Global survey on newborns' HOspitalisation and Parental Experiences

Brief Title:
HOPE study

Study protocol and statistical analysis plan

Study Protocol Version 4 (03.04.2025)

Table of content

1. Study Synopsis

Funding organisation	Global Foundation for the Care of Newborn Infants (GFCNI)
Protocol Title	Global survey on newborns' HOspitalisation and Parental Experiences
Short Title	**HOPE study**
Study Aim(s)	Study aims are to • explore parents' experiences, needs, concerns, social and emotional burdens and perceived stress related to the hospitalisation of their newborns, • explore the presence and implementation of IFCDC principles and support through political framework conditions, • identify areas in need for improvement for individual countries and provide country-specific guidance to advance structural frameworks if required.
Design	• Retrospective cross-sectional survey • Multinational, multilingual online survey, using a web-based online questionnaire
Inclusion criteria	• Parents and caregivers of newborn infant born on January 1, 2023, or thereafter, who received special/intensive care starting within the first week of life such as oxygen therapy or other respiratory support, incubator treatment, intravenous infusions, treatment of (suspected) sepsis, pneumonia, necrotising enterocolitis, malformations, jaundice, nutritional/feeding problems, hypoglycaemia, etc.
Exclusion criteria	• Other family members than parents/(primary) caregivers • Parents of newborns that did not receive special/intensive care • Parents or caregivers of infants born before January 1, 2023

Study sample	• We aim to reach as many parents/caregivers as possible who respond in the timeframe of data collection (6 months). • Minimum of 25 responders per country from at least 30 countries (no upper limit).
Recruitment procedures	Multi-level recruitment strategy including sharing the survey access via • GFCNI's parent network • GFCNI's social media channels • GFCNI's newsletter • Confirmed supporting experts (n = 76) from worldwide • Confirmed collaboration partners (n = 7)
Trial intervention(s)	This is not an interventional trial but an observational study
Main Outcome measures	• Number of respondents • Baseline characteristics, socio-demographic characteristics • Qualitative and quantitative data of parent's experiences, concerns and unmet needs related to the hospitalisation of their infant • Qualitative and quantitative data of parent's experiences related to implementation of infant and family-centred developmental care (IFCDC) principles • Qualitative and quantitative data of parent's experiences related to infrastructural, social and political barriers and supportive measures
Additional Outcome measures	• Evaluation data of the pre-testing to re-fine the questionnaire • Country-specific information and comparisons regarding outcomes • Sub-group specific results from parents/caregivers of SGA, preterm and sick newborns regarding outcomes • Sub-group specific results related to different length of stay

Statistical Analysis	• Descriptive statistics with standard statistical tests if applicable • Qualitative analysis with testimonials of open-text fields. Sub-group analysis related to different length of stay • Tabular and graphical mapping of number of responses broken down by geographical region (continent and country) • Non-completer analyses • Drop-out analyses • Subgroup analyses related to preterm, sick and SGA infants • Subgroup analyses related to countries and continents
Ethics	The ethics committee of the Maastricht University UMC+ (Netherlands) waived the need for a formal ethical approval (METC 2024-0411). Informed consent will be obtained from all participants prior to study participation.
Study registration	This study has been registered at www.ClinicalTrials.gov (NCT06827028).

2. Background

Newborns who are born too soon (<37+0 weeks' gestation), too small (< 2500 g birth weight; SGA), or acutely sick are a very vulnerable group of patients (1,2); and rates of preterm birth (4% to 16%) and low birthweight (4% to above 20%) highly vary across countries. Preterm birth is the most common cause of death in children aged under five years (3–7). During the last decades neonatal mortality has improved (4,5); however, the required specialised care to prevent mortality, to support adequate growth and development, and to reduce the risk of morbidities in later life is extremely challenging, especially for parents and is accompanied by a tremendous social and economic burden (8,9). Irrespectively being born preterm, small and sick may have lifelong medical and social consequences (2,10). The underlying situation is an extreme psychological burden for parents and caregivers.

