A project led by the
European Foundation for the Care of Newborn Infants (EFCNI)

Hospital self-assessment tool for the implementation of the European Standards of Care for Newborn Health (ESCNH)

Brief Title:
Self-assessment tool for implementing the ESCNH

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Study Protocol and statistical analysis plan

Version 1 from 17.04.2024

Background

Uniform reference standards for the optimal care of preterm and ill newborns were developed and published in 2018 by the European Foundation for the Care of Newborn Infants (EFCNI) and a transdisciplinary network (1).

The so-called European Standards of Care for Newborn Health (ESCNH) cover a broad range of topics associated with preterm birth and neonatal mortality and morbidity. These 102 evidence-based standards are not legally binding but should be considered as guidance to develop binding country-specific guidelines, regulations or laws (1).

Alongside the continuous update and development of new standards, 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 most important areas to efficiently change established procedures or to evaluate the extent to which the ESCNH are pursued. Therefore, we are aiming to develop a self-assessment tool in different languages helping care providers across Europe to measure the level of implementation of the ESCNH, to pinpoint possible inhibitors and to identify areas of a successful implementation.

With the goal to develop the ESCNH self-assessment tool, we advance the implementation of the ESCNH and pursue the mission to ensure harmonised, high-quality treatment and care throughout Europe in order to reduce care- and health-related inequalities for newborn infants and their parents and families.

Aim

We are aiming to develop a uniformly applicable self-assessment tool in different languages with the overall goal to support care providers across Europe to measure the level of implementation of the ESCNH recommendations, to pinpoint possible inhibitors, to demonstrate areas of a successful implementation, and ultimately to increase the extent of implementation and thereby reduce variation in care practices.

Study design and methods

eDelphi surveys and workshop

Covering the broad variety of the 102 standards in one hands-on and easy-to-use self-assessment tool requires their abbreviation and careful prioritisation. By means of qualitative research, we aim to approach this in a systematic and scientific manner using the eDelphi method to condense and prioritise the ESCNH into one questionnaire, the preliminary framework of the self-assessment tool. For this purpose, we will conduct a two-stage, electronic (e)Delphi survey followed by an expert workshop among invited healthcare professionals from various related disciplines as well as parent representatives.

The study preparation includes planning meetings with the Project Expert Group (PEG) consisting of 8 renowned experts and EFCNI members to define the methodological approach, the project timeline and to support and monitor of the development process of the eDelphi

survey. Within 4-5 meetings with the PEG, the first template for the eDelphi questionnaire will be developed and refined.

In the first eDelphi round, a group of approximately 100 healthcare professionals and parent representatives (see **Inclusion criteria** and **Exclusion criteria**) - the eDelphi panel - is invited to fill out the eDelphi questionnaire. The panel will receive an access-link to the online questionnaire, created using SurveyMonkey software, which will be completed anonymously. Next to participant-related information such as expertise or country of location, the questionnaire will cover specific aspects of the eleven major topics of the ESCNH. In addition, the questionnaire entails evaluation questions asking for the appropriateness of the wording and the completeness of the questionnaire with regards to the ESCNH content. In a subsequent eDelphi round, the panel will receive an updated questionnaire showing the aggregated results of the first eDelphi round. Thus, panellists will have the chance to re-assess the questionnaire based on the added quantitative and qualitative information provided by the responses of other participants. This will help to build consensus among disparate stakeholder groups. The final step of the eDelphi procedure is a digital expert workshop with 15–20 panellists preselected with regards to their respective expertise and country representation. In this workshop remaining disagreements will be discussed until consensus is reached. The final agreed-upon questionnaire will constitute the first version of the self-assessment tool, which will then be piloted.

