







Study protocol for the development and pilot-testing of a Self-assessment tool for the implementation of the European Standards of Care for Newborn Health (ESCNH)

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ABSTRACT

Introduction In Europe, disparities exist in having access to optimal neonatal care. With the European Standards of Care for Newborn Health (ESCNH), evidence-based reference standards are available which provide guidance to improve the care for preterm and ill newborns. To support healthcare professionals (HCPs) and hospital/clinic management in identifying the extent of ESCNH implementation, a feasible assessment tool is required. Such a tool should help identify areas in need of improvement and provide clear recommendations for action. We aim to develop a digital self-assessment tool for HCPs to detect the local level of ESCNH fulfilment and identify areas in need of improvement, and thus provide recommendations for action.

Methods and analysis The self-assessment tool will have the form of a digital questionnaire with condensed ESCNH content. A Project Expert Group provides scientific input. With pretesting among HCPs, a template of a questionnaire section is evaluated and adapted accordingly. The subsequently developed full questionnaire will be appraised within a two-round eDelphi survey by at least 50 invited HCPs. Statements and formulations need to be accepted by at least 80% of participants. The remaining discrepancies will be solved in a final workshop. The resulting digital self-assessment tool (SAT) will be translated into several languages and evaluated in a pilot-testing among at least 20 hospitals/clinics across Europe.

Conclusion With the self-reflection through the SAT, HCPs, hospital/clinic managers, policymakers and other stakeholders will receive feedback on the conformity with the ESCNH and guidance for improvement.

Trial registration number NCT06379828.

INTRODUCTION

Newborns who are born too soon (<37 weeks gestation), too small (<2500 g birth weight) or acutely ill are a very vulnerable group of patients,^{1,2} and rates of preterm birth (5.3%–11.3%) and low birth weight (4.0%–10.1%)

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ The European Standards of Care for Newborn Health (ESCNH) are evidence-based reference standards for neonatal mortality and morbidity, the care, treatment and follow-up care of affected infants and families, including all aspects of maternal care. Especially the topic of infant-and family-centred developmental care, which includes interventions such as Kangaroo Mother Care, has received growing attention and importance. However, little is known about the current state of the implementation in hospitals/clinics across Europe. Healthcare professionals need support in the assessment of the extent of implementation and possible need for improvement.

WHAT THIS STUDY HOPES TO ADD

⇒ Using pretesting, eDelphi process and pilot-testing, an interactive digital self-assessment tool will be developed and validated for applicability.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ By measuring current performance, healthcare professionals will receive guidance on how to improve implementation of the ESCNH. An increase in the ESCNH implementation is expected to improve the care and health outcomes of preterm and ill neonates, and their families in Europe and can be a cornerstone for hospital/clinic management and future policy recommendations.

highly vary across European countries, with complications of preterm birth as most common cause of death in children aged under 5 years.^{3–5} During the last decades, neonatal mortality improved^{4,5}; however, the subsequent care is accompanied by a high economic burden,^{6,7} but most importantly,

preterm born or ill newborns may have lifelong medical and social consequences.²⁸

Quality of care provision varies between European countries, regions or hospitals/clinics. Thus, the place of birth can be decisive for long-term health outcomes, demonstrating heterogeneity in care provision and inequity in having access to optimal care.^{9,10}

Therefore, uniform reference standards starting from before birth up to follow-up care were urgently needed and are key in providing equal access to resources and optimal care. For this purpose, the European Foundation for the Care of Newborn Infants (EFCNI) initiated the European Standards of Care for Newborn Health (ESCNH) project aiming to address the existing disparities by the development of evidence-based reference standards that cover a broad range of topics associated with preterm birth and neonatal mortality and morbidity.¹¹ In a complex process, 96 standards across the range of areas in perinatal and neonatal care were developed and published in 2018. To decrease cultural barriers, strengthen acceptance and pave the way for a national adaptation, more than 220 international participants, including multidisciplinary healthcare professionals (HCPs), together with patient (parent) representatives, stakeholders and third parties from 31 different countries were involved in the development.¹¹ The ESCNH underlie a predefined revision cycle ensuring them to align with the latest evidence and are extended by new standards of yet neglected or emerging medical areas.^{11,12} The ESCNH are not legally binding but should be considered as guidance to develop binding country-specific guidelines, regulations or laws.