Applying an infant and family-centred developmental care (IFCDC) approach is considered to be beneficial for the growth and development of hospitalised newborns and for their families, and is associated with long-term benefits (11,12). During the last decade IFCDC elements have been gradually introduced in many neonatal units around the world (11,13), however not systematically. Albeit initiatives, such as the European Standards of Care for Newborn Health (ESCNH) that made IFCDC as one central element of uniform reference standards for evidence-based and high-quality neonatal care (14), the implementation of IFCDC needs to be improved in many sites across the world (15). The place of birth remains decisive for long-term health outcomes which clearly demonstrates heterogeneity in care provision and inequity in terms of access to optimal specialised care (16,17). In addition, there are differences in infrastructural, political and social framework conditions for parents' rights and supportive measures during pregnancy and especially during the time of their infants' hospitalisation and beyond. This indicates that parents and caregivers across the globe face different challenges and barriers related to the care of their hospitalised newborn and during follow-up. While we maintain advocating for IFCDC principles as integral of optimal care provision for preterm, small and sick newborns, there is a general lack of information about global implementation of IFCDC principles and country-specific comparisons related to their implementation in neonatal care. Moreover, it is not transparent which social and political frameworks are established on the country level to support parents during the hospitalisation of their newborn infants, and how parents in different countries perceive the implementation/omission of deliberately supportive measures.

Therefore, we aim to conduct a multi-national, multi-lingual, online survey among parents to assess their experiences, needs, concerns, social and emotional burdens and perceived stress related to the hospitalisation of their newborn infants, the presence and implementation of IFCDC principles and the support available through political framework conditions. The overall goal is to identify areas in need for improvement for individual countries and provide country-specific guidance to advance structural frameworks if required.

3. Aim

With this multi-national, multi-lingual, online survey, we aim to explore parents' experiences, needs, concerns, social and emotional burdens and perceived stress related to the hospitalisation of their newborns, the presence and implementation of IFCDC principles and support through political framework conditions. The overall goal is to identify areas in need for improvement in individual countries and provide tailored country-specific guidance to advance structural and social frameworks as necessary.

4. Study Design and Methods

The study will be designed as an observational cross-sectional survey using a self-administered, web-based questionnaire for retrospective data collection. The study will use a multi-lingual, multi-national online questionnaire collecting data from parents worldwide whose newborn infant was hospitalised.

4.1 Collaboration partners, expert working groups and their roles

This project will be carried out in close collaboration with representatives of national parent organisations and professional healthcare societies. The following societies are involved as collaboration partners: ANA (African Neonatal Association), CNN (Canadian Neonatal Network), COINN (Council of International Neonatal Nurses), ESPR (European Society for Paediatric Research), NFI (NIDCAP Federation International), UENPS (Union of European Neonatal and Perinatal Societies), WHO Collaborating Centre for Maternal and Child Health. All collaboration partners delegate one representative that supports the Core Working Group (CWG).

The CWG, with n=27 members, and a Support Group (SG), with n=48 members, both consisting of individual multi-professional experts from all continents working in the field of maternal and newborn health, will be assembled. Both groups support the development of the questionnaire in a two-step approach, translations of the questionnaire, the recruitment of participants, data analysis, data interpretation, and publication and dissemination of results. While the CWG, will be actively involved in the initial development of the draft questionnaire, the SG will be involved for a broader review for the revision and final correction of the questionnaire in a second step (Figure 1).

4.2 Development of the Questionnaire

For this purpose of this study, we performed a scoping review (18) to explore the available literature related to this topic and to identify the most relevant topics to be included in the questionnaire.

After this literature research, the questionnaire was drafted considering the already existing and validated EMPATHIC-N and the PICKER questionnaires (19,20), as well as the questionnaire, we previously developed to explore parents' experiences related to challenges during the COVID-19 pandemic regarding the care of their newborns (21,22). In addition, questions related to political, social and infrastructural framework conditions were included.

The online questionnaire includes single, multiple choice answer models and some open-text fields. Besides questions related to participant characteristics such as age, sex, country of location, infant birthweight, duration of hospitalisation, etc., the questionnaire includes questions related to the parents' perception of political, social and infrastructural framework conditions as experienced within their country as well as elements of neonatal care mainly involving aspects of IFCDC such as the use and support of breast/human milk and early breast feeding, skin-to-skin care (kangaroo-mother care), parental presence and involvement in the care, shared decision making, stress and pain control etc. during their hospital stay (details of the questionnaire content are outlined in the Appendix A).

