european standards of
care for newborn health

EFCNI

European Standards of Care for Newborn Health project

Medical care & clinical practice

Ola Didrik Saugstad

Why European Standards of Care for Newborn Health?



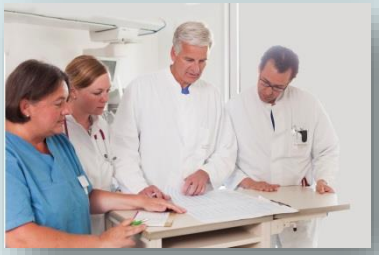


Differences between European countries

Infrastructure for high-risk pregnancies

Organisation of medical centres

Transport systems



Education of healthcare professionals

Follow-up and continuing care

Medical treatment

Level of implementation of infant- and family-centred care

Nutrition

NICU design

European Standards of Care for Newborn Health project in a nutshell

Aim:

Development of standards for the key topics in neonatal health in the context of an interdiscipliary European project

Focus:

Preterm and ill newborn infants

Method:

Work in topic-specific expert groups; about 220 high-level experts of different professions, parent representatives and selected industry specialists from more than 30 countries developed 96 standards

Over 150 international supporting organisations

Time:

2013 – 2018

Special feature:

Active collaboration of different stakeholders

Next steps:

National implementation of the standards

Project website: www.newborn-health-standards.org

Medical care & clinical practice

https://newborn-health-standards.org/

EFCNI

Topic Expert Group

Topic group: BPD in the NICU
Prof Christian F. Poets (Topic Lead), Germany
Dr Mikko Hallman, Finland
Dr Gianluca Lista, Italy
Prof Anton van Kaam, The Netherlands
Prof Boris Kramer, The Netherlands

Topic group: ROP
Prof Ann Hellström (Topic Lead), Sweden
Dr Anna-Lena Hård, Sweden
Prof Andreas Stahl, Germany

Topic group: Sepsis
Dr Martin Stocker (Topic Lead), Switzerland
Prof Rolf Maier, Germany
Dr Tuuli Metsvaht, Estonia
Dr Rene Kornelisse, The Netherlands
Prof Claus Klingenberg, Norway

Topic group: Treatment of asphyxia
Prof Frank Van Bel (Topic Lead), The Netherlands
Dr Deirdre Murray, Ireland
Prof Elie Saliba, France
Prof Marianne Thoresen, UK

Topic group: Vitamin K
Prof Berthold Koletzko (Topic Lead), Germany
Prof Mary Fewtrell, UK
Dr Serafina Perrone, Italy
Prof Henkjan Verkade, The Netherlands

Topic group: Hypoglycaemia
Prof Delphine Mitanchez (Topic Lead), France
Dr Kathryn Beardsall, UK
Dr James Boardman, UK
Prof Win Tin, UK

Topic group: Neonatal jaundice
Prof Maria Borszewska-Kornacka (Topic Lead), Poland
Prof Eren Özek, Turkey
Dr Serafina Perrone, Italy
Dr Justyna Tołłoczko, Poland

Topic group: Neonatal resuscitation
Prof Andreas Flemmer (Topic Lead), Germany
Prof Mario Rüdiger, Germany
Dr Daniele Trevisanuto, Italy
Prof Ola Didrik Saugstad, Norway
Dr Michael Steidl, Germany
Prof Máximo Vento Torres, Spain

Topic group: Neurological monitoring including haemorrhage
Dr Adelina Pellicer Martínez (Topic Lead), Spain
Dr Jeroen Dudink, The Netherlands
Prof Pierre Gressens, France

Topic group: Pulmonary hypertension
Prof Irwin Reiss (Topic Lead), The Netherlands
Dr Eduardo Villamor, The Netherlands
Prof Anne Greenough, UK
Dr Heike Rabe, UK

Topic group: RDS including surfactant
Dr David Sweet (Topic Lead), UK
Prof Egbert Herting, Germany
Dr Kajsa Bohlin, Sweden

Postnatal support of transition and resuscitation

Authors
Steidl MF, Buonocore G, Zimmermann L, Hellström-Westas L, Flemmer AW, Rüdiger M, Saugstad OD, Trevisanuto D, Vento M

Target group
Newborn infants, pregnant women with risk factors, their partners, and parents

User group
Healthcare professionals, neonatal units, hospitals, and health services

Statement of standard
Support of postnatal transition to extrauterine life is based on internationally consented guidelines, which are based on scientific evidence, and is performed in an appropriate structured and equipped environment by trained personnel.

