Issues and Opinions in Nutrition

Length of Exclusive Breastfeeding: Linking Biology and Scientific Evidence to a Public Health Recommendation

Chessa Lutter

Food and Nutrition Program, Pan American Health Organization, Washington, DC 20037

The recommended length of exclusive breastfeeding (EBF)[1] and hence the age at which complementary foods should be introduced pose as challenges with respect to biology, scientific evidence and public health policy. The current recommendation of the World Health Organization (WHO) is that infants should be fed exclusively on breast milk from birth to 4–6 mo of age and resulted from a joint WHO/UNICEF Meeting on Infant and Young Child Feeding in 1979 (WHO 1979). Since then, this recommendation has been reviewed in two WHO publications (Brown et al. 1998, Lutter 1992). In addition, new scientific evidence is available for both normal and low birth-weight infants (Cohen et al. 1994, Dewey et al. 1999). Based in part on this evidence, UNICEF, the American Academy of Pediatrics (1997), as well as most Ministries of Health in Latin America have changed their recommendation to 6 mo of age or "about 6 mo."

The actual duration of EBF tends to be quite short in most countries, although it is increasing in some countries (Lutter, in press). It has been argued that the 4–6 mo recommendation is too vague and that many women introduce foods at 2–3 mo so that infants will be "eating well" by the fourth month (Konis-Booher et al. 1990). While this may be correct, the implications of the recommended length of EBF for maternal breastfeeding behavior have not been studied. The recommended length of EBF has implications for the Code of Marketing of Breast-milk Substitutes (WHO 1981) as it defines the period during which breast-milk substitutes cannot be promoted (Article 5.1). Thus, a change in the recommendation to 6 mo from 4–6 mo would extend the period when breast-milk substitutes cannot be promoted by 2 mo.[2] Neither the implications for maternal behavior nor the Code is relevant for the recommended length of EBF, which should be based solely on scientific evidence.

The objective of this commentary is to briefly review key issues related to i) the uses of energy balance vs. growth to determine the recommended length of EBF; ii) the merits as well as criticisms of the most recent scientific evidence on its recommended length; and iii) the conceptual and practical issues in using this information to make a public health recommendation.

The biology of EBF as it relates to infant energy intake and growth. Ideally, the biological considerations as to the recommended length of EBF should be based on a number of outcomes. These include infant total dietary intake (energy and micronutrients), physical and cognitive development and risks of both short- and long-term morbidity and mortality as well as on the short- and long-term effects on maternal nutritional status and health.[3] In practice, outcomes are usually limited to infant energy intake and growth, primarily weight and length. It is well established that breast-milk production is related to infant demand (Daly and Hartmann 1995) and is extremely plastic as demonstrated by the numbers of women who successfully breastfeed twins and triplets (Saint et al. 1986). Based on this evidence, it has been argued that it is futile to base the length of EBF on the point where the energy provided by breast milk no longer meets the energy requirements and that infant growth should be used instead (Brown et al. 1998). However, the issues involved in assessing the recommended length of EBF are sufficiently complex that both infant nutrient requirements and growth should be considered, recognizing that both contribute toward a better scientific basis for this recommendation.

Since the 1979 WHO recommendation was developed, there is general scientific consensus that recommended energy intakes should be based on total energy expenditure as assessed by doubly labeled water plus the energy required for growth (Brown et al. 1998). The new estimated energy requirements based on total energy expenditure and total energy deposition (Butte 1996) for breastfed infants are very similar to that provided by breast milk during the first 6 mo of life in affluent populations and very close to that provided by breast milk in disadvantaged populations (Brown et al. 1998). When comparable methods for measuring breast-milk production have been used, that of poorly nourished women is remarkably similar to that of well-nourished women (Brown and Dewey 1992, Prentice et al. 1986).

Breastfed infants have a different growth pattern compared to nonbreastfed infants (Butte et al. 1984, Whitehead and Paul 1984). WHO is currently conducting a multi-country

[1] Abbreviations used: EBF, exclusive breastfeeding; WHO, World Health Organization.

[2] It is unlikely that a public health recommendation for length of EBF would ever extend beyond 6 mo of age as this is the age when most infants can grab things and crawl, and thus are exposed to environmental pathogens, apart from complementary foods, which affects their risk of diarrhea. Delaying the introduction of foods past 6 mo is likely to be in conflict with other cognitive and social developmental needs of the infant.

[3] The assumption that if energy requirements are met by exclusive breastfeeding then the requirements for micronutrients would be met as well should be explicitly tested in research assessing the length of EBF for meeting infant nutrient requirements because other nutrients such as iron and zinc may become limiting before energy.

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growth study to develop new growth charts based on growth patterns of breastfed infants to replace those now widely used that are based on predominantly nonbreastfed infants (Dewey et al. 1995). It has been argued that this study will permit a reassessment of the current WHO recommendation on length of EBF; however, because it is observational, it is not designed to address the effect of the feeding regime vs. other factors related to the mother-infant dyad that affect infant growth. Only research trials that replicate the studies described below in terms of random design will provide data relevant to the recommendation. Given its public health importance, such studies are urgently needed.

