European Standards of Care for Newborn Health – a project protocol

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Abstract

Aim: Among children who receive hospital care, preterm infants are Europe's largest group, whose numbers are continually increasing. Currently, no pan-European standards of care for preterm or critically ill infants are available, except for a few specific topics, and practices vary widely in different regions.

Methods: The European Foundation for the Care of Newborn Infants (EFCNI) has initiated a transdisciplinary collaboration project to provide agreed standards for high-quality perinatal and neonatal care, whose implementation will ensure fairer and more equitable care across Europe. This will improve care for these vulnerable infants and their families, ameliorate the long-term conditions found in preterm and critically ill infants, and enhance the quality of family life of affected families. More than 220 experts – healthcare professionals, patient representatives, and other relevant stakeholders – have come together for the first time to develop a broad reference guidance in neonatology and associated fields.

Results: 96 standards on 11 overarching topic areas were developed and endorsed.

Conclusion: This reference framework serves as a basis for the development of binding national standards for high-quality care. A robust translation and implementation strategy is facilitated, with the goal of improved health outcomes following preterm birth all around Europe.

Key notes

- Outcomes for preterm and critically ill infants across Europe differ reflecting differences in availability of treatments and care practices.
- A transdisciplinary collaboration (experts and patient representatives) has been initiated to develop a framework of evidence-based pan-European reference standards.
- This framework is a reference and starting point for the establishment of binding national guidelines and neonatal unit policies to ensure equal treatment and care in Europe.

Key words

European collaboration, neonatal treatment and care, patient representatives, preterm birth, reference standards

1. Background and rationale

Care for preterm and critically ill infants across Europe has developed using a range of different practices (e.g. for sedation and analgesia practices). (1) In a first publication in 2010, we demonstrated this heterogeneity (2) and subsequently suggested directions for harmonisation. (3) Variation in provision of healthcare between different health systems, regions or hospitals may lead to inequities in opportunity, safety of care and outcomes for infants and their families. However, available European statistics are limited by different definitions and indicators used during collection on a national level. (4)

About 6% to 12% European live births are preterm (5) Care of these infants may have life-long social and economic consequences for some individuals. (6-9) This variation itself has its roots in economic and social differences, but provision of high-quality, safe, and effective healthcare is key to improving the long-term chances for preterm children, and reducing associated impairment and cost.

In Europe, health is a national issue and care policies, including guidance and operational policies at hospital level, are sometimes lacking. (2,10) In general, clinical guidance is developed by hospital teams, national expert panels, specialised bodies, or professional healthcare societies. In only a few topic areas European professional bodies provide broad non binding guidance for practice, such as the European consensus guidelines on the management of respiratory distress syndrome (11) and the guidelines on pediatric parenteral nutrition by several scientific societies. (12) Individual opinion and experience leads to even wider variations in care at the patient level, despite professionally agreed practices. Harmonised definitions for infrastructure, medical interventions, care procedures, and competencies of staff have the potential to reduce the inequity of opportunities for infants and families following preterm birth. (4,13)

The European Standards of Care for Newborn Health project (ESCNH) has been developed as a response to parental concern about this inequity. It is a collaboration project that aims to address the existing disparities by developing reference standards covering a broad range of issues associated with preterm birth and neonatal mortality and morbidity. As healthcare in Europe is regulated on a national level, no binding guidance can be developed. This framework is intended to be used as a reference source for the development or updates of respective national binding guidelines, protocols, laws, or cost regulations. Up to now there is no comparable framework at a European level. By generating European reference standards of care for newborn health, the project and methodology presented here are a unique exemplar for future transdisciplinary cooperation. Professionals and families may benefit from multi-level recommendations and underlying evidence in their daily practice and in decision-making.

2. Project design and methodology

The European Foundation for the Care of Newborn Infants (EFCNI) initiated the transdisciplinary project in 2013 and has been coordinating it by setting the overall project strategy, facilitating the development process, organising communication and dissemination, as well as preparing measures for later translation and implementation).

