IMPORTANT ASPECTS RELATED TO THE PROPOSED GUIDANCE DOCUMENT

BACKGROUND:

The Baby-Friendly Hospital Initiative (BFHI) was launched in 1991 by WHO and UNICEF as a worldwide strategy to protect, promote and support breastfeeding from its very beginnings in maternity facilities.

The initiative proposed the adoption of a set of standards: the Ten Steps and the International Code of Marketing of Breast-milk Substitutes (hereafter called the International Code), a complete set of tools to facilitate implementation, and an accreditation program leading to a global recognition award.

The initiative refers to the Ten Steps as universal principles and was first endorsed by Member States during WHA 43.3 (*Protecting, promoting and supporting breastfeeding: The special role of the maternity services. A joint WHO/UNICEF statement*, Geneva: WHO, 1989). The BFHI, the 10 Steps and the International Code are all part of WHA subsequent resolutions and numerous WHO and UNICEF documents and also serve as important indicators for countries to measure progress.[i]

It set a "before and after" that has measured significant progress in improving breastfeeding rates worldwide, and has created awareness about the importance of infant and young child feeding practices and the impact of predatory marketing practices on breastfeeding.

The BFHI was last revised and globally approved in 2009[ii]. During the revision process (2004-2009), WHO clearly stated that the labelling of each step and the re-ordering of the Ten Steps was not to be changed as it was internationally recognized as a brand for a quality of care and services program. What was to be done (and was done in 2009) was to re-interpret each step according to the newest evidence.

Recently, the WHO undertook a massive re-design of the BFHI, including a reordering, renumbering, and rewording of the Ten Steps and the elimination of one step (Step 9) all together. While reviewing and updating the BFHI is necessary, the radical reorganization proposed is not truly based on evidence nor any solid rationale, despite the evidence document that has been put forth. It will be financially and philosophically costly as it means major revamping in all countries and it risks further stalling the BFHI since the Ten Steps and the International Code are now globally known and more and more frequently adopted by governments and professional organizations as well as referred to in healthcare professionals' textbooks, journals, and educational offerings.

OUR PROPOSAL:

1. All revisions to the BFHI should be made within the context of the current Ten Steps and International Code.
2. There is enough published evidence to retain Step 9 within the BFHI.
3. Standardization at the global level is needed especially for the training and assessment components.

MAIN ELEMENTS OF CONCERN AND RATIONALE:

1. **Global standardization.** The current BFHI sets the Ten Steps and the International Code as universal principles. WHO-UNICEF provide implementation guidelines about global criteria and

definitions, monitoring processes, assessment methods and tools which are used by all countries to ensure as much standardization as possible. This is how countries can be compared on key basic indicators such as breastfeeding initiation rates, breastfeeding rates from birth until discharge from a maternity facility, percentage of births in a Baby-Friendly hospitals [iii], breastfeeding duration rates. The proposed guidance document leaves much latitude to countries to define their own standards and implement the BFHI without any assessment process or international recognition. Those changes will derail our ability to compare countries and collect this important data.

We believe that the BFHI should retain global guidelines, criteria, streamlined monitoring and assessment tools and methods, and scoring systems and update standard tools and materials for adaptation and use at the country level.

RATIONALE:

- Maintaining the quality of the Baby-Friendly brand is essential to ensuring that standards of care are the same or very similar throughout the world. This quality would be endangered in the case that the BFHI rests on the setting of national standards and individual national guidelines, criteria, tools and scoring systems as proposed in the WHO-UNICEF guidance document.
- Global standardization is necessary, especially for training and assessment, to ensure world-wide implementation of the BFHI. While we agree it is important to also encourage pre-service education, monitoring, and integration of the Ten Steps with other accreditation processes, etc., these changes take time. In the meantime, designation should NOT be discouraged by being presented as a secondary "option".
- Evidence around the world and feedback from delegates during the BFHI Congress indicate that assessment and accreditation are a key part of improving and measuring hospital or maternity adherence to the Ten Steps in many countries.
- There are significant financial and other resource considerations associated with the development of the tools necessary to train, implement and assess the progress of BFHI. Many countries do not have the resources and/or the expertise to develop these, especially for a brand-new program from the beginning.
- If global streamlined tools (training, monitoring and assessment) are not provided by WHO-UNICEF, it is likely that standards around the world will become quite varied, and, in many cases, lowered, potentially resulting in negative impact on breastfeeding support and breastfeeding rates.
- Keep external assessment conducted by knowledgeable individuals as part of the process, and recognition by accreditation, based on these assessments, as an important option.
- Keep all three levels of program evaluation for facilities' assessment. Most program evaluation are based on a three-level assessment such as the current BFHI assessment: process, structure and outcomes. In this model, clients' interviews are crucial as they are the receivers of the services. For the BFHI assessments, pregnant women's and mothers' interviews provide an unfiltered view of the standard of care and are, therefore, an essential component of the external audit process.
- Having the Baby-Friendly assessment limited to a review of records/documents as part of a quality certification process will likely not accurately reflect actual practice.

2. **Metrics for assessments.** The current BFHI document from WHO-UNICEF (2009) sets the metrics for assessment purposes. For example, a birthing facility (hospital, maternity) must demonstrate a rate of at least 75% of exclusive breastfeeding from birth until discharge and

attain a minimum score of 80% for each step during the external assessment of the facility. The proposed guidance document sets the breastfeeding rates from birth until discharge, as well as other indicators, at 90%.
We believe this is currently unrealistic.

RATIONALE:

- Many maternity facilities throughout the world already experience difficulty achieving the 75% exclusive rate from birth to discharge as well as the 80% standard for each Step during the assessment process.
- Raising the metrics will demotivate facilities to implement the BFHI.

3. **Renumbering of the steps and removal of Step 9.** The Ten Steps are widely known and increasingly included in health priorities throughout the world as well as adopted by professional bodies and inserted in healthcare professionals' textbooks and journals. The order of the Steps and the total number of Steps are well known and have been the subject of subsequent WHA Resolutions without altering them. The proposed guidance document is renumbering the Ten Steps and removing one Step (Step 9) altogether without documented rationale.
We believe the current structure, numbering and subject matter of the original Ten Steps should be retained as has been the case for all previous revisions, and updated evidence should be used to interpret each Step as appropriate.

RATIONALE:

- The Ten Steps have become the "brand" for maternity care practices that support breastfeeding.
- For consistency and branding purposes, it is important to keep the original Ten Steps and their original numbering. This matters because there are hundreds of publications, courses, books and resolutions of the WHA that endorse "The Ten Steps".
- There is no research or experiential evidence that re-numbering the Ten Steps and removing one of those (Step 9) will strengthen the BFHI or lead to a larger global adoption by governments, professional bodies or maternity facilities.
- Barriers to implementation of BFHI have been described[iv] but the order of the Ten Steps or the Ten Steps themselves have never been identified as barriers.
- The reasons for maintaining them in their current structure, which include the number of resources already devoted to them and the large number of institutions that have incorporated them into their work, are significant.
- There should be very strong and salient reasons to dismantle them; there is no actual evidence that supports their decommissioning.
- Reinterpretation of a Step following new evidence is what has been done in the previous revisions of the Ten Steps and what is suggested be done here. For example, originally, Step 4 read: Help mothers initiate breastfeeding within a half-hour of birth. The 2009 Interpretation is: Place babies in skin-to-skin contact with their mothers immediately following birth for at least an hour. Encourage mothers to recognize when their babies are ready to breastfeed and offer help if needed.
- Eliminating step 9 (which reads: "Give no artificial teats or pacifiers-also called dummies or soothers-to breastfeeding infants") based on a lack of evidence from randomized controlled trials is inadequate because only a very few randomized controlled trials conclude they do not affect breastfeeding. Much scientifically sound quantitative research is available showing how harmful the early introduction of a pacifier or teat, as early as during the postpartum stay, is for breastfeeding initiation, and must be taken into account.