Rationale

Postnatal adaptation to extrauterine life is a complex process during which air breathing is established and circulatory changes take place. Difficulties may occur with transition in situations such as preterm birth and following perinatal asphyxia. These situations account for much of the associated neonatal mortality and morbidity. (1–4) Certain problems that arise during birth may be anticipated. (5) Transition should be supported appropriately and formal resuscitation instituted when necessary. High-risk deliveries should be attended by individuals trained in advanced resuscitation, but all healthcare professionals attending deliveries should be trained in basic neonatal resuscitation techniques. The International Liaison Committee on Resuscitation (ILCOR) provides comprehensive recommendations for the management at transition and resuscitation of the newborn infant, which are adapted by international bodies such as the European Resuscitation Council. (6–8) These recommendations are updated regularly, translated and adapted by the respective regional or national organisations. Training in the practical skills of resuscitation should be undertaken in all maternity settings, including all responsible disciplines, using a neonatal resuscitation courses.

Benefits

Short-term benefits

Reduced mortality and morbidity (6,8)

Long-term benefits

Improved neurodevelopmental outcome (6,8)

Components of the standard

Component	Grading of evidence	Indicator of meeting the standard
For parents and family		
1. Pregnant women with risk factors and their partners are informed by healthcare professionals and counseled before birth. (see TEG Birth & transfer)	B (High quality)	Patient information sheet
2. Parents are informed by healthcare professionals about the possible need for support at transition and the risks thereof in infants at high-risk for resuscitation.	B (Moderate quality)	Patient information sheet
3. Parents are invited to be present during resuscitation. (8–10)	A (High quality)	Guideline
4. Parents are provided with opportunities to debrief following a resuscitation of their infant.	B (High quality)	Clinical record, parent feedback
For healthcare professionals		
5. A guideline on resuscitation, including post-resuscitation care, is adhered to by all healthcare		

6.	Training on current resuscitation recommendations, guidelines and local equipment is attended by all responsible healthcare professionals using accredited courses. (6,8) (see TEG Education & Training)	A (Moderate quality) B (High quality)	Training documentation
7.	Equipment needed for resuscitation is regularly checked.	B (High quality)	Guideline
For neonatal unit			
8.	A guideline on neonatal resuscitation, including post-resuscitation care, and arrangements for transfer to expert services where necessary, is available and regularly updated. (6,8)	B (High quality)	Guideline
9.	Information to support emergency calls is clearly displayed within the delivery suite and neonatal unit to cover: •further help (manpower) •consultation (knowledge) •neonatal transport	B (High quality)	Guideline
10.	Team debriefing after resuscitation is provided.	B (High quality)	Healthcare professional feedback
11.	Healthcare professionals trained	B (High quality)	Audit report

Where to go

Further development For parents and family	**Grading of evidence**
N/A	
For healthcare professionals	
•Video recording of transition management is conducted and structured feedback is given. (13)	B (Moderate quality)
•Provide emergency telemedicine consultation for neonatal resuscitation. (14)	A (Low quality)
For neonatal unit	
•Establish debriefing rounds for resuscitation situations, including interdisciplinary work with psychologists.	B (Moderate quality)
•Establish regular quality meetings within one week after delivery to check defined quality parameters of pre- and postnatal management (lung maturation, admission temperature etc.) together with nurses, midwifes, obstetricians, neonatologists, psychologists.	B (Moderate quality)
For hospital	
•Establish the chance of bonding with the mother immediately after successful support of postnatal transition.	B (High quality)
For health service	
•Support research into new techniques and approaches for neonatal resuscitation.	B (

Management of Respiratory Distress Syndrome

Authors
Sweet DG, Zimmermann L, Hellström-Westas L, Buonocore G, Bohlin K, Herting E

Target group
Newborn infants at risk of Respiratory Distress Syndrome (RDS) and parents
User group
Healthcare professionals, neonatal units, hospitals, and health services

Statement of 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.