2.1 Standard definition

In general, a medical standard of care has been described as “a diagnostic and treatment process that a clinician should follow for a certain type of patient, illness, or clinical circumstance.“ (14)

In terms of evidence-based medicine, a standard reflects the current best available scientific evidence and best practice experience, taking an individual patient’s rights and preferences into consideration. (15)

Within this project, a standard is defined as a “systematically developed statement with the purpose to support decision making of physicians and patients for adequate care regarding specific health problems”. The standards serve as a benchmark and blueprint for the development of standards in each individual country.

2.2. Partners and topic areas

To ensure that neonatal practices are more closely aligned throughout Europe in the future, any newly developed reference standards need to be widely acknowledged and implemented on a national basis. For this reason EFCNI involved about 220 international participants. These include healthcare professionals from obstetrics, neonatology, paediatrics, nursery, midwifery, and psychology, together with other experts like architects and patient (parent) representatives as well as other stakeholders, like relevant third parties. Experts from 31 countries are involved: 15 Western European countries, 13 Eastern European countries and

3 countries overseas were represented. Few countries of the Balkan peninsula were not represented by healthcare professionals but by the national patient organisations.

A total of 96 standards across the range of areas in perinatal and neonatal care with a focus on preterm birth and ill infants were developed. To cover the complexity of neonatal medicine, the field was divided into eleven topics:

1. Birth & transfer (5 standards)
2. Care procedures (12 standards)
3. Data collection & documentation (2 standards)
4. Education & training of the multidisciplinary team working in neonatology (8 standards)
5. Ethical decision-making & palliative care (4 standards)
6. Follow-up & continuing care (15 standards)
7. Infant- & family-centred developmental care (10 standards)
8. Medical care & clinical practice (14 standards)
9. NICU design (3 standards)
10. Nutrition (10 standards)
11. Patient safety & hygiene practice (13 standards)

For each of these areas a transdisciplinary *Topic Expert Group*, the project's writing group, was established. All members worked voluntarily. Each Topic Expert Group is led by a Chair and at least one co-Chair (n=25), who were both healthcare professional experts. The *Chair Teams*, the current *EFCNI Parent Advisory Board* (n=8), and the current *Executive Board of EFCNI* (n=3) together make up the *Chair Committee*, the central decision-making and steering body of the project. An additional supporting body, which can be consulted to get a broader users' perspective to specific questions is the *Parents' Knowledge Forum* comprising the EFCNI's worldwide patient organisations' network.

2.3 Development of standards

The drafting, review, and editing process

Within the initial development phase, a total of 96 standards were modelled. Standards were initially drafted by one or more responsible authors, followed by at least one peer-review loop within the Topic Expert Group .An editing process over all standards was performed to harmonise wording and layout. A final review of the pre-final standards was provided by the respective Chair Team.

Standard template

To facilitate a harmonised format and structure of the standards, a specific template was created by the Chair Committee for the standard development process.

- Header: *Topic Expert Group name*, *title of the standard*, *authors*)
- *Target group*: Group of stakeholders who will benefit most from the implementation of the standard, frequently the infants, their parents and families)
- *User group*: Group of people who need to implement the standard, e.g. healthcare professionals, hospitals, the neonatal units or health services
- *Statement of the standard*: Summarises in one sentence the key message of the respective standard (see examples below)
- *Rationale*: Comprises background information on the issue described; this is kept deliberately short as an introduction
- *Benefits*: Outlines the potential short-term and long-term advantages (defined as before and after hospital discharge of the infant)

Statement of Standard on Management of Respiratory Distress Syndrome

Statement of the standard: Newborn infants at risk of Respiratory Distress Syndrome (RDS) receive appropriate perinatal care including place of delivery, antenatal corticosteroids, guidance around optimal strategies for delivery room stabilisation, and ongoing respiratory support.

Statement of Standard on Parental involvement

Statement of the standard: Parents are members of the caregiving team and, with individualised support, assume the primary role in the provision of care of their infant, and are active partners in decision-making processes.

The most important part of the template is the *component table*, which displays the standard per se, separated in a section for parents and family, for healthcare professionals, for hospitals, and for health service. These sections can be adapted according to the respective parties involved in a certain area of care. The single components are graded according to their level of evidence (see below) and indicators of meeting the standard are included for each component (see below).

