

Prologue

The Dutch version of the statement written below was sent to the National Institute of Public Health and Environment (RIVM) on 25th June 2008. On account of this statement, there was a meeting at the RIVM on 27th October 2008. Those who endorsed the lactation consultants' statement were offered the possibility to clarify their concerns. In the spring of 2008, the Dutch institute of psychologists, NIP, had also presented a statement¹ to the RIVM and they were also present at the meeting. The minutes of this meeting were received on 12th November 2008 and were an incomplete and incorrect report of what was discussed.

After that, several alterations were made in the draft Guideline and on 12th December 2008 we received this provisionally final version and were asked to comment on it.

We found that a number of essential objections we made, were not met. In our opinion, a bothersome fact was added: the publications 'Regelmaat brengt rust'² ('Regularity brings peace') and 'Inbakeren brengt rust'³ ('Swaddling brings peace'), written by Ria Blom, were now an integral part of the Guideline. Therewith, the RIVM had engaged in an extra responsibility, because the publications contain several disputable opinions, which are not based on scientific research. Although a new version of 'Regelmaat brengt rust' was published November 2008, it still contains many misstatements and on top of that, old versions have not been withdrawn from circulation.

On 8th January 2009 we objected to the minutes and, after careful analysis, also integrated our main objections against the provisionally final version of the Guideline. With respect to the content of this letter, we have, up until this day, not received a reaction from the RIVM.

On 9th January 2009, the Royal Dutch Organisation of Midwives (KNOV) objected⁴ to the Guideline with the RIVM. In this letter, critical side notes have been made with regard to the following aspects:

- the method of guideline development as followed by the RIVM in this specific case;
- the very weak scientific substantiation of the Guideline (only one study, dealing with different issues than the Guideline);
- a very disputable operational definition of risk factors;
- lack of clear explanation about possible interventions and therewith a lack of uniformity for healthcare providers about the policies to be practised;
- the objections brought forward by psychologists and lactation consultants with regard to psychological and social development of the child and the success of breastfeeding.

On 26th January 2009, the objections of the midwives, added to the objections the psychologists and lactation consultants had already presented, were reason for the RIVM to decide not to finalize and implement the Guideline.

Meanwhile, the process of developing a multidisciplinary guideline regarding excessive crying has started. The RIVM intends to complete this project by the end of 2010.

Again, the study 'Comparison of behavior modification with and without swaddling as interventions for excessive crying' will be the starting point and basic assumption, on which the interventions suggested in the Guideline (regularity, predictability and stimuli reduction, when necessary combined with swaddling) will be built.

It is, therefore, of vital importance that the bottlenecks in this study are recognized. We will closely monitor the process and, in the interest of young children and their parents, will keep introducing research that positively contributes to the development of the new guideline. International experiences and feedback will provide an essential contribution to this monitoring.

The position we advocate is also supported by the National Committee for Unicef, the Netherlands. This organisation endorses the lactation consultant statement.

Assen/Apeldoorn, 3rd February 2009

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STATEMENT in reaction to the (draft) guideline 'Dealing with excessive crying in nurslings' (Centrum JGZ / RIVM, Centre for Child Healthcare/National Institute of Public Health and Environment), version 2007/version 2008)

by

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This statement is endorsed by:

Stichting Zorg voor Borstvoeding (BFHI-awarding body)
 Kenniscentrum Borstvoeding (biggest Dutch website on breastfeeding)
 Vereniging Borstvoeding Natuurlijk (VBN, Dutch breastfeeding association, similar to LLL)
 Borstvoedingorganisatie LLL (Dutch branch of LLL International)
 Stichting Baby Voeding (Dutch foundation for monitoring the WHO-Code/IBFAN-group)
 Nederlandse Vereniging van Lactatiekundigen (NVL, Dutch professional association for IBCLC's)

Introduction

As lactation consultants we have noted major concerns with the (draft) guideline 'Dealing with excessive crying in nurslings (2007)⁵ (from now on referred to as Guideline).