4. **Important costs.** The proposed changes to the BFHI structure bring significant costs: financial and philosophical in nature.
   We believe this will weaken the BFHI globally and exacerbate health inequities.

   RATIONALE:
   - The Ten Steps as they currently exist are well and widely known and applied.
   - The order and number of the Steps have remained unchanged through subsequent WHA resolutions.
   - The re-numbering the Ten Steps and removing of Step 9 will add to the burden of currently designated facilities by requiring the retraining of previously trained staff in the original Ten Steps.
   - We applaud the recommendation to incorporate pre-service breastfeeding education; however, this will take time to effect and incorporate.
   - The costs of in-service training are real, along with costs of changing content of everything that has been written on the BFHI already in medical and healthcare textbooks and training manuals.
   - Cost at the philosophical level also exists, as the BFHI itself (not only breastfeeding) has been officially endorsed or adopted by governments and professional organizations and incorporated into health and public health priorities.
   - Member States that do not have the resources and/or the expertise to develop these materials will be left behind, thereby emphasizing already existing health inequalities and making it more difficult to reach the Sustainable Development Goals on health and nutrition.

5. **The International Code.** The International Code has been an integral part of the BFHI since its inception, although not as one of the Ten Steps. The proposed guidance document places it as one of the Ten Steps by replacing a current Step.
   The International Code must continue to be an integral part of BFHI and serve as an overarching principle to the BFHI implementation rather than being placed in a lesser position as a single Step. The Code is a separate international document that addresses many aspects of infant and young child nutrition (IYCN), not just the BFHI, and needs legal implementation and enforcement at national levels.

   RATIONALE:
   - The International Code is a fundamental component of a strong initiative to protect, promote and support breastfeeding.
   - There is strong evidence of the importance of the International Code for the protection of breastfeeding and IYCN. At the 2016 BFHI Congress, WHO and UNICEF were asked by delegates to make strong statements about regulating the marketing of breast milk substitutes as formula companies are known to lack respect for families and healthcare professionals and to market their products unethically, not abiding by the International Code and in so doing, undermining efforts to promote, protect, and support breastfeeding.
   - Supporting breastfeeding with appropriate good practices (the Ten Steps) and protecting it from predatory practices (with the International Code) should be kept inseparable in the BFHI.

6. **Mother-Friendly Childbirth Component.** A Mother-Friendly component was developed within the BFHI concept and described in the 2009 revision of the BFHI. It consists of evidence-based practices recognized as facilitators for the initiation of breastfeeding while at the same time respecting the wishes, culture and personal rhythm of a birthing woman. The 2017 proposed guidance document does not include those practices as WHO-UNICEF considers this subject is covered elsewhere.
   We believe we should keep safe and respectful birth practices as a component of the BFHI and establish clear links between the BFHI, Mother-Friendly and other WHO and UNICEF programs related to safe and respectful birth (Prevention and elimination of disrespect and abuse during childbirth, WHO Sexual and Reproductive Health, http://www.who.int/reproductivehealth/topics/maternal_perinatal/statement-childbirth-data/en/).

   RATIONALE:
   - The evidence is compelling: birth practices have a significant impact on initiation of breastfeeding.[v]
   - Mother-Friendly should be kept as in the 2009 BFHI update while referring users to additional WHO guidance in other documents.
   - Most of the Mother-Friendly practices are enacted in birthing facilities and therefore it is important to address them within all important maternal and child health documents, including the BFHI.

7. **Including preterm and sick infants.** In all previous versions of the BFHI, all Ten Steps refer to practices with term healthy infants, excluding sick and preterm infants. The 2017 proposed guidance document requires that the BFHI cover all types of infants within the Ten Steps.
   We believe different standards or a different implementation of the Ten Steps has to be explicitly developed to suit the needs of those vulnerable infants.

