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Chinese Neonatal Follow-Up Network: a national protocol for follow-up assessment and collaborative research to improve developmental outcomes of high-risk preterm infants

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ABSTRACT

Introduction The objective of the Chinese Neonatal Follow-Up Network (CHNFUN) is to establish a standardised follow-up protocol for the assessment of high-risk preterm infants, and collaborative research aimed at improving early intervention and neurodevelopmental outcomes for preterm infants with gestational age less than 32 weeks in China. The CHNFUN is the first national neonatal follow-up network and has the largest geographically representative cohort from neonatal intensive care units (NICUs) in China.

Methods and analysis A survey of neonatal follow-up clinics participating in CHNFUN was used to inform the development of a standardised protocol for the assessment of high-risk preterm infants in China. Training in the use of assessment tools and data collection was provided to all participating centres. Individual-level neurodevelopmental outcomes data from participating neonatal follow-up clinics will be collected at corrected age, 40 weeks, 3–4 months, 12 months, 18–24 months, 3 years and 6 years of age, using a unique database developed by the CHNFUN and linked to NICU outcomes data in the CHNN Database. Data will be prospectively collected on an ongoing basis from all surviving infants born at <32 weeks' gestation or <1500 g birth weight and discharged from 34 participating NICUs from 1 June 2023. Infant neurodevelopmental outcomes and interinstitutional variations in outcomes will be examined and used to inform quality improvement measures aimed at improving outcomes, development and evaluation of early intervention programmes and other collaborative research, including clinical trials.

Ethics and dissemination This study was approved by the ethics review board of Children's Hospital of Fudan University (#CHFU 2022-112), which was recognised by all participating hospitals. Waiver of consent was granted at all sites. Only non-identifiable patient-level data will be transmitted, and only aggregate data will be reported in CHNFUN reports and publications.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Standardised definitions and data collection to ensure consistency across sites.
- ⇒ Links follow-up data with neonatal intensive care unit outcomes for risk analysis and quality improvement.
- ⇒ Limited generalisability to non-tertiary hospitals.

INTRODUCTION

Preterm birth is increasing globally,[1 2] and the incidence in China is 7.3 per 100 births.[3 4] Preterm is the single most common cause of adverse neurodevelopmental outcomes like cerebral palsy, cognitive deficits, learning and behavioural disorders, autism and attention deficit disorders,[5 6] and it is associated with enormous personal, economic and societal burden. Tracking long-term neurodevelopment is therefore critical to understanding the status of perinatal care and how advances and changes in maternal and neonatal care impact on neonatal intensive care unit (NICU) graduates and their families beyond discharge home. Neonatal follow-up programmes have been established and protocols standardised in many developed countries. Multi-institutional networks like the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Neonatal Follow-Up Network[7] and the Canadian Neonatal Follow-Up Network[8] have been established to monitor outcomes, conduct research and improve quality of care, and have demonstrated the importance and benefits of using standardised data collection and sharing to enable identification of deficiencies in care, facilitate quality improvement, diminish practice variability, improve health services delivery and support parental counselling and decision-making.

In China, the Chinese Neonatal Network (CHNN) was founded in 2018 as a national collaboration of 58 NICUs and has since grown to 98 tertiary level NICUs from 30 provinces across China, including all government-designated neonatal centres of excellence, all 4 national children's medical centres, 5 regional children's medical centres, 30 provincial perinatal or children's medical centres and other major regional referral centres.[9] CHNN maintains a prospectively collected standardised database of outcomes and NICU practices in China, provides a robust platform for collaborative research and training, and outcomes evaluation and quality improvement for very preterm infants (VPI) with gestational age less than 32 weeks or <1500 g birth weight.[10] However, the database only includes outcomes up to initial hospital discharge.

To address this, the Chinese Neonatal Follow-Up Network (CHNFUN) was established in 2023 to standardise neonatal follow-up assessments in China and establish a standardised neonatal follow-up database for infants <32 weeks' gestation or <1500 g birth weight linked to the CHNN Database. The objective of this manuscript is to describe the organisation, database and research protocols for CHNFUN.