This concern mainly focuses on the following aspects:

- the success of breastfeeding:
 - by advising against responsive interaction, the amount of physical contact is reduced, which negatively impacts oxytocin levels in mother and child, and this can have a negative effect on the breastfeeding process;
 - demarcating (and thereby often lengthening) the intervals between feedings has a negative impact on the self regulation of milk production as well as intake by the baby;
 - wordings like "naps", "drinking little bits" and "waking up too early" are, in many cases, based on incorrect patterns of expectations and false assumptions, and obstruct good understanding of the physiology of lactation and the related sleeping-behaviour;
- the emotional and psychological development of the child:
 - by encouraging parents to be non-responsive, healthcare providers cause difficulty for the infant with regard to establishing secure attachment;
- patterns of expectations by parents and society:
 - by considering frequent feedings and short sleep episodes problem behaviour, caregivers create the risk of the baby not receiving the care he needs, based on his biological development;
- the underlying research and the 'marketing' of the results:
 - by using parental perception as criterion for participation in the research project, a subjective definition of crying behaviour has been adopted;
 - there is no control group to which both interventions can be compared;
 - there is no longitudinal prospective research available, on the basis of which can be stated that the recommendations can be safely used as a common and acceptable policy in dealing with 'whiners';
 - by moving from intervention to preventative application of the proposed measures without supporting evidence, there is a risk that a problem situation may be supposed or created where none is present.

In the following paragraphs these four aspects will each be elaborated upon separately. This will lead to a number of conclusions that will culminate in a couple of recommendations.

An important part of the work of lactation consultants (IBCLC's, International Board Certified Lactation Consultants) in mother and childcare is increasing the understanding of the effects of long term breastfeeding as it relates to the development of the child, physically as well as psychologically and societally, and improving care for children who have experienced a difficult start.⁶ The Standards of Practice⁷ of the International Lactation Consultant Association (ILCA) includes, as important standards for lactation consultants:

- to act as an advocate for breastfeeding women, infants and children and:
- to provide positive feedback and emotional support for continued breastfeeding, especially in difficult or complicated situations.

The Scope of Practice⁸, a core document for the IBCLC-lactation consultant, contains these and other obligations with regard to the integration of cultural, psychosocial and nutritional aspects of breastfeeding in daily practice.

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Endorsement of this statement by:

Stichting Zorg voor Borstvoeding (Foundation Care for Breastfeeding)

Foundation Care for Breastfeeding was founded in 1996 by UNICEF Netherlands to implement the worldwide breastfeeding campaign 'Baby Friendly Hospital Initiative' (BFHI) in the Netherlands. This combined initiative by UNICEF and the World Health Organization (WHO) is based on the conviction that a quality healthcare system offers the best guarantee that parents will receive consistent and reputable breastfeeding care..

Kenniscentrum Borstvoeding (Centre of Breastfeeding Knowledge)

Kenniscentrum Borstvoeding offers a wide range of breastfeeding information through the website www.borstvoeding.com; this site is run by a team of renowned breastfeeding specialists and mothers with breastfeeding experience, led by Stefan Kleintjes, child dietician, manager of dietician practice 'Kleintjesconsult', author of 'Eten voor de kleintjes – van borst tot boterham' ('Food for the little ones – from breast to sandwich') and co-author of 'Borstvoeding' ('Breastfeeding').

Vereniging Borstvoeding Natuurlijk (Association Breastfeeding Natural(ly))

Vereniging Borstvoeding Natuurlijk (VBN) was founded in 1978. As a volunteer organisation, it gives scientifically based, consistent information about breastfeeding to parents (to be) and others who are interested. The strength of the association lies with the contact persons that work from expert knowledge and who are continuously trained within the organisation to support mothers with practical information about breastfeeding.

Borstvoedingorganisatie LLL (Breastfeeding organisation LLL)

Borstvoedingorganisatie LLL (Foundation La Leche League the Netherlands) is the Dutch branch of La Leche League International (founded in 1956). It gives scientifically based information about breastfeeding to parents (to be) and offers support to women who have problems with nursing. LLL is a non-profit volunteer organization and the leaders are mothers who are or were breastfeeding. They have expert knowledge and have completed training within LLL. LLL further aims at promoting societal recognition of breastfeeding as an important element in healthy development of the child and of the value of conscious parenthood and close family ties.

Stichting Baby Voeding (Foundation Baby Feeding)

Stichting Baby Voeding is the Dutch IBFAN-group (International Baby Food Action Network). The foundation strives for protection and support of breastfeeding and optimal infant feeding by implementation of the international WHO-Code and the following, relevant resolutions of the World Health Organisation. This is done through networking with politicians and other relevant organizations and institutions to improve and expand Dutch legislation regarding infant feeding.