Components of the standard

	Component	Grading of evidence	Indicator of meeting the standard
	For parents and family		
1.	Parents are informed by healthcare professionals about Respiratory Distress Syndrome (RDS), survival rates/morbidity, treatment, and short- and long-term care. (7)	A (Low quality) B (High quality)	Patient information sheet
	For healthcare professionals		
2.	A unit guideline on management of RDS is adhered to by all healthcare professionals.	B (High quality)	Guideline
3.	Training on detection and treatment of RDS in the neonatal intensive care unit (NICU) is attended by all healthcare professionals. (8)	A (Low quality) B (High quality)	Training documentation
4.	A unit guideline to determine which pregnant women have to be transferred for care to a perinatal centre is adhered to by all healthcare professionals. (9) (see TEG Birth & transfer)	A (Moderate quality)	Guideline, audit report
	For neonatal unit		
5.	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 (10)	A (High quality)	
	•access to CPAP from birth (2)	A (High quality)	
	•access to manual ventilation with devices that control pressures (11)	A (Moderate quality)	
	•access to pulse oximetry from birth (12)	A (Low quality)	
	A unit guideline is available and regularly updated including surfactant administration, criteria for intubation, and ventilation strategies with optimal lung protection. (1,13–16)	A (High quality) B (High quality)	Guideline
	For hospital		
	Women at risk for very preterm birth are referred in a timely fashion for expert care during pregnancy and delivery. (17) (see TEG Birth & transfer)		

Prevention of Bronchopulmonary Dysplasia (BPD)

Authors
Poets C, Zimmermann L, Hellström-Westas L, Buonocore G, Hallman M, Lista G, van Kaam A, Kramer B

Target group
Very preterm and particularly extremely preterm infants, SGA infants, and parents

User group
Healthcare professionals, neonatal units, hospitals, and health services

Statement of standard
Bronchopulmonary Dysplasia (BPD) is prevented using evidence-based strategies including avoiding mechanical ventilation, minimally invasive administration of exogenous surfactant, volume targeted ventilation and early caffeine, and administration of systemic steroids in infants still requiring ventilation during their 2nd postnatal week.

Rationale

Bronchopulmonary Dysplasia BPD results from the effects of non-physiologic stimuli (e.g. inflammation, ventilator induced lung injury, high supplemental oxygen levels) in an infant with underdeveloped lungs and defence mechanisms (e.g. anti-oxidant capacity). (1) Interventions that reduce inflammation (e.g. steroids) or any of these non-physiologic stimuli (e.g. mechanical ventilation) are likely to reduce BPD rates. Some of these interventions may additionally promote the survival of the target group; none decreases the chances of survival. (2)
BPD, defined as supplemental oxygen requirement at 36 weeks post-menstrual age, is a risk factor for later respiratory hospitalisation in infancy, compromised lung function in childhood, neurodevelopmental impairment, and a potential risk factor for chronic obstructive pulmonary disease in later life. (1,3)

Benefits

Short-term benefits

Reduced risk of BPD by avoiding invasive mechanical ventilation (risk ratio (RR), 0.91; 95% Confidence Interval 0.84-0.99) (2)

Reduced risk of BPD by use of minimally invasive surfactant administration (RR 0.75; 0.59-0.94) (4,5)

Reduced risk of BPD by use of volume targeted ventilation (as opposed to pressure targeting) (RR 0.61; 0.46-0.82) (6)

Reduced risk of BPD by starting caffeine on postnatal day one or two instead of later (RR 0.51; 0.40-0.64) (7,8)

Reduced risk of BPD by administration of vitamin A intramuscularly for the first four postnatal weeks (RR 0.87; 0.77-0.98) (9)

Reduced rate of death or BPD by administration of systemic steroids in ventilated infants (RR 0.72; 0.63-0.82) without increasing the risks of cerebral palsy (10)

Long-term benefits

Reduced adverse neurodevelopmental outcome if BPD can be prevented (3)

Components of the standard

	Component	Grading of evidence	Indicator of meeting the standard
	For parents and family		
1.	Parents are informed by healthcare professionals about Bronchopulmonary Dysplasia (BPD) and strategies to minimise its risk. (1)	A (High quality)	Patient information sheet
	For healthcare professionals		
2.	A unit guideline on the management and prevention BPD is adhered to by all healthcare professionals, and includes the following advice: •Surfactant is administered via a thin intra-tracheal catheter if FiO_2 is >0.30 or using INSURE (intubate surfactant extubate). (11) •Volume targeted ventilation (at 5-7 ml/kg) is used plus adequate PEEP level, if intubation cannot be avoided. (6) •Infants on n-CPAP are switched to synchronised nasal ventilation if respiratory distress visible while on CPAP. (12) •Caffeine is administered from day 1-2 after birth (10 mg/kg loading, 5 mg/kg/d maintenance for caffeine base). (7,8) •Vitamin A is considered (5000 IE i.m. three times/week for week 1-4 after birth). (9) •If mechanical ventilation is still necessary during postnatal week 2, postnatal steroid use is considered (dexamethasone at the lowest effective dose possible. (13,14)) •Efforts to reduce rates of nosocomial infection, as a risk factor for BPD, are made. (15)	A (High quality)	Guideline

Hypoglycaemia in at risk term infants
Medical care & clinical practice

Statement of standard

Measures are taken to identify, prevent, and manage hypoglycaemia in newborn infants who are at risk for impaired metabolic adaptation, including those with growth restriction, maternal diabetes, asphyxia, maternal beta-blocker medication.