   RATIONALE:
   - The needs and care of the sick and preterm infant are completely different from that of the healthy term infant and the scientific literature reflects this.
   - In-depth work is required to adapt the Ten Steps for their applicability to the highly specialized setting of care for vulnerable infants. A tremendous body of work for these most vulnerable infants has been done by the NEO BFHI group,[vi] as well as in individual countries.
   - The current wording in the proposed guidance document does not address the specificity of the type of support needed to initiate breastfeeding with a vulnerable mother-infant dyad.
   - Some of the recommendations offered in the proposed guidance document are inappropriate for this special population, particularly for the very preterm infants.
   - Mixing recommendations for preterm infants and sick infants with those for healthy term newborns weakens some recommendations, for example Step 9.

8. **Evidence supporting the whole BFHI program vs individual steps.** The literature review document on which WHO-UNICEF bases the proposed guidance document does not take into account the quantitative research showing that the implementation of the BFHI as a comprehensive quality of care and services program positively impacts breastfeeding initiation, exclusivity and duration rates.

We believe that the guidance document should include a robust discussion regarding the interrelationship between of each of the Ten Steps and how they work together as a comprehensive program.

RATIONALE:

- Only evidence from randomized controlled trials was reviewed and only for each of the Ten Steps taken singly, ignoring the very important synergy of the Steps in forming a greater whole.
- There is very limited evidence from randomized controlled trials for some individual Steps, for example for Step 9, but there are many other types of scientifically sound quantitative research which were not considered[vii]
- Not all of the evidence for each individual Step is as strong as the evidence for the combined Steps.
- The literature review never considered evidence for the BFHI program as a whole which is surprising as the evaluation of a program is normally conducted by reviewing each element of the program singly and the program as a whole.
- This evidence exists and must be taken seriously as it shows that the effectiveness of the BFHI increases with the number of Steps implemented, and is even better when considered as a whole program[viii]

9. **Ethical issues with RCTs.** The proposed guidance document Executive Summary refers "low-quality evidence", which is only the case if we use the GRADE system or only randomized controlled trials. Many other types of scientifically sound quantitative research exist to support every Step and the BFHI as a whole but they were not taken into consideration.
We believe the guidance document should include a solid discussion of the ethical issues related to performing randomized trials on breastfeeding, on perinatal practices (e.g. immediate skin-to-skin with mother at birth, no mother-infant separation, etc) and on the BFHI. Mention of this discussion should also appear in the Executive Summary.

RATIONALE:

- Many individuals will only review the Executive Summary of the literature review which forms the basis for the proposed guidance document. It is likely they will misunderstand statements such as "low-quality evidence" and conclude that the recommended practices to support breastfeeding are not evidence-based.
- If the GRADE system[ix] is not explained, readers will not understand that a very strict approach was taken by WHO-UNICEF to review only certain types of research for each Step singly which is different than systems generally used for systematic reviews.
- A solid discussion of the GRADE system versus other widely accepted and used levels of evidence[x] should clarify this.

[i] - Food and Agriculture Organization of the United Nations (2015). *The second international conference on nutrition: Committing to a future free of malnutrition* (The Second International Conference on Nutrition, 19-21 November 2014 - Better Nutrition, better lives). Rome: Food and Agriculture Organization of the United Nations. Retrieved from http://www.fao.org/3/a-i4465e.pdf.
- World Health Organization. (2016). *Report of the commission on ending childhood obesity. 2016*. Geneva: World Health Organization. Retrieved from:
http://apps.who.int/iris/bitstream/10665/204176/1/9789241510066_eng.pdf?ua=1.
- World Health Organization, & UNICEF. (2016). *Guideline: Updates on HIV and infant feeding: The duration of breastfeeding, and support from health services to improve feeding practices among mothers living with HIV*. Geneva: World Health Organization. Retrieved from http://www.who.int/maternal_child_adolescent/documents/hiv-infant-feeding-2016/en/
- World Health Organization. (2016). *Breastfeeding in the 21st century*. Retrieved from http://www.who.int/pmnch/media/news/2016/breastfeeding_brief.pdf
- World Health Organization, & UNICEF. (2014). *Every newborn: An action plan to end preventable deaths*. Geneva: World Health Organization. Retrieved from

https://www.everynewborn.org/Documents/Every_Newborn_Action_PlanENGLISH_updated_July2014.pdf

[ii] - WHO-UNICEF (2009). *Baby-Friendly Hospital Initiative. Revised, updated and expanded for integrated care*. Geneva: WHO and UNICEF.