Nederlandse Vereniging van Lactatiekundigen (Dutch Association of Lactation Consultants)

The Nederlandse Vereniging van Lactatiekundigen (NVL) is the professional organisation of IBCLC lactation consultants and aims at increasing awareness of the profession of lactation consultant among the general public, the government, public healthcare and health insurers. The lactation consultant is the expert par excellence when it comes to breastfeeding. She professionally guides parents (and their child) with all aspects of breastfeeding, cooperates in developing and implementing policies in the lactation field and provides information and training to protect, promote and support breastfeeding. The NVL, offers information and networking for its members, and works towards raising professionalism of the lactation field.

Many thanks to Mrs. M. van den Nieuwenhuizen MSc, IBCLC, medical biologist and teacher of Human Lactation at the Hogeschool Utrecht, for reviewing the paragraph 'The underlying research and the 'marketing' of the results'.

Many thanks as well, to Theresa Hoch, Laura Wright and Jacquie Nutt for editing the English translation, made by Marianne Vanderveen, and to a number of colleagues from the Lactnet-mailing list, who were kind enough to give their feedback with regard to this document.

The success of breastfeeding

Breastfeeding is the gold standard of infant feeding. WHO recommends six months of exclusive breastfeeding, and continued breastfeeding for quite some time after that, in combination with appropriate solids. This advice not only applies to developing countries, but to more industrialized areas as well, such as the Netherlands. The grounds for this recommendation are supposed to be generally known.

In 1991, WHO and UNICEF launched the worldwide 'Baby Friendly Hospital Initiative' (BFHI) to promote breastfeeding. In the Netherlands, the BFHI-campaign has been known as *Zorg voor Borstvoeding* (Care for Breastfeeding) since 1996. The focus is on improving guidance of and support for breastfeeding in healthcare based on international criteria regarding high standard breastfeeding policies. Lactation consultants are closely involved in this program. The criteria mentioned are based on the 'Ten steps to successful breastfeeding'⁹. In the Netherlands, these are called the 'Tien vuistregels voor het welslagen van borstvoeding'¹⁰. For child healthcare they are transformed to the '7 Stappen voor de JGZ'.¹¹ They count as prerequisites for acquiring the WHO/UNICEF-certification from *Zorg voor Borstvoeding*. The basic 'rules of thumb' are found on the document 'Evidence for the ten steps to successful breastfeeding'¹².

Good breastfeeding care requires the implementation of these criteria in everyday practice, of which the international WHO-Code (International Code of Marketing of Breast-milk Substitutes)¹³ is an essential part.

In the (draft) guideline 'Dealing with excessive crying in nurslings' (2007) the role of breastfeeding in the way babies are handled is not mentioned, although the procedures recommended by the guideline will often impact breastfeeding.

Humans belong to the class of mammals. There are four types that can be clearly distinguished, by looking at milk composition and maturity of the young at birth. On these biological grounds, Nils Bergman¹⁴ states that humans should be classified as carry-mammals. Human milk has the lowest fat and protein content of all mammalian milks, explaining why feeding intervals are short under natural circumstances. Frequent feedings are normal biological behavior for this type of mammal. This also applies to night feedings, which are still very normal at the end of the first year of life.¹⁵

Anthropologist Ashley Montagu¹⁶ describes humans as 'extero-gestators'. Their infants are extremely immature at birth and accomplish a substantial part of their physical and neurological development outside the womb. The length of this extra-uterine phase is estimated to be nine months to one year, as this is the age at which a baby has 80% of its brain volume, a percentage comparable to other mammals at birth. Until that age, a baby is completely dependent on primarily the mother for satisfaction of his physical needs. Separation from the mother leads to the 'separation distress call', crying, aimed at restoring maternal proximity.¹⁷ The carrying of infants can fulfill a very important role in preventing this kind of stress.¹⁸

Letting a baby cry ((draft) guideline 'Dealing with excessive crying in nurslings' (2007), p. 17, 19), on the other hand, causes exhaustion and restlessness. This leads to high cortisol levels, which hinders effective, nutritive suckling at the breast as well as digestion and absorption of nutrients. The Guideline does not explain that frequent, positive interaction between mother and child is the basis for a satisfying breastfeeding relationship and good growth and development. It also fails to explain that interaction with the baby simultaneously stimulates self-confidence in the mother the parents.