In order to maximise the reach and to prevent the loss of study participants due to time constraints, a multi-stage approach will be used, beginning with 47 high-priority questions (single and multiple answer options), followed by more specific second lower-priority questions (single and multiple answer options) (n=21). This first/second layer approach aims to increase the response rate for the most important questions and to keep the effort for participants with limited time resources to a minimum, while taking advantage of the motivation of participants who are willing to share the full scope of their experiences related to their baby's hospitalisation.

The questionnaire draft will be reviewed by the CGW and after having implemented necessary changes, the updated version will be shared with the larger SG for feedback and review. Both groups will ensure that the questionnaire considers the specific national perspective and that the questions are phrased sensitively (Figure 1). All implemented changes and the finally updated version of the questionnaire will be discussed with both groups including the representative from the collaboration partners in digital discussion meetings.

In addition, comprehensive interviews with up to 10 participants resembling the target group will be performed to elucidate other relevant topics that may have not yet been covered and need to be included.

The first questionnaire draft (in English) with included feedback from the interviews and experts and will be pre-tested by a comparable target group to receive qualitative feedback on the questionnaire per se and the phrasing.

After a potential adaptation based on data and information of the pre-testing, the questionnaire will be translated in as many different languages as feasible to overcome the linguistic barrier and facilitate participation for parents worldwide. The CWG and SG will support and review the translations. The translated questionnaire versions will be transferred into the online survey software SurveyMonkey ® and will be distributed via the expert groups, GFCNI's network, GFCNI's newsletter and social media channels via an access link.