Objectives

The specific objectives of CHNFUN are to: (1) establish a standardised neonatal follow-up protocol and an ongoing prospectively collected standardised neurodevelopmental follow-up database of VPI with gestational age<32 weeks or <1500 g birth weight among NICUs in China, linked to the existing CHNN Database, as a platform for surveillance, quality improvement and research; (2) assess and monitor major neurodevelopmental outcomes of VPI and their risk determinants, linked to short-term NICU outcomes and practices, as well as interinstitutional variations to identify clinical practices associated with good or poor outcomes; (3) conduct collaborative research, including epidemiologic, clinical and health services studies and randomised controlled trials; (4) explore opportunities for research on early intervention programmes and implementation in China.

METHODS AND ANALYSIS

Participating hospitals

CHNFUN was established as a national collaboration of 34 neonatal follow-up programmes from hospitals participating in CHNN from 26 cities in 20 provinces. They include 10 children's hospitals, 13 maternity hospitals and 11 general hospitals.

Study population

We will enrol all (n=9100 annually) VPI discharged from 34 participating NICUs who were born from 1 June 2023 on an ongoing basis. At discharge from NICU, patients will be given an appointment for follow-up. At the follow-up clinic, they will be recruited into the study by a nurse and informed consent will be obtained. We will exclude neonates with major congenital or chromosomal anomalies, those who were moribund at delivery, discharged against medical advice or lost to follow-up. Patients will be followed up at corrected age 40 weeks, 3–4 months, 12 months, 18–24 months, 3 years and 6 years of age. A follow-up rate of 90% is targeted.

Patient and public involvement

Patients and/or the public were not involved in the design, or planning of this research.

Survey of existing follow-up programmes at participating hospitals

To understand the current state of neonatal follow-up programmes and to facilitate the establishment of CHNFUN protocols, we conducted a survey of participating hospitals and the results have been published.[11]

Achieving the four specific objectives of CHNFUN

Objective 1: establish a standardised neonatal follow-up protocol and ongoing prospectively collected standardised follow-up database

Governance

The steering committee of CHNFUN comprises one director and seven senior neonatal follow-up leaders representing different regions of the country, with three international advisors from the NICHD Neonatal Follow-Up Network and the Canadian Neonatal Follow-Up Network. The executive committee is responsible for setting policies and research agendas and overseeing the activities and operations of the network and coordinating centre.

Coordinating centre and data collection

The CHNFUN coordinating and data centre is located at the Children's Hospital of Fudan University, Shanghai, China, which also coordinates and maintains the CHNN Database. The data centre is equipped with dedicated servers that are managed by the Information Technology Department of the Children's Hospital of Fudan University in compliance with hospital, municipal and national standards for data security. Although separate, the CHNFUN Database builds on and is linked to the CHNN Database framework of a scalable customised database with built-in error checking that was built by a commercial contractor. A standard manual of operations and definitions was provided to all participating centres. Dedicated data abstractors under the supervision of the site principal investigator are responsible for data acquisition in each hospital. Data abstractors were trained to enter data directly on-line from patient charts to the CHNFUN Database. Only non-identifiable patient information will be transferred and only aggregate data results will be reported and published. Data quality is ensured at multiple levels using built-in error checking at data entry and quarterly checks by the coordinating centre for quality and completeness. An audit of the CHNN data system demonstrated high quality and reliability of the data.[10] Site-specific data quality reports will be fed back to each site and corrections made if needed. Data quality audit using data reabstraction of randomly selected patient charts will be performed annually. Site

Table 1 Protocol for standardised neonatal follow-up assessments and instruments used

Age	Physical	Vision	Hearing	ASQ-C	GMA	HINE	BSID-4	WPPSI-IV
40 weeks	√	√			√			
3 months	√	√	√	√	√	√		
12 months	√	√	√	√		√		
18–24 months	√		√	√			√	
3 years	√						√	
6 years	√							√

ASQ-C, Ages and Stages Questionnaire (Chinese Version https://asq.neoballoon.com/web/); BSID-4, Bayley Scales of Infant Development, V.4; GMA, Prechtl General Movement Assessment; HINE, Hammersmith Infant Neurological Examination (https://www.mackeith.co.uk/hammersmith-neurological-examinations/hammersmith-neurological-examinations-subscriber-content/recording-and-scoring-proformas/); Physical, physical examination; WPPSI-IV, Wechsler Preschool & Primary Scale of Intelligence Fourth Edition (https://www.pearsonassessments.com/).

investigators will be responsible for data quality control in each site. An annual report will be produced for the network.

