



Neo-BFHI

The Baby-friendly
Hospital Initiative

for Neonatal Wards

*Measuring compliance with the
Baby-friendly Hospital Initiative for
Neonatal Wards (Neo-BFHI)*

Measuring compliance with the Baby-friendly Hospital Initiative for Neonatal Wards (Neo-BFHI)

**An international Self-Assessment survey of policies and practices to protect,
promote and support breastfeeding in neonatal wards**

Protocol

Principal investigators

Laura N. Haiek, MD, M.Sc.

Medical consultant, Ministère de la Santé et des Services sociaux du Québec;
Assistant professor, Department of Family Medicine, McGill University;
Member, St. Mary Hospital Research Center, Quebec, Canada

Ragnhild Maastrup, RN, IBCLC, PhD

Knowledge Centre for Breastfeeding, Infants with Special Needs, Dept. of Neonatology,
Rigshospitalet, Copenhagen, Denmark

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Introduction

The expansion of the BFHI to neonatal wards

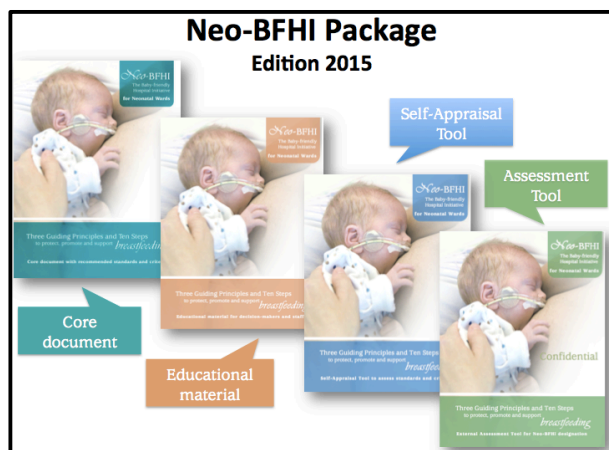
According to the WHO, an estimated 15 million babies (1 in 10 babies) are born prematurely every year (1). Breastfeeding is the normal way of providing infants and young children with the nutrients they need for healthy growth and development (2, 3), including those who are born preterm or ill (4, 5). It is now well established that breastfeeding and breast milk are particularly important for these vulnerable infants because the enzymatic, immunomodulatory, anti-infective, and anti-inflammatory properties of human milk protect against serious complications such as nosocomial infections, sepsis, and necrotizing enterocolitis (NEC) (6-9). A recent Lancet series on breastfeeding reinforces that no infant or mother should be excluded from breastfeeding promotion activities. After completing an in-depth, comprehensive review of breastfeeding health and economic benefits, the authors call for “a genuine and urgent commitment from governments and health authorities to establish a new normal: where EVERY woman can expect to breastfeed, and to receive every support she needs to do so.” (10) This commitment should include mothers with infants in the neonatal ward. Preterm and ill infants may not be able to breastfeed right from birth, but can, with appropriate support, begin breastfeeding when they mature/recover.

Since 1991 the BFHI has provided an evidence-based set of standards for the protection, promotion and support of breastfeeding in maternity wards worldwide (11-13). The province of Quebec is a leader in Canada with respect to BFHI implementation and designation.

In 2009, the WHO/UNICEF published an update of the BFHI package (14) and encouraged all concerned sectors of the health care system and other relevant settings to support the recommendation of exclusive breastfeeding for 6 months and continued breastfeeding for up to 2 years of age or beyond, while providing women with the support that they require to achieve their individual breastfeeding goals (15). That same year, the Nordic and Quebec Working Group was formed in Copenhagen by health professionals from Sweden, Norway, Denmark, Finland and Quebec, Canada, to address the special situation of preterm and sick infants and their families. The working group has developed a unified expansion of the BFHI to neonatal wards ("Neo-BFHI"). To remain consistent with the original BFHI, the expansion follows as closely as possible the WHO/UNICEF's Ten Steps to Successful Breastfeeding (Ten Steps) and related Global Criteria. It is based on evidence, expert opinion and experiences implementing Baby-friendly practices in neonatal wards in the Nordic and other countries. The components of the Neo-BFHI are presented below. The adaptation takes into consideration that neonatal wards provide various levels of neonatal care, ranging from care for extremely preterm infants and infants with serious medical/surgical conditions, to care for late preterm infants, term low birth weight infants, and term infants, who may require episodic or short-term monitoring or medical interventions.

In order to disseminate the expansion, the working group has published a Neo-BFHI package with a core document (16), a self-appraisal tool, education materials and a (confidential) external assessment tool (17) and two peer-reviewed articles (18, 19). These publications can be consulted

to obtain detailed information on the background and rationale for the expansion, as well as recommended standards and criteria.



The first 3 documents of the package can be downloaded from the International Lactation Consultant Association (ILCA) website: <http://www.ilca.org/main/learning/resources/neo-bfhi> website after filling a registration requiring limited information in order to monitor interest for the program.