Several initiatives across Europe were undertaken to implement the ESCNH in the hospital setting. However, it remains a challenge for care providers to identify the need for change, to alter obsolete procedures or to retrace the extent to which the ESCNH are adhered. Therefore, we are aiming to develop a self-assessment tool (SAT) in different languages helping HCPs across Europe to measure the level of ESCNH implementation, to identify areas in need of improvement and ultimately to increase the extent of implementation.

METHODS AND ANALYSIS

Aim and study design

Covering the broad variety of standards in an easy-to-use SAT requires a systematic condensation. The Delphi method is promising to organise and manage group communication processes and has already frequently been applied in the field of medicine and healthcare.¹³⁻¹⁶ It is based on the concept of repeating the first examination round within the second round completed by aggregated results from the first examination. This leads to a re-consideration of the individual expert assessment and a more accurate consolidation of different opinions and supports anonymous consensus finding,¹³ making it a

suitable method to consolidate the broad range of topics within one SAT.

This study follows a qualitative research approach, combining the eDelphi method with a pilot-testing to develop a SAT.

The final SAT is foremost targeted at HCPs who are actively involved in the care and treatment of preterm or ill neonates and their families. It should serve as a checklist for quality improvement, which illustrates the status quo in terms of care provision according to the ESCNH of a hospital/clinic. The SAT indicates (after completion) which areas are lagging behind and additionally provides suggestions on how to improve the current care provision by fulfilling the statements and its components. The results of the SAT can be used by HCPs and hospital/clinic managers and, if results are made publicly available (which is strongly encouraged), by policymakers alike to improve care provision. The full implementation strategy after development (including the implementation process, its evaluation and ways for sustainable changes) lies outside the scope of this paper and will be described elsewhere.

Primary and secondary outcome measures

The primary outcome is the final version of a digital SAT. Secondary outcomes include:

- ▶ Response rates and dropout rates of the pretesting, the two eDelphi rounds and the pilot-testing
- ▶ Demographics and characteristics of participants from the pretesting, the two eDelphi rounds and the pilot-testing
- ▶ Evaluation of the development process of the SAT
- ▶ Evaluation data on the formulation of the questions and understandability
- ▶ Evaluation data on the condensation of the ESCNH content
- ▶ Qualitative feedback on the illustration of output
- ▶ Appraisal on the utilisation of the SAT
- ▶ Scalability of the SAT and dissemination

ESCNH and the scope

Giving a direction for Europe and European countries, the 102 standards cover 11 core topics around the pre- and perinatal phases until follow-up in childhood (figure 1).

As described elsewhere,¹¹ every standard follows a harmonised format with the ‘Statement of the standard’ summarising the key message. More details and clear guidance for practice is given in the ‘component table’ displaying recommendations for action, separated by user groups.¹¹ As these parts are key for the practical implementation, they are the major focus for the development of the SAT.

Project Expert Group and its role

Experts with different areas of expertise were consulted via online calls in the planning phase to enable the consideration of various aspects. These preliminary discussions



Figure 1 Overview of the 11 ESCNH core topics. The number of standards per topic is given in brackets. ESCNH, European Standards of Care for Newborn Health; NICU: neonatal intensive care unit.

were instrumental in refining the study's framework and addressing potential challenges. A Project Expert Group (PEG) was assembled, which consists of members of the EFCNI study team and eight renowned external experts from different European countries with multidisciplinary professions and differing methodological expertise relevant to the study. Members of the PEG were recruited either via the preparatory calls, through suggestions from consulted experts or via the EFCNI network.

The PEG supports the planning process of the study, provides scientific and methodological input and assists in the development of the first questionnaire, recruitment of participants, and the eDelphi survey, interpretation of data, and dissemination through online discussions and written feedback (figure 2).

Development of the first questionnaire template and pretesting

Given that the SAT is sought to be easy to use during the daily working routine with a manageable scope of effort, the content of the 102 ESCNH needs to be restructured and summarised. For this purpose, one member of the EFCNI study team screens the ESCNH content for overlapping and redundant information and makes suggestions on how the content can be grouped within an 'ESCNH condensation sheet' (ECS). The second member of the study team verifies suggestions and, if required, makes adaptations to the grouping. The remaining discrepancies are discussed in a working meeting with

the third study team member and will finally be approved (figure 2).^{11 17}

Using the ECS as the backbone, the first-questionnaire template will be elaborated for 1 of the 11 core topics of the ESCNH and has to pass a pretesting. The aim of pretesting is to receive the first evaluation data during the development stage of the questionnaire. Depending on the pretesting data, if necessary, adaptations will directly be realised and incorporated into the full questionnaire.