Maternal proximity in the form of frequent bodily contact has a positive impact on mother and child. Professor of physiology, Kerstin Uvnäs-Moberg, is a leading expert in the field of research concerning the importance of the hormone oxytocin. Skin contact promotes the production of oxytocin in mother and child. This hormone triggers the milk ejection reflex during breastfeeding, but apart from that has many other favourable effects. It promotes interaction by sensitivity and responsiveness, reduces the production of stress hormones that are released with separation and crying, promotes diges-

tion and absorption of nutrients and, with repeated surges, has a positive effect on the physical and psychological balance of mother and child.¹⁹

All of these factors underpin the premise that it is necessary for a baby to have unlimited access to the breast in order to get lactation off to a good start and safeguard its continuation. The number of feedings in the early post partum period has a minimum (eight effective feedings per 24 hours), no maximum. Later on, there is a wide range in the number of feedings between individual mother-infant dyads. Indicating averages (Guideline, p. 29) is therefore quite insignificant.

The mother's production of milk is mainly determined by the degree of breast emptying by the baby.²⁰ This process of supply and demand is the foundation of Step 4, 5, 6, 7 and 8 (initiation of breastfeeding within half an hour, maintaining lactation even in case of separation, no supplementing, rooming-in and breastfeeding on demand).

Demarcating (and thereby often lengthening) the intervals between feedings, as indicated in several segments of the Guideline (p. 17, 19, 29) has a negative impact on the self-regulation of milk production as well as intake by the baby. Increased crying in a baby can very well be a signal of hunger, which may or may not be caused by faltering milk production. Many lactation consultants will recognize this: *"In December I received a letter from the foundation Zorg voor Borstvoeding with regard to the annual evaluation of certification. In my answer, I dedicated a few words to the so called prevention of excessive crying, implemented during the childbed days¹. As it happens, in a short period of time I already encountered two alarming breastfeeding situations that were in danger of resulting in silent malnutrition, with a baby failing to thrive."*²¹

Another aspect influencing feeding frequency is storage capacity. This is the amount of milk a breast can comfortably hold between two feedings.²² With a smaller storage capacity, more feedings are needed to guarantee sufficient milk transfer than with a bigger capacity. A high feeding frequency is therefore usually the best way to safeguard production. There is no biological substantiation for a general limitation of the number or length of feedings.

The average sleep, wake and feeding times mentioned in the Guideline contribute little to a good understanding of normal interaction between mother and child. The characteristic sleeping pattern of babies during the first months of their lives is one of frequent, short episodes of sleep, alternated with waking periods that may be coupled with crying and restlessness. During the evening hours babies may 'cluster feed', having many feedings in a very short time span or a long session of feeding, during which the baby is switched from the one breast to the other. The sleeping pattern of breastfed babies differs from artificially fed babies. Breastfed babies may wake more often during the nighttime hours and show shorter sleeping episodes^{23 24 25}. Appointing risk children, for whom anticipating information would have a preventive effect, in our opinion, runs counter to that, especially because within the risk groups behaviour is described that is completely normal for young children in general and for breastfed children in particular. Formulations like "naps", "not falling asleep by themselves" and "waking up too early", coming from the (draft) guideline 'Dealing with excessive crying in nurslings (2007), p. 9, 13 and 14, are very often based on incorrect expectations and assumptions and obstruct good understanding of the physiology of lactation and the related sleeping behavior. The text about the disturbed sleeping pattern, for example, based on R. Blom²⁶, has an ominous tone, although scientific evidence is lacking.

*"So Hidde is now 11 weeks old and cries a lot. My well baby clinic suggested I let him cry. My feeling goes totally against that, but because I was desperate, I tried it, but as soon as he was crying upstairs, I was crying downstairs. I went to the family doctor with him; he said that if this little boy becomes quiet with his mum, why should you let him cry? To be on the safe side, he referred me to a pediatrician to check whether he was medically okay. He was. Letting him cry is definitely not for me. I follow my own feeling and I think that is the most important thing."*²⁷

¹ The Netherlands have a unique, well-developed system of midwives who guide home-deliveries, and nurses who assist 7-8 (sometimes 10) days at the family's home. This is a clearly defined period, that differs from the postpartum period, that may well extend into the 6th or 7th week. The term 'childbed' will be used as translation for the Dutch word 'kraambed', to refer to the timeframe of these early days following labour and birth.