New scientific evidence on the recommended length of EBF. As noted in a previous review, "the scientific basis for the current recommendation of 4–6 mo as the length of EBF is not adequately documented. . . ."; however, until further research data become available, "any change in the current recommendation would be premature" (Lutter 1992). Since this review was published, two randomized studies that examined the length of EBF in infants of normal birthweight (Cohen et al. 1994) and in term but low birthweight infants (Dewey et al. 1999) have become available. In these studies, infants who were EBF for 4 mo were randomized into three groups: i) continued EBF on demand; ii) continued breastfeeding on demand with solid food at 4 mo; and iii) continued breastfeeding maintaining preintervention breastfeeding frequency with solid food at 4 mo. All foods were hygienically prepared and nutritionally adequate. The main outcomes were infant energy intake and growth in weight and length. The intervention ended when infants were 6 mo of age.

In normal birthweight infants, the results showed that EBF between 4 and 6 mo resulted in small and statistically nonsignificant increases in length and weight gain. Between 6 and 12 mo when all infants were receiving complementary foods, there were no differences in weight or length gain among the treatment groups. Energy intakes of infants who were exclusively breastfed for 6 mo were lower but not statistically different from those in the other two groups. Infants receiving complementary foods significantly reduced their consumption of breast milk even in the group that was supposed to maintain breastfeeding frequency. Infants in all three groups appeared to satisfy their energy needs as they regularly left breast milk in the breast (Perez-Escamilla et al. 1995).

Among low birthweight infants, at 6 mo of age total energy intake did not differ significantly between the EBF infants and those receiving complementary foods among the subsample of infants for whom these measures were available (Dewey et al. 1999). However, between 16 and 26 wk the change in total energy intake was significantly greater in the complementary food groups compared to the EBF group. With respect to weight and length gain, there were no significant differences between intervention groups in either the total sample or subsample for whom dietary intake data are available between 16 and 26 wk; both weight and length gain were slightly greater in the EBF group. The results did not change when subjects who did not comply with treatment allocation after randomization were included in the analysis, which included five subjects in the EBF group and one in the complementary feeding groups for whom such data were available.

It has been argued that the <10% difference in energy intake among normal weight infants, though statistically nonsignificant because of the small sample size, is of theoretical importance and may be of biological importance with respect to growth (see **Table 1** in Frongillo and Habicht 1997). This argument is not convincing for two reasons: i) infants in all three groups regularly left breast milk in the breast, which suggests that their energy needs were met and ii) there were no statistically differences in growth among the three treatment groups, and small sample size was not a problem as infants exclusively breastfed for 6 mo were at a slight advantage with respect to weight and length, albeit a nonsignificant one.

Another key issue with the study concerns a statistically significant difference in the number of dropouts between treatment groups in the normal birthweight study (Frongillo and Habicht 1997). Ten from the EBF group vs. 13 for the other two groups combined dropped out ($P = 0.052$). In the low birthweight study, there were eight dropouts in the EBF group and only one in the complementary feeding group ($P = 0.02$). Although there was no indication of insufficient milk intake among normal birthweight infants who dropped out in the EBF group, one infant was clearly not growing well between 4 and 5 mo (Frongillo and Habicht 1997). The relative importance of this infant compared to the 50 that completed the study as it affects a public health recommendation is discussed in the next section. Among the low-birthweight infants, dropouts were significantly lower in birthweight, head circumference, Apgar score at 5 min and maternal age (Dewey et al. 1999). None of these variables was significantly associated with weight and length gain from 16 to 26 wk except birthweight, which was negatively correlated with length gain though not weight gain. Thus, if these infants had been included in the analysis the overall mean length gain among EBF infants would probably have been greater than that found among those that finished the study.

Developing a public health recommendation: conceptual and practical issues. Given the importance of the recommendation as it affects infant nutrition and health, it is useful to explicitly outline the issues that are scientific and the evidence that is necessary to address them vs. the issues that relate to judgment and consensus. Although extremely useful for other reasons, the WHO multi-country growth study will not provide new evidence to evaluate the recommended length of EBF. Only a study that replicates the random design of the studies described above will provide this evidence. Such a study should also provide comprehensive measures of energy and micronutrient requirements and intake from breast milk for individual infants and hence provide the scientific information necessary to determine the statistical relationships (i.e., means, standard deviations and overall distribution) for energy requirements and energy intake from breast milk. Such information would also permit the statistical tests to be conducted on the relationship between these two distributions to determine the length of time energy requirements are satisfied by EBF and the variability around this number. There are three possible ways of describing this variability (**Fig. 1**).

i) The recommendation could be made in the form of an age range that encompasses some lower and upper boundary of the distribution. The current WHO recommendation is expressed as a range though not based on the concept of biological variability but rather the need for a transitional period to allow exclusively breastfed infants time to adapt to new foods (Akre 1989). The question of food acceptability was addressed in the Honduras study, where it was found that the introduction of complementary foods at 4 vs. 6 mo of age did not affect food acceptance between 6 and 12 mo of age and that infants needed very little time to adapt to complementary foods (Cohen et al. 1995).

ii) The recommendation could be made conservatively, based on the age at the lower boundary to ensure that those infants who need complementary foods at the younger ages are covered. Setting the recommendation at 2 SD below the mean age would ensure that the needs of virtually all infants are met.