Follow-up assessment schedule

A standard schedule of follow-up assessments was established by the steering committee based on the availability of validated and reliable instruments in China, availability in the Chinese language, appropriateness for use in China, current prevalence of usage in China,[11] ease of application, ability to assess different dimensions of disability, availability of training and international recognition. The assessment schedule is shown in table 1.

Training

Standardised training was provided by certified trainers for all instruments (except Bayley Scales of Infant Development, which will be provided at a later date) to all participating sites through a series of training workshops prior to commencement of data collection. Ongoing support will be provided in case participants have queries about the conduct of the tests involved.

Data variables

Data variables were selected by the CHNFUN executive committee based on relevance and pertinence to the assessment instruments (table 2).

Definitions of variables were standardised and mapped to the International Classification of Diseases and Related Health Problems, 10th Revision, and Systematised Nomenclature of Medicine dictionaries as appropriate. Since the data will be linked to the CHNN Database, standard definitions for CHNN variables will be adopted from the CHNN data manual.[12]

Objective 2: assess and monitor major neurodevelopmental outcomes of VPI and their risk determinants, and interinstitutional variations in outcomes

Infant neurodevelopmental outcomes will be summarised as counts and percentages for categorical variables and using the means and SD or medians and IQR for continuous variables. Subgroup analysis and interinstitutional comparisons will use the χ^2 test for categorical variables and Analysis of Variance (ANOVA) F-test or Mood's

Table 2 Chinese Neonatal Follow-Up Network data variables

Categories	Variables
Demographic	Birth weight, gestation, sex, discharge measurements (weight, length and head circumference), brain ultrasound and MRI
Obstetric/perinatal risks	Maternal age, nurturing environment, caregiver, maternal and parental education and employment, number of people in household
Medical history	Rehospitalisation frequency, duration, reason, source of information, surgery number, type, anaesthesia, medications, aid and support needed at home
Physical examination	Length, weight, head circumference, blood pressure, diagnosis affecting development, neurological, auditory and visual
Developmental	Cerebral palsy type, severity, interventions; attention deficit hyperactivity disorder; autism spectrum disorder; Ages and Stages Questionnaire (Chinese Version); Prechtl General Movement Assessment; Hammersmith Infant Neurological Examination; Bayley Scales of Infant Development, V.4; Child Behavior Check List; Parental Stress Index; Modified Checklist for Autism in Toddlers; Wechsler Preschool & Primary Scale of Intelligence
Intervention	Early intervention programme, dietician, neurologist, physiatrist, physical therapist, psychologist, speech or language therapist, behaviour therapist, rehabilitation programme, social work

median test for continuous variables. Multivariable logistic regression models with adjustment for confounders will be used to assess outcomes and associated risk factors.

To study interinstitutional variations in neurodevelopmental outcomes, the ratios and 95% CI will be calculated, and differences between sites will be graphically displayed as 'caterpillar plots'. The 'indirect standardisation' approach will be used to compute the standardised outcome ratios in order to adjust for multiple baseline characteristics. Each follow-up clinic can compare its own observed rate with the average CHNFUN rate to identify the relative level of its own unit. For each outcome, the expected number of events will be computed as the sum of predicted probabilities from a multivariable model (logistic regression or zero-inflated negative binomial models based on data distribution) derived using data from all follow-up clinics with adjustment for confounders. Standardised outcome ratios will be graphically displayed using 'funnel' plots with 95% prediction intervals for comparison between follow-up clinics. Pairwise comparisons will be performed using multivariate regression models adjusted for confounders. The generalised estimating equation models will be used for adjusting analyses for infant cluster within the follow-up clinic. Hierarchical random-effects regression models will be used to allow for variation at unit level. In addition, statistical significance will be evaluated by applying a Bonferroni correction to account for multiple pairwise comparisons.