Two other tables display the *future developments of care*, in case a hospital already meets all core components of the standard, as well as *initial steps*, for those hospitals where the components or some of the components seem to be beyond the current levels of care.

Table 1: Components of Standard on Management of Respiratory Distress Syndrome

Component	**Grading of evidence**	**Indicator of meeting the standard**
For neonatal unit		
A unit guideline to ensure a standardised approach to initial stabilisation after birth for newborn infants at risk of RDS is available and regularly updated, including	B (High quality)	Guideline
• access to blended oxygen (Saugstad OD et al., 2014)	A (High quality)	
• access to CPAP from birth (Rojas-Reyes MX et al., 2012)	A (High quality)	
• access to manual ventilation with devices that control pressures (Guinsburg R et al., 2017)	A (Moderate quality)	
• access to pulse oximetry from birth (Schmölzer GM et al., 2010)	A (Low quality)	

Table 2: Components of Standard on Parental involvement

Component	**Grading of evidence**	**Indicator of meeting the standard**
For neonatal unit		
A unit guideline on parental involvement in terms of being the primary caregivers, participation in medical rounds, and partnering in decision-making is available and regularly updated. (O'Brien et al., 2013; Ortenstrand et al., 2010, Westrup, 2015; Warren, 2017)	B (High quality)	Guideline

For further information on a specific standard topic, a *description* section is included if considered necessary by the authors. The *lifecycle* section determines the anticipated date of re-evaluation, and every standard ends with the *recommended citation*, which should be used to reference the respective standard.

Grading of evidence framework

The components of the standards are based on scientific evidence or practical expert experience, for which a specific grading of evidence framework has been developed by the Chair Committee. The system includes three categories of evidence, each with several quality levels:

A. Category A refers to scientific evidence generated by systematic research on the basis of the *GRADE approach*. (16) Scientific evidence is judged in terms of methodological flaws, consistency of results across different studies, generalisability of research results, and effectiveness of treatments and is accordingly assigned to a specific quality level i.e. high, moderate, low, and very low.

B. Category B was introduced to complement the grading of evidence, as several components of individual standards are not based on scientific evidence but on shared cultural values or on best practice experiences. This involves judgement of the basis for components by the project's experts during the development of the standards. Levels of cultural values derived evidence are assessed by the geographic scope of these shared values as judged by the project's experts. The composition of the Topic Expert Groups with representatives from all over Europe, ensures a minimum of objectivity and wide and shared knowledge as well as best practice.The chairs of the overall topics were responsible for consistency between the standards of their topic.

    - High quality: Based on cultural values that are shared **within geographical Europe**
    - Moderate quality: Based on cultural values that are shared **on a national level, in one or more countries within Europe**
    - Low quality: Based on cultural values that are shared **on a local level within a country within Europe**
    - Very low quality: Based on cultural values that are **subjective at the hospital or individual level**

C. The third category (C) implies evidence from *legal certainties* such as laws, regulations, or court practice. This type of evidence is also assessed based on the geographic scope of the legal source.
    - High quality: Required by **EU wide** valid laws, regulations and other legal sources
    - Moderate quality: Required by **national** laws, regulations and other legal sources

Indicators

In order to measure the components of standards and further implementation activities, suggestions for later benchmarking and verification activities to measure whether a component is complied with, are provided (e.g. patient information sheet, guideline, training documentation, audit reports).

2.4 Voting, endorsement and publication

After finalisation and editing of all standards, the Chair Committee members voted electronically on each individual standard, taking into account the provided evidence base, completeness, relevance, and readability for their decision. For publication of a single standard an 80% majority of all "yes" and "no" votes is required (the third voting option was to abstain from voting on a standard). All 96 standards met this criterion and were compiled in a

comprehensive standards package. All patient organisations, academic and professional societies that had been supporting the standard development already, as well as additional parent organisations and healthcare societies were then provided with the standards package for their review and invited to support the standards. In the meanwhile, the standards receive the global support of more than 170 academic and professional societies as well as patient organisations.