[iii] - http://www.fao.org/3/a-bt436e.pdf
- https://www.cdc.gov/breastfeeding/pdf/2016breastfeedingreportcard.pdf

[iv] - Semenic S, Childerhose JE, Lauzière J & Groleau D (2012). Barriers, facilitators, and recommendations related to implementing the Baby-Friendly Initiative (BFI): an integrative review. *Journal of Human Lactation*, 28 (3), 317-334.
- Wieczorek CC, Marent B, Dorner TE & Dur W (2016). The struggle for inter-professional teamwork and collaboration in maternity care: Austrian health professionals' perspectives on the implementation of the Baby-Friendly Hospital Initiative. *BMC Health Services Research*, 16, 91-105.

[v] - Department of Nutrition for Health and Development + Department of Maternal, Newborn, Child, and Adolescent Health (2014). Including Mother-Friendly care in the Baby-Friendly Hospital Initiative. Power Point presentation by Carmen Casanova at the 10th meeting of the BFHI coordinators and focal points from industrialized countries, Vilnius (Lithuania), June 6-8.
- The Mother-Friendly childbirth practices are included in Part Three of the *WHO/UNICEF Infant and young child feeding: A tool for assessing national practices, policies and programmes (2003)* is available from http://www.who.int/nutrition/publications/infantfeeding/9241562544/en/index.htm

[vi] Nordic and Quebec Working Group (2015). Neo-BFHI. The Baby-Friendly Hospital Initiative for neonatal wards. Three guiding principles and Ten Steps to protect, promote and support breastfeeding. Available at: http://www.ilca.org/i4a/pages/index.cfm?pageid=4214

[vii]- Dos Santos Buccini G, Pérez-Escamilla R & Venancio SI (2016). Pacifier use and exclusive breastfeeding in Brazil. *Journal of Human Lactation*, 32 (3), NP52-NP60.
- Howard CR, Howard FM, Lanphear B, Eberly S, deBlieck EA, Oakes D & Lawrence RA (2003). Randomized clinical trial of pacifier use and bottle-feeding or cupfeeding and their effect on breastfeeding. *Pediatrics*, 111, 511-518.

- Kronborg H & Vaeth M (2009). How are effective breastfeeding technique and pacifier use related to breastfeeding problems and breastfeeding duration? *Birth*, 36 (1), 34-42.
- Nelson EAS, Yu L & Williams S on behalf of The International Child Care Practices Study Group Members (2005). International child care practices study: Breastfeeding and pacifier use. *Journal of Human Lactation*, 21, 289–294.

[viii] -Pérez-Escamilla R, Martinez JL & Segura-Pérez S (2016). Impact of the Baby-Friendly Hospital Initiative on breastfeeding and child health outcomes: a systematic review. *Maternal & Child Nutrition*, 12 (3), 402-417.
- Nickel NC, Labbok MH, Hudgens MG & Daniels JL (2013). The extent that non compliance with the Ten Steps to successful breastfeeding influences breastfeeding duration. *JHL*, 29 (1), 59-70.
- DiGirolamo AM, Grummer-Strawn LM & Fein S (2001). Maternity care practices: implications for breastfeeding. *Birth*, 28 (2), 94-100.
- Kramer MS, Chalmers B & Hodnett ED for the PROBIT study group (2001). Promotion of Breastfeeding Intervention Trial (PROBIT): A randomized trial in the Republic of Belarus. *Journal of the American Medical Association*, 285(4), 413-420.

[ix] Guyatt GH, Oxman AD, Vist GE, Kunz R, Falck-Ytter Y, Alonso-Coello P, et al.; GRADE Working Group. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. BMJ. 2008 Apr 26;336(7650):924–6. PMID: 18436948

[x] -National Guidelines Clearinghouse uses Shekelle PG, Woolf SH, Eccles M & Grimshaw J (1999). Developing clinical guidelines. *Western Journal of Medicine*, 170 (6), 348-351.