Prevention, detection, documentation, and treatment of ROP

Authors
Hellström A, Hellström-Westas L, Zimmermann L, Buonocore, G, Hård AL, Stahl A

Target group
Preterm infants at risk of severe retinopathy of prematurity (ROP) defined by national guidelines and parents

Statement of standard
Screening programmes for detection, documentation, and treatment of sight threatening retinopathy of prematurity (ROP) in all units caring for very preterm infants, as well as preventive measures such as control of oxygen supplementation and promotion of optimal nutrition are established.

Preterm infants at risk of severe retinopathy of prematurity (ROP) defined by national guidelines and parents

ROP

screening inclusion criteria,

timing of eye examination:

- first examination generally at 4-6 weeks of age but not before a postmenstrual age of 31 weeks
- follow-up screening examinations biweekly to twice a week depending on findings

choice of dilating drops and information on how to avoid systemic absorption

any topical anaesthesia

indication for treatment

follow-up of treated infants following appropriate protocols based on the type of treatment

Postnatal management of newborn infants with hypoxic ischaemic encephalopathy (HIE)

Authors
Van Bel F, Hellström-Westas L, Zimmermann, L Buonocore G, Murray D, Saliba E, Thoresen M

Target group
Term and near term infants with hypoxic ischaemic encephalopathy (HIE) and parents
User group
Healthcare professionals, neonatal units, hospitals, and health services
Statement of standard
Newborn infants who have suffered from severe hypoxic-ischaemia receive early evaluation and appropriate postnatal management including therapeutic hypothermia and monitoring.

Rationale

The goal is to reduce long-term effects of hypoxic ischaemic brain injury. Moderate to severe perinatal asphyxia in term and near term infants is one of the most important causes of neonatal death and adverse motor and cognitive outcome, with an incidence of 2-20 per 1000 live born infants, depending in which part of the world they are born. (1) Until recently, therapy was limited to stabilisation of the newborn infant and treatment of hypoxic ischaemic encephalopathy (HIE) induced seizures. Reduction of the body temperature to 33.5°C is the only established therapy which has shown a decrease in adverse outcomes after perinatal asphyxia (death or substantial disability at 18 months of age) from about 66% for non-cooled infants to 50% in cooled infants. (2,3) Intensive research is ongoing to explore (pharmacological) neuroprotective interventions which could be used in addition to hypothermia to improve outcome. (4–7)

Benefits

Short-term benefits

Reduced brain injury due to excitatory neurotransmitters and reactive oxygen species (8,9)

Improved prognosis using stratified hypoxic ischaemic encephalopathy (HIE) severity, e.g. using neurophysiological monitoring (a-EEG (10–12) or EEG) (13) (see TEG Medical care & clinical practice)

Reduced brain injury by early treatment of seizures (13,14)

Reduced mortality (3)

Long-term benefits

Improved neurocognitive outcome, increasing the rate of disability free outcome at 5 years (3,15) reduced health and societal costs (16), reduced occurrence of epilepsy at 2 years (7), less severe cerebral palsy in survivors (15)

Management of persistent pulmonary hypertension of the newborn infant (PPHN)

Rationale

Persistent pulmonary hypertension of the newborn (PPHN) is characterised by sustained elevation of pulmonary vascular resistance (PVR) after birth resulting in extrapulmonary shunting from right to left via the fetal circulatory pathways (patent ductus arteriosus and patent foramen ovale). (1) PHN leads to severe hypoxaemia that may not respond to conventional respiratory support and to avoid severe cardiorespiratory failure. (2) The management of delivery and neonatal care should be transferred to a specialised centre to ensure optimal outcomes. (3,4)

Benefits

Short-term benefits

Reduced mortality and morbidity (2,4,5)

Reduced need for extra-corporeal membrane oxygenation (ECMO) (6)

Long-term benefits

Why is this project so unique?

- Initiated by patient (parent) representatives for patients
- Parents are involved in every step of the development process

→ A true patient centred project

- About 220 experts from more than 30 countries developed the standards
- Supported by more than 150 professional healthcare societies and parent/patient organisations
- Covers the complexity of neonatal care
- Promotes the equitable and high levels

Aim: Catalysing a systematic change for hamonisation and quality improvement of newborn care in Europe

Need for standards in Neonatology

Bamako
Mali
11/12-2018

Thank you very much for your attention!

EFCNI