The emotional and psychological development of the child

At birth, the human baby has only 25% of the adult brain volume. His natural habitat is his mother's body, states Nils Bergman.²⁸ In all mammals, there are primarily two systems present: defense and feeding. They are the key to our survival. If either is active, the other is not. When a baby is in a defensive state, the body closes off the feeding system and therewith growth. When the feeding program is running, a baby is open and vulnerable. Bergman describes four basic needs in mammals: oxygen, warmth, food and protection. These needs should be met by keeping the young or the child in the right habitat. Maternal presence meets these requirements: oxygen through the air, warmth and protection through skin-to-skin contact with the mother and food from the breast. The neonatal attachment process can easily be disturbed. Separation of the newborn from the mother leads to crying, setting off the 'protest-despair-detachment'-process. This causes an increase in stress hormones. Blood pressure and intracranial pressure rise, causing insufficient oxygen saturation in the brain.²⁹ With regard to heart rate, blood pressure, body temperature, digestion and sensitivity, exactly the opposite happens in this 'flight-or-fight'-mode, as compared to the 'calm-and-connection'-mode that is accompanied with high oxytocin levels.

Skin stimulation through body contact, but also through auditory and visual closeness causes the secretion of oxytocin in the mother-infant dyad. Repeated surges of this hormone, in the blood as well as through neural pathways, result in a mutual, positive cascade of physical and psychological effects. Behaviorally, these are translated into a less defensive attitude, inclination towards interaction, improved learning skills, empathy, confidence and loving feelings.³⁰

All these processes, necessary for secure attachment and healthy growth and development, require a responsive attitude in parents/caregivers. Such an attitude, in most cases, reduces stress related crying.³¹

Breastfeeding as a process fulfills this concept. It is a relationship not only meant for transfer of calories; it most certainly includes physical contact.³²

The Guideline does not explain that frequent, positive interaction between mother and child is the basis for a satisfying breastfeeding relationship and good growth and development. Signs of restlessness, crying and whining (Guideline, p. 12) will occur in almost all babies and are no reason to immediately apply interventions like quietness, regularity and swaddling or to leave the baby alone in his crying, feeling restless and insecure (p. 17).

There is no biological substantiation for the idea that a human infant thrives by being left alone, as crying is an overly clear signal of discomfort.

Crying is one way a child communicates with its environment; sensitive, responsive interaction teaches him confidence in that environment. On biological grounds, it can be stated that human babies, given their characteristics as carry-mammals, will develop optimally when the primary caregiver speaks and answers the baby's body language. The Guideline (p. 22) indicates: "Crying is normal behaviour in the development of children. (...) It is a signal that elicits caring behavior.."

The guideline further advises for the first two months to only give 'inclusive attention' to the child during feeding and nappy changing. After two months, cuddling can also take place after feeding, just like making contact on the caregiver's lap. This bears testimony to a 'mechanical' view.

The wording with regard to playing alone as opposed to asking for attention shows little understanding of normal interactive behaviour and normal development of young babies.

The way of dealing with a (crying) baby, as recommended in the Guideline, can cause feelings of maternal deprivation in the child.³³ In parents, this routine can lead to lack of self-confidence as they are encouraged to deny their own feelings and their inclination to show caregiving behaviour.

Patterns of expectations by parents and society

The way contemporary society views young children is reflected in legislation, policy plans and guidelines. In those documents, the rights of mothers and parents to self-determination have a very important position. Next to that, the baby has certain rights, based on the 'Convention on the rights of the child'³⁴, such as "the right of the child to the enjoyment of the highest attainable standard of health" (article 24). The European Union has taken a clear standpoint in the Blueprint for Action, citing the Lancet: "*If a new vaccine became available that could prevent one million or more child deaths a year, and that was moreover cheap, safe, administered orally, and required no cold chain, it would become an immediate public health imperative. Breastfeeding can do all of this and more, but it requires its own "warm chain" of support - that is, skilled care for mothers to build their confidence and show them what to do, and protection from harmful practices. If this warm chain has been lost from the culture or is faulty, then it must be made good by health services*³⁵." In conclusion: "Protection, promotion and support of breastfeeding fall squarely into the domain of human rights."