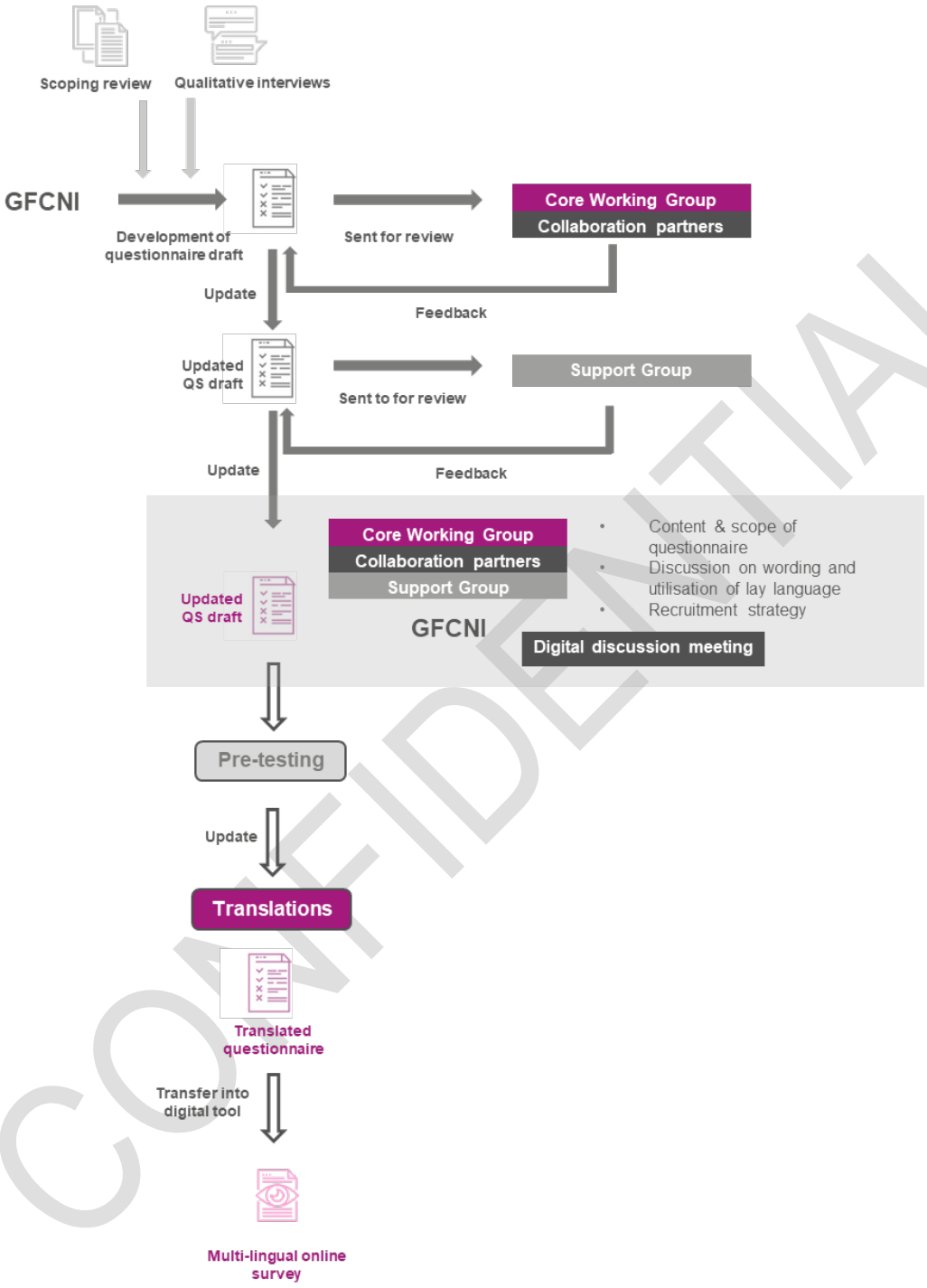

Figure 1: Process of questionnaire development

4.3 Study population and inclusion/exclusion criteria

The target group includes parents or caregivers of newborns worldwide who were born as of January 1, 2023, and received special/intensive care e.g. preterm born, acutely sick and SGA.

Inclusion criteria

The target group are parents and caregivers eligible for participation if they fulfil the following inclusion criteria:

- Being a parent or caregiver of a
  - newborn infant born on January 1, 2023, or thereafter,
  - who received/is receiving special/intensive care staring within the first week of life such as oxygen therapy or other respiratory support, incubator treatment, intravenous infusions, treatment of (suspected) sepsis, pneumonia, necrotising enterocolitis, malformations, jaundice, nutritional/feeding problems, hypoglycemia, etc.

Exclusion criteria

- Other family members than parents/(primary) caregivers
- Parents of newborns that did not receive special/intensive care staring within the first week of life
- Parents or caregivers of infants born before January 1, 2023

4.4 Sample size

It is aimed to reach as many parents/caregivers as possible who respond within the timeframe of data collection (between 1 September 2025 and 28 February 2026). The goal is to include a minimum of 25 responders per country from at least 30 countries. If less than 25 responders/country are recruited, the data from that particular country will not be considered in the final analysis.

4.5 Recruitment of study participants

For recruitment, GFCNI will develop a recruitment toolkit with printable posters, and postcards, digital recruitment infographics, and quote cards from peers, all including the survey access link. The toolkit will be made available to all supporting experts and collaboration partners.

Participants will be recruited primarily through social media outreach efforts and online advertisements by GFCNI including recurrent newsletter promotion as well as supporting partners and experts.

In addition, the established global network of national and international parent organisations and healthcare professional societies will support the recruitment by sharing the content and survey access link with their network, consisting of parents across the world. Special emphasis will be paid on reaching indigenous populations, migrants and refugees. For this matter, national experts will be asked to pay special attention to support the inclusion of particularly hard-to-reach communities within their respective country.

4.6 Study outcomes and analysis

The study outcomes and analyses will be determined by the final questionnaire. We aim to include the following outcomes, however, the final decision will rely on the expert discussions.

Main outcomes

- Baseline and socio-demographic characteristics
- Qualitative and quantitative data of parent's experiences, concerns and unmet needs related to the hospitalisation of their newborn infant
- Qualitative and quantitative data of parent's experiences related to implementation of IFCDC principles
- Qualitative and quantitative data of parent's experiences related to infrastructural, social and political barriers and supportive measures

Analysis and reporting

- Evaluation data of the pre-testing to re-fine the questionnaire
- Country-specific information and comparisons of outcome variables
- Sub-group specific results from parents/caregivers of SGA, preterm and sick newborns of outcome variables
- Sub-group specific results related to different length of stay
- Identification of barriers for implementing IFCDC principles
- Identification of the influence of COVID-19 related restriction policies

4.7 Ethics and data collection

The ethics committee of the University of Maastricht, The Netherlands was consulted (Nr: METC 2024-0411) and waived the need for a formal ethical approval. The study is registered on clinicaltrials.gov and currently reviewed (NCT06827028).

Data collection, processing and storage will adhere to the general data protection regulation and the declaration of Helsinki. The study will follow the Strengthening and Reporting of Observational Studies in Epidemiology (STROBE) reporting guideline for cohort studies.