Associations of risk factors with outcomes will be assessed under the general framework of individual patient-level data meta-analyses. Random-effects models with adjustment for confounding variables and important risk factors will be used to assess the association and residual variation due to unknown or unmeasured unit-specific factors. These analyses will identify treatment practices and healthcare services with significant effects on neurodevelopmental outcomes. Multivariable logistic regression analyses will pool data from follow-up clinics to assess changes in neurodevelopmental outcomes over time with adjustment for potential confounders and important risk factors and accounting for clustering.

Objective 3: conduct collaborative research, including quality improvement, epidemiologic, clinical and health services studies and randomised controlled trials

CHNN is conducting a quality improvement study to reduce nosocomial infection in the NICU using the evidence-based practice for quality improvement methodology that incorporates three features: (1) systematic review of evidence in the published literature, (2) quantitative and qualitative analysis of outcomes and practices to identify practices associated with good or poor outcomes for targeted change and (3) use of a collaborative network of clinicians, researchers and administrators to facilitate mutual learning and implement change using rapid Plan-Do-Study-Act (PDSA) cycles. CHNFUN will provide neurodevelopmental outcomes that will be linked to the CHNN data to examine long-term outcomes associated with practice changes. Multivariable logistic regression analyses will pool data from units to assess changes in outcomes over time with adjustment for potential confounders and important practice-related risk factors, which may be targeted for practice change. Additional studies will be conducted, including epidemiological, clinical and health services studies, and randomised controlled trials with neurodevelopmental outcomes as the primary outcome.

Objective 4: explore opportunities for research on early intervention programmes and implementation in China

We will conduct a systematic review of the literature and visit reputable international institutions that are currently conducting early intervention programmes. The CHNFUN executive committee will use the available evidence to develop a standardised protocol for early intervention that is appropriate for China. This will be done in partnership with other available resources in the community for support of infants and their families and to maximise efficacy and efficiency.

Training will be provided to participating sites, and the programme will be evaluated in a systematic way that will provide opportunities for revision and improvement over time.

Statistical analysis

A team of statisticians at the CHNFUN coordinating centre will conduct analyses of the cohort data under the leadership of the CHNFUN Director. For specific research projects, relevant data may be released to specific research groups for their analysis. Participating sites may perform analysis of their own individual site data.

Ethics and dissemination

Central ethics approval was obtained from the ethics committee of the Children's Hospital of Fudan University (#CHFU 2022-112) and recognised by all participating sites. All participating sites have signed data transfer agreements with the CHNFUN coordinating centre and obtained ethics approval from their affiliated institutions or hospitals to allow sending deidentified data to the CHNFUN coordinating centre in compliance with national, provincial and local hospital regulations for ensuring patient privacy and confidentiality and are consistent with international standards. Only aggregate data will be used for analyses, and waiver of consent was granted at all sites. The results of CHNFUN studies will be disseminated by (1) an annual report that will be published and provided to participating hospitals and regional health authorities; (2) reports at national and international scientific meetings;(3) publication in domestic and international scientific journals.

DISCUSSION

This is the first standardised neonatal follow-up protocol and database for VPI that has been established in China, with a large cohort from 34 tertiary level NICUs from across China. It is significant for several reasons. First, neurodevelopmental outcomes are ultimately the most relevant outcomes for infants and their families and society because they impact heavily on the patient's quality of life, burden to the family and society, social relationships and potential for economic contribution to society. This is particularly relevant in China, which is facing huge challenges with decreasing birth rates and an ageing society.[4] Second, neonatal follow-up programmes are a recent development in China and have been established independently at different institutions with different protocols and using different assessment instruments and different resources. Many did not have formalised training but, instead, they learnt how to perform assessments through observation or trial and error. Consequently, it was difficult to know whether their assessments were valid and how to compare outcomes from different institutions and regions. CHNFUN standardises not only the protocol and database but also provides standardised training by fully trained and internationally certified trainers. This provides confidence that assessments performed in CHNFUN will meet internationally accepted standards. Third, the CHNFUN follow-up database is built on the already established CHNN Database infrastructure, which has been in existence since 2019. Since the CHNN data system has demonstrated high accuracy and reliability, and it provides assurance that the CHNFUN Database will perform just as well, although we will definitely assess this going forward.[10] Finally, the CHNFUN Database is linked with the CHNN Database and will provide seamless ability to link and examine patient data from demographic to antenatal and neonatal management, clinical practices, resource use, mortality, short-term NICU outcomes and long-term neurodevelopmental outcomes.[9] This rich source of data from a large patient cohort will be invaluable for examining risk factors, improving quality of neonatal care and conducting research including clinical trials.