This statement is aimed at the importance and value of societal support for breastfeeding, as mentioned in the Rights of the Child, and therefore advocates the relevance of knowledge about normal development of human babies. The 'warm chain' means that parents should be supported in their wish to breastfeed their child. Peer counselling, as given by the volunteer breastfeeding organisations e.g., can play a very important role in that, as mentioned in the Blueprint and also confirmed by research.³⁶ In these contacts, emphasis is on 'empowerment', strengthening the self-confidence of parents. This also helps to increase the carrying capacity of parents.³⁷ When parents feel more powerful, they are better able to achieve positive interaction with their child and avoid negative labelling ("our child is a 'whiner' ", instead of "together, our child and we cannot yet find a comfortable routine").

In the end, parents are responsible for their child and seriously need a socially supportive environment. Rules and regulations from a healthcare institution, when they are formulated as they are in the (draft) guideline 'Dealing with excessive crying in nurslings', contribute little to the self-confidence of the parents and may well constitute a threat for parental autonomy. In general, parents find it very confusing when advice from healthcare providers does not coincide with their intuition and their own wishes. Even when they want to ignore certain pieces of advice, this will cause unnecessary commotion and loss of precious energy.

*"My experience is this. Nine months ago I gave birth to a son. The childbed care was excellent as far as starting off with breastfeeding. Without my childbed nurse I would not have made it (my compliments to the WHO-initiative). But when my son was in his bed, crying, the advice was to first let him cry and if that would not work, pat him on his bottom and comfort him. But what happened when I picked him up? He would quiet down. As a young mother, having delivered her first child, I felt guilty for a long time at moments when I comforted my child in my arms, as I was told he should be in his bed and fall asleep there on his own. Why would you feel so guilty about something that comes so naturally? Today, I no longer believe in sleep training my son and this gives me much peace of mind. When he cries, I prefer him to do that in my arms, but without the breastfeeding websites I would never have found this peace of mind."*³⁸

There is no biological or anthropological substantiation for the idea that infants should be able to function independently as soon as possible. The immature brain is not ready for that in the early post partum period and even after a number of years, learning processes still take place through imitating and contact with adults and other children. Oxytocin, released through bodily contact and positive experiences, contributes to that learning capacity and to the inclination to interact with others. Stress hormones, set free through loneliness, slow down growing and learning processes.

From all this, it may be obvious that especially carrying a child should not be considered a sporadically permitted intervention (Guideline p. 17, 20), but behaviour that is completely normal for the kind of mammal humans are, and can be regarded as very primal.³⁹ The parental carrying capacity, literally as well as figuratively, is, to a great extent, determined by support from the social network. This

support is important, as in principle, the resources of an infant in the first period of life, are zero. Until a child has established secure attachment, he will not be able to deal with little stressors initially or bigger stressors in a later phase. That competency should not be put to the test in the first weeks of life by letting the child cry for half an hour. Adults around the child need to be informed about the fact that a child in this stage is not capable of self-regulation. When parents think their child is unhappy when it cries, they give evidence of a good understanding of how a baby communicates. This deserves praise; parents deserve support while they are learning to deal with these feelings in their child. Then they can look for a solution for the discomfort. Trying to make them unlearn these basic communication signals on the part of the baby, harms the baby's physical and psychological health.

The underlying research and the 'marketing' of the results

The (draft) guideline 'Dealing with excessive crying in nurslings' (2007) is a sequel to the memorandum 'Swaddling' (2001). Part 1 of the Guideline is new and based on research conducted by Van Sleuwen, 'Comparison of behavior modification with and without swaddling as interventions for excessive crying'.⁴⁰

In recruiting participants for the project, the Wessel-definition⁴¹ for excessive crying was used. Excessive crying was defined as "crying that occurs more than three hours per day, at least three days a week, during three preceding weeks". The (only?, main?) criterion for participation was the parental and/or doctor's perception regarding the degree of crying. The researchers decided to use this subjective criterion because it is the parental perception that causes frustration and undesirable reactions towards the baby. The preceding paragraph, 'Patterns of expectations by parents and society', made clear that it is possible that parents may have an incorrect expectation pattern with regard to biologically normal baby behaviour.

The Wessel-definition for excessive crying is more objective and crying is therefore more easily measurable. A substantial part of the research population, in using this definition, would not have been included in the study. The researchers indicate that only 32,3% of children whose parents indicated that their child cried more than three hours per day actually did so. This means that 68% of the children did not cry excessively, but participated in the study nevertheless. Here, it becomes obvious that perception and reality can diverge considerably. It is astonishing that this distinction was not made before the research was conducted.