Pilot-testing

The pilot-testing will be carried out in diverse real-life settings (n = min 10 hospitals) in Germany, UK, France, Italy, Sweden, Portugal, and Spain. Cooperating hospitals will receive online access to the self-assessment tool to appraise the implementation of the ESCNH in their hospital. Participants of the pilot study will have the option to appraise the self-assessment tool via an adjacent evaluation form. Both, the self-assessment tool and the evaluation form will be made available in the respective language via online questionnaires in SurveyMonkey. The pilot-testing will assess the user-friendliness of the self-assessment tool (duration of completion, illustration on screen, understandability) and also gather feedback on the applicability of selected ESCNH content, the formulation of statements, illustration of output and the utilisation of the self-assessment tool. Based on the results of the pilot-testing, the self-assessment tool will be updated and subsequently published.

Study population

The *PEG* consists of 8 renowned experts of multidisciplinary professions: neonatologists, neonatal nurses, midwives, obstetricians, parent representatives, health sociologists and a statistician and is completed by EFCNI members.

The *eDelphi panels* will consist of experts from various European countries from the following fields: neonatology, midwifery, (neonatal) nursing care, obstetrics, parent representing institutions, psychology, health sociology and physiotherapy.

Participants for the *pilot-testing* will be hospital staff with varying professional background, depending on the respective target groups which will be derived from the eDelphi questionnaires.

Inclusion criteria

Participants will be eligible if they are

- parent representatives or representatives of caregivers of infants who received special/intensive care,
- healthcare professionals in the field of neonatology, midwifery, neonatal nursing care, obstetrics, psychology, health sociology, physical therapy, or
- hospital management.

Exclusion criteria

Participants will be excluded if they

- provide insufficient proficiency of English for the eDelphi questionnaires or the languages of the self-assessment tool in the pilot testing, or
- have a professional background that is not related to the ESCNH / individuals that are not parent representatives or representatives of caregiver of infants who received special/intensive care.
- primarily work in the industry.

Sample size

To gain meaningful descriptive data, the eDelphi panel is aimed at about 100 participants with a minimum size of 50 participants. For pilot-testing a minimum of 10 participating neonatal intensive care units is targeted.

Recruitment of study participants

EFCNI's European network of parent organisations and healthcare professional societies of more than 220 institutions as well as supporters of the ESCNH project including, next to organisations, also authors, co-authors, and chair committee members of the ESCNH, will be approached via mail and invited to participate in the eDelphi. In addition, members of the PEG will share information on participation in the eDelphi within their network and will provide support in the identification of respective hospitals for the pilot-testing. The recruitment will take place over the European associations of the respective healthcare professionals as well as through targeted invitations in order to reach a representative panel size and mix.

Study outcomes

Primary outcome measures

- Online self-assessment tool (including statements and questions)

Secondary outcome measures

- Response rates
- Demographics and characteristics
- User-friendliness score of the self-assessment tool (time taken to fill in, illustration on screen, understandability)
- Applicability score of selected ESCNH content
- Applicability score of the formulation of the questions
- Qualitative feedback on illustration of output
- Appraisal on the utilisation of the self-assessment tool
- Scalability of the self-assessment tool and dissemination

Statistical analyses

The analyses will include descriptive statistics such as frequencies with percentages, mean and variance (metric scaling, variables with approximately symmetrical distribution), median and interquartile range (ordinal scaling as well as metric scaling for clearly skewed distributed variables). Tabular and graphical mapping of response rates for the pilot-testing including error margins plotted and broken down by type of healthcare facility and geographical region. Analyses will be performed with MS Excel and (if needed) R Studio.

Informed consent and data collection

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.

They will be explicitly asked to agree, to have read and understood the provided information. By clicking on the agree button, they will give their informed consent to participate in the study.

Data will be collected anonymously and stored on a protected cloud. After completion of the data collection, data will be kept for a period of 10 years and then irretrievably destroyed.

References

1. Lindacher V, Altebaeumer P, Marlow N, Matthaeus V, Straszewski IN, Thiele N, et al. European Standards of Care for Newborn Health—A project protocol. Acta Paediatr. 2020 Dec 22;apa.15712.