Prior to the study participation, interested individuals will be informed about the following points:

- background and relevance of the study,
- type and form of data collection (anonymous) and data usage,
- the General Data Protection Regulation (GDPR), voluntariness of participation,
- revocability of consent without disadvantages and without giving reasons,
- the right to ask further questions, and
- the right for information about stored data.

Participants will be informed about the potential for distressing reactions regarding their personal experiences related to the birth and treatment of their newborn infant and will have the opportunity to terminate participation in the survey at any time. No financial incentives will be provided to the participants.

Participants will be explicitly asked if they have read and understood the provided information and to agree thereafter. By clicking on the agree checkbox, they will give their informed consent to participate in the study. Data collection will be anonymous.

4.8 Statistical analyses

An attrition analysis to explore patterns in participants who drop-out within the high-priority and lower-priority part will be conducted. Multiple response questions will be analysed as sum of answers per answer option (n (%)). Qualitative data from open text-fields will be categorised and unified, if possible, and shown as relative frequencies and percentages (n (%)) but also with the 1:1 wording.

The analysis will include descriptive statistics (determinations of frequencies, percentages, and continuous variables as mean ± standard deviation / median, interquartile ranges for parametric/non-parametric distribution) for background data and collected responses. Fisher's exact test or Chi-square tests will be used for categorical variables, and t-tests and analysis of variance and respective tests for non-parametric data to compare potential differences between subcategories, where appropriate.

Tabular and graphical mapping of response rates and broken down by geographical region (continent and country) will be done. Non-completer and drop-out analyses will be performed. Qualitative analyses will be performed to harmonise and unify – if possible – open-text fields. Subgroup analyses are planned to identify differences or congruences in the needs and concerns of parents/caregivers from preterm, sick and SGA infants. Additional subgroup analyses aim to elucidate differences on the continent and country level.

Data will be analysed using R Statistical software and MS Excel. Statistical significance will be determined with a $p<0.05$. Since there is no hypothesis to be tested, statistical analysis will be descriptive only, and thus no correction for multiple testing is needed.

4.9 Dissemination of results

Results will be published in scientific journals after peer-review and made publicly available (Open Access). A comprehensive project report with all applied subgroup analyses showing single-country data will be released. Dissemination activities through the GFCNI network, partner organisations, CGW and SG members will follow the scientific publications.

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Appendices

Appendix A

List of questionnaire content (preliminary)

Baseline characteristics and socio-demographic characteristics

- No. of respondents
- Age of responders
- Gestational age at birth
- Birth weight (g)
- Multiple pregnancy or singleton pregnancy
- Prenatal care visitation
- Pregnancy-related appointments
- Other person (partner/family member) allowed at prenatal care appointments (yes/no)
- Parental education
- Further socio-economic variables of interest

Data related to birth and neonatal care

- Birth mode (vaginal birth/caesarean section)
- Allowance of other person (partner/family member) at birth
- Duration of special/intensive care
- Delivery of supplemental oxygen (yes/no)
- Delivery of continuous positive airway pressure
- Delivery of intubation and mechanical ventilation (yes/no)
- Marriage status
- Provision of adequate health information of the baby
- Provision of adequate health information at discharge related to home aftercare
- Provision of adequate information at discharge related to follow-up appointments
- Provision of adequate information about mental health support
- Mental health support offered
- Open questions

Data on IFCDC principles

- Initiation of skin-to-skin contact
- Frequency of skin-to-skin contact
- Access to the ward
- Duration of visitation time
- Permission to touch the baby in the incubator or infant bed

- Permission of other persons to be with the baby
- Involvement of mother in care provision
- Involvement of partner in care provision
- Availability of breastfeeding supported by staff
- Availability of milk sources
- Initiation of breastfeeding or provision of pumped own breast milk
- Open questions

Social and political support/barriers

- Qualitative information on parental leave
- Qualitative information on accommodation provision
- Data on compensation for expenses related to work absence
- Data on compensation for expenses related to the transportation to the hospital
- Data on compensation for expenses related to the accommodation
- Data on compensation for expenses related to the transportation to home
- Financial burden/support
- Open questions

Appendix B

Information on Authorship in Scientific Publications related to the HOPE study

Regarding Authorship GFCNI follows the recommendations given by the International Committee of Medical Journal Editors (ICMJE) as described here: ICMJE | Recommendations | Defining the Role of Authors and Contributors. An internal Authorship guideline along with the ICMJE recommendations is available and can be requested individually.