The pretesting will be performed by a selected group of invited HCPs suggested by the PEG, resembling the targeted participants of the eDelphi and pilot-testing. The pretesting will be conducted through a digital version of this first questionnaire (including 1–2 exemplary topics) transferred into SurveyMonkey, an online survey software. The aim of the pretesting is to ensure that the questionnaire is clear/targeted and to test the application and evaluation of answers using SurveyMonkey. Based on adaptations and the ECS, self-assessment questions for the remaining 10 ESCNH topics will be worked out which constitute the first template of the SAT. This template will be reviewed by the Topic Expert Group Chairs that initially developed the ESCNH with their Topic Expert Group team. After including adaptations, if necessary, the SAT template will be transferred into SurveyMonkey and then evaluated through a comprehensive eDelphi procedure (figure 2).

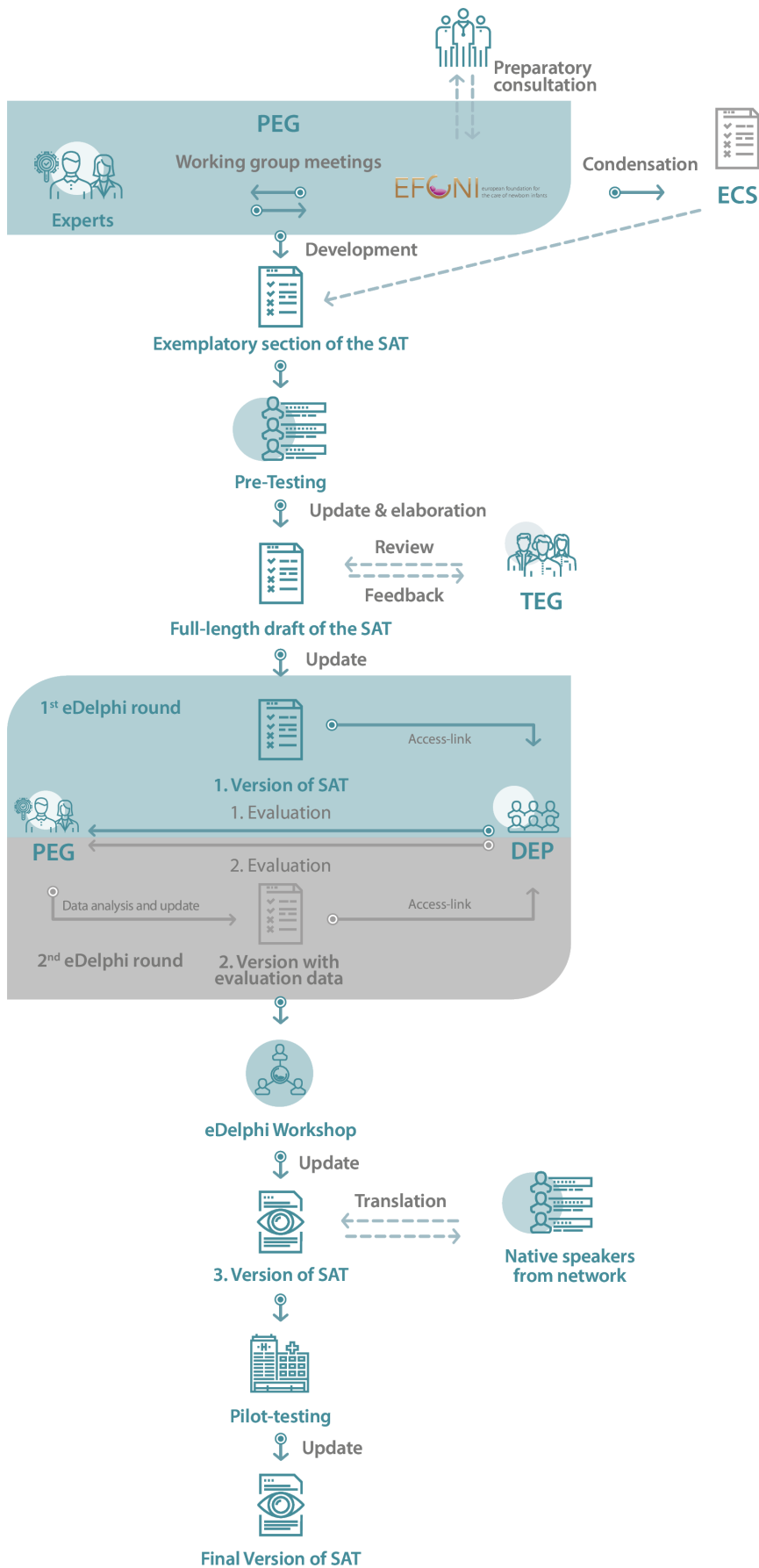


Figure 2 Workflow of the study. DEP, eDelphi expert panel; ECS, ESCNH condensation sheet; ESCNH, European Standards of Care for Newborn Health; PEG, Project Expert Group; SAT, Self-assessment tool; TEG, Topic expert group.

eDelphi Expert Panel and recruitment

While in previous Delphi studies, the number of participants varied approximately between 10 and 200 participants,^{13 18–22} the consensus of the PEG is to aim at about 100 participants with a minimum size of 50 participants for the eDelphi Expert Panel (DEP) from various European countries to gain sufficient descriptive data and substantiated results. As this is a qualitative research approach, a power calculation cannot be performed, and the sample size is based on estimations from previous Delphi studies and the PEG experience.

The inclusion and exclusion criteria are applied to the pretesting, the eDelphi, as well as the pilot-testing with minor deviations.

Persons are eligible for participation if one of the following criteria is fulfilled (**inclusion criteria**):

- ▶ Parent representatives or representatives of caregivers of infants who received special/intensive care
- ▶ HCPs in the fields of midwifery, neonatal care, obstetrics, psychology, health sociology, physical therapy
- ▶ Working in the field of hospital management
- ▶ Working in European countries.

The following criteria are considered as **exclusion criteria**:

- ▶ Insufficient proficiency in English (or for pilot-testing, the respective language of the translated SAT)
- ▶ (Professional) background that is not related to the ESCNH
- ▶ Working primarily for industry
- ▶ Working outside European countries
- ▶ Indicating no time resources to participate in two eDelphi rounds (only applicable for the eDelphi).