Another question that arises is: how to explain the difference between the percentage of 'whiners' as defined by the Wessel-definition (2-2 ½%) and the number of parents visiting a well-baby clinic with this problem (22%)? It is not easy to determine whether this vast difference points towards a child related problem or a parent related problem; the interventions, however, are aimed to solve what is being perceived as a child related problem.

With regard to the research design we want to discuss the following. The study is called a "randomized trial", yet from the results, we cannot deduce the answer to the question whether the intervention preference of the parents remained 'blinded' for the researchers. In this context, for the analysis of the results it is worrisome that in week 5, parents were offered the possibility to switch to the other intervention groups when there was a lack of effect in the group in which they had been placed. After that, the results were included in the original intervention group. Randomisation gets lost here, with a bias in results as the consequence.

On page 9, the Guideline mentions the study is a "randomised controlled trial". This term is incorrect, as the design does not provide a control group without intervention.

The population studied was only followed until the age of fourteen weeks. No prospective, longitudinal follow-up research was conducted to see what the long-term effects of the intervention are regarding various physical and psychological aspects of the development of the child and the parent-child relationship. Without such follow-up research, it cannot be stated that the intervention can be safely used without short-term or long-term risks. This puts great responsibility upon the shoulders of institutions that (want to) implement the Guideline.

In reviewing the demographic characteristics, it is indicated that firstborn children were overrepresented in the population (56% versus 45,8% in the total Dutch population). It may well be possible that other factors can explain the crying, such as inexperience on behalf of the parents. Additionally, 16,6% of the mothers smoked during the study period. This is a commonly known risk factor for restlessness in young babies, especially in combination with breastfeeding. It is unfortunate that the researchers did not choose to give more attention to these aspects in the discussion.

The Guideline recommends that the research be extended to premature and 'small-for-gestational-age'-children. However, this seems contrary to the research that demonstrates that kangaroo care significantly reduces crying and promotes growth and development.⁴²

The researchers also failed to discuss that a 'reduction in crying' may have been due to the increased attention towards the parents during the study period.

One of the strengths of the study is described to be that the children, despite an increase in crying on the first intervention day, quickly gave up their protest and seemed to adjust to the new routine. This negates all of Bowlby's research⁴³ which clearly proves that this kind of behavior is not a sign of habituation and adjustment, but of withdrawal due to fatigue and desperation.

The draft Guideline, that is waiting to be approved by the RIVM, includes swaddling in the recommendations, while the research clearly states in the conclusions that "swaddling did not bring any benefit when added to regularity and stimuli reduction in baby care". The researchers conclude that swaddling can be applied as additional intervention, but only has a moderate effect. Although babies in the 1-7 weeks age group showed a greater decrease in crying with than without swaddling (12 minutes difference) and this difference can be called statistically significant (meaning: not coincidental), the difference is not clinically significant (meaning: big, relevant). Apart from that, after a week the difference between both groups was no longer statistically significant either, as the researchers say. It is therefore astonishing that so much attention is paid to swaddling.

There is no evidence for application of the routine that is suggested as intervention and is now presented as prevention. At first, the Guideline was praised as being suitable for the early post partum period in the flyer in which the workshops about regularity, predictability and stimuli reduction were announced. This flyer, which was sponsored by a company producing artificial baby milk, is no longer handed out, but many healthcare providers remember the message. The fact that the Guideline was brought to people's attention all over the country by means of sponsorship from a formula company is a blatant violation of the WHO-Code. BHF-certified institutions risk their certificate when they make room for advertising activities of formula companies.

Although the researchers warn against the tendency of first line healthcare providers to, "through lack of evidence-based interventions" offer several "coping strategies", the RIVM is about to implement a guideline in which swaddling is recommended, even though this intervention cannot be considered useful or beneficial on the basis of research. The Guideline, despite the draft-status, is being introduced throughout the country and child healthcare well-baby clinics give out the information (summarized on two pages, page 4 in the Guideline, appendices 4 and 5) fairly routinely in certain locations, even to parents who have no complaints whatsoever about the crying of their baby.