It should also be noted that the CHNFUN protocol was deliberately created only after careful preparation by a large group of leaders in neonatal follow-up from different regions across China and with advice and input from established international leaders from the USA and Canada. A systematic review of neonatal follow-up protocols and assessment tools used was first conducted. A survey of the current status of neonatal follow-up was then conducted to provide information about protocols in place at different institutions, assessment tools used, training and resources available.[11] A cross-China executive committee examined the evidence and then created a protocol that was pragmatic, relevant, and easily achievable by most institutions in China, based on the availability of validated and reliable instruments in China, availability in the Chinese language, appropriateness for use in China, current prevalence of usage in China, ease of application, ability to assess different dimensions of disability, availability of training and international recognition. These criteria were adopted to ensure that the protocol will be acceptable to most institutions in China and will enable it to become the national protocol over time.

Another potential benefit of the CHNFUN protocol and database is for supporting initiatives in early intervention for high-risk VPI. This is particularly important in China as the increasing survival of extremely preterm infants will lead to an increasing incidence of cerebral palsy, neurodevelopmental delay, behavioural and learning disorders, and psychosocial and mental health needs for both affected infants and their families. Their needs for early intervention, developmental care, educational and psychosocial support will correspondingly increase, and China must prepare their health services in anticipation of this. There is also a growing body of literature that shows that neuroplasticity can lead to neurodevelopmental improvements well beyond 2 years of age. Taylor *et al*[13] showed that one-third of surviving children classified as having profound neurodevelopmental impairment and nearly two-thirds of those classified as having moderate to severe neurodevelopmental impairment at 2 years had none to mild neurodevelopmental impairment at 10 years. Consequently, there is potential for early intervention programmes to significantly improve outcomes of infants with neurodevelopmental impairment. Similar to neonatal follow-up programmes, the development of early intervention programmes in China has been fragmented and uncoordinated. CHNFUN will provide an opportunity to develop a coordinated early intervention programme in China using the best available evidence that is relevant, pragmatic and affordable.

There are several limitations of the CHNFUN Database. First, data are derived from a select group of tertiary level NICUs with the highest level of neonatal care in China and may not be generalisable to the whole population. While these tertiary hospitals provide specialised NICU care and follow-up clinic evaluations, the outcomes observed may not fully reflect the experiences of patients in non-tertiary hospitals with fewer resources and limited NICU and follow-up expertise, which could affect their outcomes. However, our study will provide a reference for improving neonatal follow-up practices across all hospital levels. We plan to share our findings with NICUs at all levels in China and eventually expand our network to include lower-level institutions and provide guidelines to promote more equitable neonatal care nationwide. Second, large cohort databases may have biases, including reporting bias, selection bias and others. We will standardise data collection, conduct quality control checks and use sensitivity analyses and statistical adjustments to minimise biases and ensure robust results. Third, data from patients discharged against medical advice are not included, which may bias the outcomes. We will perform sensitivity analyses to assess the impact of excluding patients discharged against medical advice and compare their characteristics with those included in the study to gain a better understanding of potential biases. Finally, data on resource use are limited. Future studies will incorporate economic evaluations to address this gap.

In summary, the CHNFUN protocol and database will serve as a strong national platform for collaborative research, outcomes evaluation and quality improvement for VPI, and it has the potential to benefit infants and families in China and internationally.

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