EFCNI's network organisations (>200 international healthcare societies and supportive organisations; >100 parent and patient organisations) will be informed about the project and invited via email to suggest suitable candidates for participation. In addition, the PEG will support the recruitment by sharing information among their networks. Different measures, such as personal invitation email and reminder mailings, will be applied to improve response rate and maintain compliance.

eDelphi rounds and workshop

In the eDelphi, the DEP will be invited to give feedback to the SAT by filling out the eDelphi questionnaire provided in SurveyMonkey (figure 2). In both eDelphi rounds, the panel will receive an access link via email. In the *first eDelphi round*, the DEP will critically appraise the first version of the SAT (figure 2). Based on the evaluation data, the SAT will be adapted. In the *second eDelphi round*, the updated SAT will be re-evaluated by the DEP through a similar online evaluation questionnaire with the difference that changes made as well as aggregated results, such as the percentage of participants who expressed the need for rewording and inclusion of additional topic, will be indicated. Thus, panellists will have the chance to reconsider their previous assessment based on the added quantitative and qualitative information.

The final step of the Delphi procedure is a digital workshop with 20–25 preselected panellists and the PEG where remaining divergences will be discussed and finally decided if and how to make respective changes on the SAT. The resulting version of the SAT will then be tested in a real setting (pilot-testing).

Pilot-testing

The aim of the pilot-testing is to assess the user-friendliness of the SAT, including usability testing, and to gather feedback on the applicability of the content, the formulation of statements, the illustration of output and the utilisation. The pilot-testing will be carried out in ≥ 20 hospitals covering several regions within Europe. Potential cooperating hospitals will be informed by the PEG, participants of the workshop and contact persons from the EFCNI network. Candidates will receive online access to the SAT to appraise the ESCNH implementation in their hospital. The format of the SAT (SurveyMonkey questionnaire, Excel sheet or similar) will depend on the results of the eDelphi. Participants of the pilot-testing will have the option to appraise the SAT itself via an adjacent evaluation form. The SAT and the evaluation form will be made available in the respective language. Translations will be done using the DeepL (pro version) translation software and will be corrected and approved by native-speaking HCPs of the respective countries. Based on the results of the pilot-testing, the SAT will finally be updated and made publicly available (free of charge) on the ESCNH website.