The registration process has provided a clear indication that the Neo-BFHI has a global pertinence. As of August 12, 523 persons from 63 countries had registered to download Neo-BFHI documents from the ILCA website. Furthermore, the two articles presenting the Neo-BFHI expansion published in the Journal of Human Lactation in 2012 (19) and 2013 (18) remain among the journal's ten most downloaded articles (3rd and 7th place respectively). In order to get a kind of baseline information of breastfeeding support in neonatal wards in countries across the world a survey should be conducted before massive implementation of the Neo-BFHI.

The components of the Neo-BFHI

The Baby-friendly Hospital Initiative for Neonatal Wards or Neo-BFHI	
Three Guiding Principles	
Guiding Principle 1	Staff attitudes toward the mother must focus on the individual mother and her situation.
Guiding Principle 2	The facility must provide family-centered care, supported by the environment.
Guiding Principle 3	The health care system must ensure continuity of care from pregnancy to after the infant's discharge.

Expanded Ten Steps to Successful Breastfeeding	
Step 1	Have a written breastfeeding policy that is routinely communicated to all health care staff.
Step 2	Educate and train all staff in the specific knowledge and skills necessary to implement this policy.
Step 3	Inform hospitalized pregnant women at risk for preterm delivery or birth of a sick infant about the benefits of breastfeeding and the management of lactation and breastfeeding.
Step 4	Encourage early, continuous and prolonged mother-infant skin-to-skin contact/ Kangaroo Mother Care.
Step 5	Show mothers how to initiate and maintain lactation, and establish early breastfeeding with infant stability as the only criterion.
Step 6	Give newborn infants no food or drink other than breast milk, unless medically indicated.
Step 7	Enable mothers and infants to remain together 24 hours a day.
Step 8	Encourage demand breastfeeding or, when needed, semi-demand feeding as a transitional strategy for preterm and sick infants.
Step 9	Use alternatives to bottle feeding at least until breastfeeding is well established, and use pacifiers and nipple shields only for justifiable reasons.
Step 10	Prepare parents for continued breastfeeding and ensure access to support services/groups after hospital discharge.
Compliance with the International Code of Marketing of Breast-milk Substitutes and relevant World Health Assembly resolutions.	

Methodology

Study objectives

The main objective of the proposed evaluation is two-fold:

- 1) to assess compliance with the Neo-BFHI recommendations in neonatal wards in a set of countries/regions,
- 2) to conduct international comparisons of the level of implementation of the Neo-BFHI in neonatal wards in different countries. This comparison will be possible because parallel research projects using the same methodology will be conducted in participating countries.

Research design

The evaluation will use a cross-sectional survey to measure compliance with the policies and practices outlined in the Neo-BFHI from the perspective of managers and professionals working in the neonatal ward.

Description of study population

The study population will consist of neonatal wards in countries or regions from all continents.

All neonatal wards, from basic care (level I) to the most intensive (level IIIC) are eligible and will be invited to participate. No exclusion criteria have been identified.

The study will be coordinated by the two principal investigators. Each country/region will have a designated “survey leader”.

Sample size

October 20, 2016: Twenty-six countries or a region in a country have shown interest in the study including a total of more than 1000 neonatal wards.

Europe: Denmark, Norway, Sweden, Finland, Iceland, UK, Estonia, Lithuania, Latvia, France, Portugal, Spain, Luxemburg, Poland, Croatia, and Russia.

Asia: Israel, Kuwait, and Singapore,

Oceania: Australia and New Zealand.

Americas: Canada, Brazil, and Argentina.

Africa: South Africa and Nigeria.

Measurements and study instruments

Neo-BFHI policies and practices will be measured with a questionnaire based on the Neo-BFHI Self-Appraisal Tool, one of the documents in the Neo-BFHI package. The tool includes also a hospital data sheet used to describe participating neonatal wards. The English version of the original document is available at <http://www.ilca.org/main/learning/resources/neo-bfhi>.

The Neo-BFHI Self-Appraisal Tool is modeled after the one published by the WHO/UNICEF BFHI package, “Section 4: Hospital Self-Appraisal and Monitoring” (20). Although developed to measure readiness for external assessment or to monitor continued compliance of designated facilities, the tool can also be used for planning, research or quality-improvement exercises. Using the Neo-BFHI as a framework, the tool assesses compliance with a set of criteria formulated for each of the Three Guiding Principles, the Neo-BFHI Ten Steps and the Code.

For the purpose of this survey, the Self-Appraisal Tool has been adapted and renamed the Neo-BFHI Self-Assessment questionnaire. The main changes include: converting the self-appraisal questions into statements, and replacing most of the Yes/No answer choices in the original document by Likert scales. The principal investigators will enter the questionnaire into an online survey using the tool “EasyTrial”. In this tool the questionnaire will be offered in English, French, Danish, Spanish (will be translated by the Spanish country survey leaders), and Portuguese (will be translated by the Brazilian country survey leaders) for free use. Each country/region will be responsible for any further translations. The principal investigators could help you enter the translated questionnaire in EasyTrial if the country has more than 10 neonatal wards. The EasyTrial system has standard auto text in English, Spanish, Danish, Swedish, and Norwegian.