"I experienced that the Guideline in the region of The Hague is already being discussed with parents. I also read the statement from the psychologists and, of course, I fully agree with them. I get really negative reaction from mothers with regard to the recommendations and I think we should do everything possible to prevent this from really becoming standard advice. It is bad for breastfeeding, but what is worse, very bad for the bonding and attachment between mothers and babies and that in itself is bad for breastfeeding. I hope many reactions will come in and implementation can be prevented. In fact, it already happened, with sponsoring from formula industry, as far as I know. No surprise, as they will benefit from it!"⁴⁴

This combination (no evidence for prevention and implementation nevertheless) is alarming and should, from a scientific perspective, be regarded as invalid. Considering this, we are very concerned that several experts, who occupy themselves with the issue of whether or not to finalize this Guideline for child healthcare, do not seem to show a more critical attitude about this methodology.

The Guideline mentions in the introduction that the research mentioned above has been edited and revised to provide advice for organisations in child healthcare. The draft of the Guideline, however, contains many interventions and assumptions about dealing with crying babies that bear no relev-

ance to the research. Several recommendations in the Guideline are presented as if they were based on the research, yet the cited research did not deal with those issues. For example, there are no data known to us about the (exclusive) breastfeeding rates at the start and at the end of the research project. It is also unclear to what extent the suggested interventions impact duration and exclusivity of lactation. Much of the advice given was not examined by other disciplines in the field of mother and child care and can, based on the first paragraphs of this statement, be regarded as very disputable.

Conclusions

- After carefully studying the contents of the (draft) guideline 'Dealing with excessive crying in nurslings' (2007), and considering the above mentioned research and publications that are relevant to mother-and-childcare, we have come to the following opinion: In many respects, the Guideline is not breastfeeding friendly and on several issues goes against the internationally recognized 'Ten Steps' that constitute the foundation of good breastfeeding policies.
- The Guideline is based on biologically incorrect patterns of expectations where growth and development of human babies are concerned.
- The Guideline suggests that the problem is with the child; this promotes negative image-forming. By using the Guideline, parents do not get insight into how a young baby functions. Focus is put on behavior which is perceived as being problematic, without really looking for the causes of disturbed communication and minimalised interaction.
- The Guideline ignores the importance of responsive interaction for achieving secure attachment between parents and child.
- The recommendation to put the egg timer at 30 minutes in order to let the baby fall asleep by crying it out, potentially endangers the child, as it can lead to insufficient oxygen saturation in the brain .
- The Guideline has a paternalistic tone. The frequently used imperatives are neither stimulating nor encouraging for parents. The concept of 'empowerment' as a base for self-confidence in the parents is entirely missing in the Guideline.
- The Guideline is based on research in which a questionable operational definition of excessive crying is used.
- The Guideline uses results from research that studied an intervention to promote a preventive measure, although there is no evidence to support this. This is an unscientific approach that can have serious consequences for the healthy growth and development of the (breastfed) child.
- The research gives no clarity with regard to the effects of the Guideline for the long term, as far as several physical and psychological aspects of child development and the parent-infant relationship are concerned.
- Swaddling is contra-indicated in the early post partum period. It is therefore reprehensible that the Guideline was praised as being appropriate for childbed care in the flyer in which workshops about regularity, predictability and stimuli reduction were announced.
- The way the Guideline was introduced and 'marketed' (workshops about regularity, predictability, and stimuli reduction were presented to healthcare providers via sponsoring and advertisements from a company producing artificial baby milk), is a blatant violation of the WHO-Code. BHFI-certified institutions risk their certificate when they make room for advertising activities of formula companies.
- The idea of 'anticipating information' gives an unclear message to workers in childbed care and child healthcare, which turns out to be regularly misunderstood in day-to-day practice.

We recommend that the following actions are undertaken:

- The (draft) guideline 'Dealing with excessive crying in nurslings' will not be implemented in public healthcare.
- Compliance with the international criteria of WHO and UNICEF within the framework of BFHI and the Global Strategy for Infant and Young Child Feeding are not being interfered by contradictory guidelines for child healthcare.
- Substantial prospective research will be done regarding child development and secure attachment; research in this field already published will automatically become a more obvious part of common child healthcare-guidelines.
- Information opportunities will be developed that offer clear insight in child development.
- Circumstances in the lives of parents that reduce their resources and carrying capacity in caring for their child get the attention they deserve in the interest of secure attachment, without the baby being labeled as a problem case.

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