Data handling, analysis and statistics

Data collection of the eDelphi will be anonymous and is planned between September 2025 and January 2026 through SurveyMonkey. Eligible for analysis will be all respondents who fulfil the inclusion criteria irrespective of whether they will complete all questions in the survey or the second eDelphi round. An attrition analysis to explore patterns in participants who drop out between eDelphi rounds will be conducted. Data analysis will be performed as an exploratory approach providing descriptive statistics (relative frequencies and percentages (n (%))). Multiple response questions will be analysed as the sum of answers per answer option (n (%)). Qualitative data from open text fields will be standardised, if possible, and shown as relative frequencies and percentages (n (%)). Statements and formulations need to be agreed on by at least 80% of participants. If $\geq 20\%$ of participants express the need for improvement, comments will be analysed for conformity. Adaptations have to be made if two persons from different countries indicate the same need for change. Suggested changes based on individual feedback are presented to the PEG and thoroughly discussed to determine their inclusion.

Subgroup analyses based on the profession and level of work experience of participants aim to further elucidate evaluation data and the scope of ESCNH awareness across countries. Tabular and graphical mapping of

response rates, including error margins, will be plotted and broken down by type of healthcare facility and geographical region. Statistical analysis will be performed with Microsoft Excel and R analytics.

Ethics and dissemination

A study protocol was submitted to the Ethics Committee of Maastricht UMC+ and officially waived for the need of an ethics approval (METC 2024-0140). Data collection, processing and storage will be conducted in accordance with the General Data Protection Regulation and the Declaration of Helsinki. Interested persons will be informed about the scope and relevance of the study and their rights. By ticking 'agree and continue', they give their informed consent to participate in the study. No person-related data will be stored or published. Data will not be passed on to third parties and will not be used for any other purpose. SurveyMonkey grants compliance with the GDPR and the Privacy Shield.

Results will be published in scientific journals after peer review. Dissemination activities through the EFCNI network, partner organisations, PEG members, the EFCNI newsletter and a comprehensive social media campaign are planned. The SAT will be integrated into a comprehensive implementation manual.

Strengths and limitations

We are aware of the length of the envisaged questionnaire and the required time to complete which might be accompanied by moderate dropout rates.²³ This can be a particular shortcoming of the eDelphi process.²⁴ The PEG represents only a subset of all EU countries, and the preselection members for the workshops are seen as potential weaknesses.

The principal strength of the study is its multidisciplinary composition of the PEG members with an extensive background in biometrics, obstetrics, neonatology, parent's associations, medical sociology, institutional benchmarking and healthcare management. Another strength is the conduction of the pretesting restricted to a subset of the eventual target population prior to the eDelphi rounds which will enable us to minimise methodological inaccuracies at a very early stage. The profound eDelphi process will allow a well-grounded selection of ESCNH content and critical evaluation in the development process of the SAT. With the pilot-testing, a comprehensive validation will be facilitated by identifying remaining shortcomings prior to the launch.

CONCLUSION

To develop the ESCNH SAT, we sought to advance the ESCNH implementation and pursue the mission to contribute to harmonised, high-quality treatment and care throughout Europe and to reduce care- and health-related inequalities for newborn infants and their parents and families.

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Contributors SM and IG were responsible for the ESCNH project supported by LJIZ. JH, IG, LJIZ and SM were responsible for the design and methodology of the current study. SM acted as the guarantor. JH, IG and LJIZ drafted and submitted the ethics application and were responsible for the ESCNH condensation process. JH and IG developed the first questionnaire draft. JH and SL were responsible for the finalisation, recruitment for the pretesting, eDelphi and pilot-testing. HH provided scientific advice and supported the operational procedures. All PEG members, namely, GA, NL, DS, ES, IS, YTTB, EV and JW, reviewed and corrected the questionnaire, and supported the conceptualisation of the study and the recruitment of participants. JH drafted the first manuscript which was corrected and approved by all other authors.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication EFCNI is an umbrella organisation for patients and/or parents and representing organisations. Patient representatives are equal members of the EFCNI study group, the PEG, the DEP and the pilot-tester and thus involved in every stage from the very beginning in the design, conduct, reporting and dissemination plans of this research. For more details, please see the respective sections in the article.

Ethics approval This study involves human participants but Ethics Committee of Maastricht UMC+ and officially waived for the need of an ethics approval (METC 2024-0140) exempted this study. Participants gave informed consent to participate in the study before taking part.

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