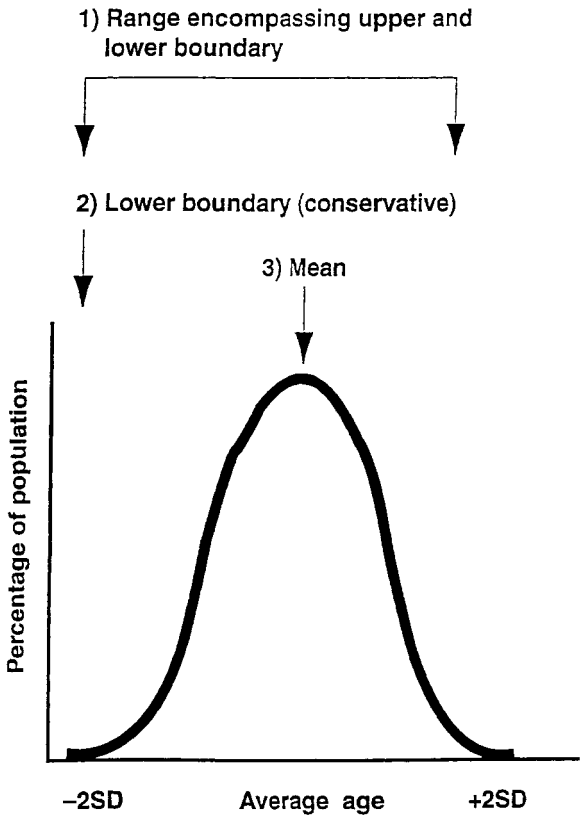

FIGURE 1 Possible ways of describing the length of time exclusive breastfeeding can satisfy infant nutrition requirements and support optimal growth.

However, it also assumes that there are no risks associated with earlier introduction for those infants who do not need complementary foods until a later time. Such a conservatively based recommendation would meet the needs of the one infant who appeared to be growing poorly between 4 and 5 mo out of 50 infants in the EBF group that completed the study.

iii) Justification could also be made for using the mean age at which nutrient requirements are satisfied by nutrients from EBF on the premise that it represents a public health recommendation based on the mean and, therefore, best reflects the balance between the overall risks and benefits of both too early and too late introduction. As recommended by WHO, any recommendation, including a recommendation regarding the length of EBF, should be tailored to individual infants based on clinical evidence.

Once a consensus is reached on how to describe the length of time EBF can satisfy infant energy and micronutrient requirements and growth, an equally important step is to translate this description into a public health recommendation that is easily understood by health professionals, mothers and their families. Because of the implications of this recommendation for the Code, it also needs a clear legal interpretation. To ensure that the public health recommendation is understood, it is critically important to undertake community-based qualitative research among health professionals, mothers and their families in a number of geographic and economic settings to ensure that it is understood as intended prior to widespread dissemination.

The studies described earlier did not have a group that received home-prepared complementary foods between 4 and 6 mo. Such foods are more likely to have been of lower nutritional quality and possibly contaminated compared to the processed foods provided as part of the study (Cohen et al. 1994, Dewey et al. 1999, Frongillo and Habicht 1997). Had such a group been included, it is likely that their growth may have been compromised with respect to those infants EBF. Frongillo and Habicht (1997) suggest that in settings where the risks of infection from nonhygienic complementary foods, a prescriptive recommendation for 6 mo of EBF is likely to be warranted. In such settings the nutritional quality of such foods is also likely to be less than that of breast milk (Brown et al. 1998, Lutter et al. 1992), making this a reasonable suggestion. However, because the recommended length of EBF is important for the interpretation of the Code, a universal recommendation is still needed.

Replication of results is a cornerstone of scientific research and calls for the results to be replicated prior to changing the long-standing WHO recommendation are understandable (Frongillo and Habicht 1997). Ideally, replication should be done in Africa or Asia so that the results can be generalized more broadly outside of Latin America. However, differences in judgment as to the level of evidence needed to some extent are inevitable as illustrated by the fact that a number of Ministers of Health, the American Academy of Pediatrics and UNICEF have changed their recommendation.

As in any biological system, there is inherent variation in the length of time EBF can satisfy infant energy and micronutrient requirements and growth (Brown et al. 1998, Lutter 1992). Therefore, the development of a public health recommendation involves not only scientific evidence but, just as importantly, judgment and consensus about how best to describe the inherent variability in the length of time EBF satisfies the energy, micronutrient and growth needs of infants.

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