as frequencies or percentages and compared using the $\chi^2$ test or Fisher's exact test. The prognosis as well as risk factors for neonates with different resuscitation intensities will be assessed by multivariable logistic regression analysis. A p value of <0.05 will be considered statistically significant.

## DISCUSSION

Neonatal resuscitation is an important topic in the field of neonatal medicine because several newborns requiring resuscitation at birth are born each year. Neonatal resuscitation almost always predicts an inability to establish spontaneous breathing,[11] and the correct implementation of neonatal resuscitation techniques can establish effective ventilation for the neonate and help him or her make a successful transition from the intrauterine to the extrauterine environment. Although guidelines for neonatal resuscitation have been updated, in China, resuscitation strategies vary widely between centres[20] and the practice and management of neonatal resuscitation are not standardised in each region. Moreover, there are very few follow-up studies on neonatal resuscitation, and the prognosis of resuscitated neonates remains unclear.

Medical registries can provide highly reliable data.[38] Many developed countries now have regional and national clinical registries aimed at improving patient health outcomes.[39] In this regard, we established the Neonatal Resuscitation Online Registry in Shenzhen and designed a prospective, multicentre, open, observational cohort study to prospectively register neonatal resuscitation cases in Shenzhen and investigate the risk factors, outcomes and resuscitation measures in actual clinical settings. Detailed documentation of the outcomes of neonates resuscitated at birth will help us gain a comprehensive understanding of the overall prognosis of this group of neonates. The long-term prognostic information will also optimise follow-up, prevent the development of severe neurodevelopmental disorders and improve the quality of life of these neonates. By exploring the risk factors for resuscitation at birth, this study is expected to show that increased monitoring of neonates with high-risk factors will help reduce the rate of resuscitation. In addition, the study will investigate resuscitation measures for neonates resuscitated at birth, identify deficient measures and provide evidence for improvement in the quality of neonatal resuscitation.

This observational study will be limited by the possibility of loss to follow-up. In order to reduce missed visits, we will establish WeChat groups, which the guardians of the subjects will join and propose that the guardians use their mobile phones to participate in follow-ups using the WeChat applet. If the guardian fails to provide follow-up results when the infant is 2 years old, we will contact the guardian via WeChat or conduct a telephone interview.

## ETHICS AND DISSEMINATION

Our protocol has been approved by the Medical Ethics Committee of Shenzhen Luohu People's Hospital, and the remaining four hospitals have signed the multicentre collaboration agreements. All guardians will be fully informed about this study. They will receive written information and sign a consent form before recruitment. The findings and results of this study will be shared among the participating hospitals and published in academic conferences and peer-reviewed paediatric journals.

**Author affiliations**
[1]Neonatology, Shenzhen Luohu People's Hospital, Shenzhen, Guangdong, China
[2]Neonatal Intensive Care Unit, Longgang District Maternity & Child Healthcare Hospital of Shenzhen City, Shenzhen, Guangdong, China
[3]Neonatology, Shenzhen People's Hospital, Shenzhen, Guangdong, China
[4]Neonatology, Shenzhen Baoan Women's and Children's Hospital, Shenzhen, Guangdong, China
[5]Neonatology, Shenzhen Yantian District People's Hospital (Group), Shenzhen, Guangdong, China

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**ORCID iD**
Hanni Lin http://orcid.org/0000-0001-9428-1883

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