Prior to starting the data collection, the country/region survey leader will be required to send any translated questionnaire to one of the principal investigators (Ragnhild Maastrup) if not entered into the EasyTrial tool.

The Self-Assessment questionnaire will be pilot tested in United Kingdom, France, Quebec, and Denmark.

Data collection

The data will be collected during Spring and Summer 2017.

Survey leaders in each country/region will enter e-mail addresses for all neonatal wards in the EasyTrial tool, and by this send one questionnaire to each eligible neonatal ward. A separate introductory letter or email could be necessary. If a given hospital has more than one neonatal ward (for example, with different levels of care), each ward should receive their own questionnaire. The instructions will ask that the questionnaire be completed by the neonatal ward head nurse or equivalent (that is the person who has direct responsibility for managing the neonatal ward) together with the professional experienced in or responsible for breastfeeding support in the ward (if there is one). The responders may consult other health care professionals in the neonatal ward if needed. If online questionnaire is not used, the completed questionnaires should be returned to the survey leader of the country/region. When needed, the survey leader will send reminders three, five and six weeks after the initial message (by e-mail or phone call) to those who don’t answer.

In order to monitor rate of participation, the survey leader from each country/region will keep a list of the number of both distributed and completed questionnaires. When known, the neonatal

ward level of care will be added to the list. This will allow to better describe the nature of neonatal wards that do not respond. Also, if online questionnaire is not used, the country survey leader will be in charge of entering all the answers from the Self-Assessment questionnaires into the EasyTrial online system. The information to monitor participation should be sent to the principal investigator in charge of supervising the data collection (Ragnhild Maastrup).

Data analysis

Compliance with each criterion will be measured by analyzing the “correct” answers. In the case of Yes/No answers, the answer YES will be considered “correct”. Likert scale responses will be dichotomized and the more favorable options will be considered correct.

To summarize compliance, composite scores will be constructed for each guiding principle and step (partial scores) and for all Three Guiding Principles, Ten Steps and the Code (global scores). To build the Guiding Principle/Step Partial Compliance Score, a value of 1 or 0 points will be attributed to each criteria measured by the Self-Assessment statement depending whether the ward is compliant or not. The score will then be calculated by adding all the points attributed to each criteria of the given Guiding Principle/Step divided by the maximum amount of points that would be accumulated if the ward was compliant with all the criteria, resulting in a score that varies between 0 (no compliance with Neo-BFHI criteria) and 1 (complete compliance with Neo-BFHI criteria). Global Compliance Scores will be thereafter obtained by adding the Partial Compliance Scores, varied between 0 and 3 for the Guiding Principles, and 0 and 10 for the Neo-BFHI Ten Steps. The Code Global Compliance Score will be calculated in the same way as a partial score, with a range between 0 and 1. Detailed description of the methodology is available elsewhere (21). Partial and Global Compliance Scores will be described and compared between the participating countries/regions. Values of $p < 0.05$ will be considered statistically significant.

Descriptive statistics will be used to quantify compliance with Neo-BFHI criteria and to describe the distribution among participating facilities. Means and standard deviations will be used when the normality assumption is not seriously violated; otherwise, medians and interquartile ranges (IQR) will be used.

Analyses will be performed in Québec, coordinated by one of the principal investigators (Laura Haiek).

Ethical considerations

This survey does not include personally identifiable data, which in most countries means it could be conducted without approval from an ethic committee.

Each neonatal ward will get a code, and each country will keep their own code key. Results will be reported by country level.

We have unfortunately no funding for this study. Country survey leaders applying for funding, should make sure that it does not come from companies that violate the International Code of Marketing of Breast-milk Substitutes. Funding from such companies will exclude the country from the study. All infant formula companies violate the Code as well as companies that market infant feeding bottles such as Medela, Evenflo, Lansinoh (see <http://kellymom.com/bf/advocacy/trail-of-code-compliance/> for more information on how to decide).

Reporting of the results

The results will be published in a peer-reviewed journal. Ragnhild Maastrup will be the first author, Laura Haiek will be the last author. Co-authors will include those who contribute substantially to the completion of the survey in their region/country and to the writing of the manuscript. Co-authorship can be discussed individually to take into account the situation of each setting.

Submission is planned during 2017. Evidently, each country will have a copy of their own data, but will be asked not to publish their data before the joint publication.

Implications

The expansion of the BFHI to neonatal care is an innovative, timely project that addresses the unique needs of the most vulnerable infants, i.e., those born too early, or ill. Since it's dissemination in 2015, the Neo-BFHI package provides a series of documents and tools to promote the implementation of Baby-friendly policies and practices in neonatal wards. For the purpose of this study, the Self-Assessment questionnaire will be used to measure and compare compliance with the Neo-BFHI recommendations within a given country and internationally. This will allow the neonatal wards to make a baseline evaluation and get an idea of their compliance compared with their own country and international.

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