The full-text versions of the final, approved standards were released on the project's website after their official launch in November 2018: https://newborn-health-standards.org/

2.5 Lifecycle

As care is a very fast-developing area, the standards need to be revised regularly. Therefore, the Chairs together with the authors have determined a certain interval (3, 5, or 10 years), after which each standard needs to be revised. New standards will be worked on during the next years following the same methodology to enlarge the standard package. One year before the determined interval, EFCNI will contact the respective Chairs and authors for a review and decision what needs to be adapted because of new developments that have happened in the meanwhile. Chairs and authors will have one year time (revision period), during which they can update the standard document. The revised standards will then again be voted on by the Chair Committee. After the voting, the life cycle will start again.

3. Dissemination and implementation

Since the early stages of the project, different awareness raising measures and activities to prepare the translation and implementation of the standards on a national level have been taken. Besides the project website the following measures were used:

Communication campaign

A year-round communication campaign was established in 2016. The campaign called "11 Months – 11 Topics" focuses on the theme of one of the eleven overarching topics every month. Each health topic is highlighted from different perspectives using a range of strategies e.g. introduction of the respective topic in general, Chair Team interviews, research news and articles about "lighthouse" projects related to the monthly topic.

Congresses

A cross-sectional promotion of the ESCNH project is conducted on international and European neonatal congresses (e.g. the World Congress of Maternal Fetal Neonatal Medicine, the Congress of joint European Neonatal Societies (jENS), the European Association of Perinatal Medicine Congress (EAPM)) as well as national congresses in fields associated with peri- and neonatology. The project is regularly introduced in congress talks by project partners.

European-wide network of societies and professionals

Through the involvement of diverse stakeholders in the standard development process from all parts of Europe and a broad supporting network of societies and organisations, the way for national adoption of the standards is meant to be paved. The collaborative character of the project seems key in decreasing cultural barriers and strengthening the backing and acceptance in the respective countries for later adoption.

Training of parent organisations

Patient organisations play a significant role within the development and later implementation process regarding the standards, since these types of organisations have to be shown to

influence and shape health systems. (17,18) To rely on these capabilities, multistage training is provided for these organisations by EFCNI. The workshops are conceptualised to provide knowledge and hands-on practice, e.g. on the reference standards and their scope on a national level, how to set up a national stakeholder network and develop a strategic implementation plan to bring the standards into practice all around Europe.

Implementation Toolkit

In September 2019, the toolkit 'Shaping the future – Combining forces to improve newborn health' was launched. The toolkit facilitates and supports the implementation of the European Standards of Care for Newborn Health on a national, regional, and local level. It can be used by various stakeholders. This practical handbook provides knowledge and background information about the standards, ideas, tools, and step-by-step advice. Many practical examples serve as an inspiration in order to raise awareness and engage with national stakeholders. The toolkit is a digital, interactive resource.

Launch event and call to action

To set newborn care and its standardisation within Europe on a policy agenda, an event introducing the project as well as a policy workshop were conducted in the European parliament in Brussels in 2018. The launch event was accompanied by a call to action to make decision-makers aware of their responsibilities in regards to newborn health.

4. Conclusion

The mission of the ESCNH project is 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. The systematic approach we have taken includes

- multiple stakeholder involvement from the very beginning,
- balancing the interplay between evidence and experience by evolving a grading system,
- inclusion of a major role for patient representatives to ensure patient focus,
- maintaining a broad range of topics covering all areas of importance to participants,
- stated review periods to allow continuous quality assurance and inclusion of state-of-the-art knowledge,
- and a multi-level dissemination and implementation strategy.

Beyond the development and implementation of the standards, the project aims at advancing national health systems: driven by a common European vision, exchanges on structures and healthcare services of national states help to identify gaps and deficiencies as well as chances and opportunities. The debate about European standards of care can serve as a key driver for the development of respective healthcare systems. Additionally, the process described can be a blueprint for consensus and standardisation measures.

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Conflict of interest

Selected industry representatives could join the Chair Committee meetings as observers. They did not have voting rights and their role was limited to sharing their knowledge and expertise without exerting influence. The financial support served to cover the coordination, administration and dissemination costs of the project at EFCNI. EFCNI, chairs and authors were solely responsible for exercising full control on the project's strategy, the development, content, voting on, design or dissemination of the standards. The chairs and authors involved in the project worked voluntarily without receiving honoraria.

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