



Optimal duration of exclusive breastfeeding: what is the evidence to support current recommendations?¹⁻³

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ABSTRACT

Before 2001, the World Health Organization (WHO) recommended that infants be exclusively breastfed for 4–6 mo with the introduction of complementary foods (any fluid or food other than breast milk) thereafter. In 2001, after a systematic review and expert consultation, this advice was changed, and exclusive breastfeeding is now recommended for the first 6 mo of life. The systematic review commissioned by the WHO compared infant and maternal outcomes for exclusive breastfeeding for 3–4 mo versus 6 mo. That review concluded that infants exclusively breastfed for 6 mo experienced less morbidity from gastrointestinal infection and showed no deficits in growth but that large randomized trials are required to rule out small adverse effects on growth and the development of iron deficiency in susceptible infants. Others have raised concerns that the evidence is insufficient to confidently recommend exclusive breastfeeding for 6 mo for infants in developed countries, that breast milk may not meet the full energy requirements of the average infant at 6 mo of age, and that estimates of the proportion of exclusively breastfed infants at risk of specific nutritional deficiencies are not available. Additionally, virtually no data are available to form evidence-based recommendations for the introduction of solids in formula-fed infants. Given increasing evidence that early nutrition and growth have effects on both short- and longer-term health, it is vital that this issue be investigated in high-quality randomized studies. Meanwhile, the consequences of the WHO recommendation should be monitored in different settings to assess compliance and record and act on adverse events. The policy should then be reviewed in the context of new data to formulate evidence-based recommendations. *Am J Clin Nutr* 2007;85(suppl):635S–8S.

KEY WORDS Infants, breastfeeding, complementary feeding, World Health Organization, public health

INTRODUCTION

In recent years, the focus of infant nutrition research has fundamentally shifted in emphasis because of increasing animal and human evidence that early nutrition in this vulnerable period of life has profound biological effects and important consequences for both short- and long-term health. Scientific research on the effects of early nutrition has largely focused on human milk feeding and experimentally designed milk-based artificial feeds. Surprisingly little research has been done on the introduction of solid foods and whether this period of significant dietary change has biological and health effects in the short term and, more

importantly, influences long-term health and development. New recommendations have been made for practice in this field; this review considers their scientific basis.

DEFINITIONS

The World Health Organization (WHO) describes the complementary feeding period as “The period during which other foods or liquids are provided along with breast milk. . . . Any nutrient-containing foods or liquids other than breast milk given to young children during the period of complementary feeding are defined as complementary foods” (1). Thus, breast milk substitutes including cow milk infant formula and follow-on formula are defined as a complementary food (CF) to emphasize and encourage breastfeeding.

We are in a period of transition in the use of common terms associated with infant feeding practices. Many working in the field of human nutrition are still using the term *weaning*. Because this term can be used in certain societies to indicate the complete cessation of breastfeeding, the WHO recommends that the terms *weaning* and *weaning foods* be avoided, and we endorse this view. The term *weaning* should be replaced by the term *complementary feeding*. Meanwhile, for the sake of clarity in this discussion, *solid food* is used to replace *weaning foods*.

Before 2001, the WHO global recommendation was that infants be exclusively breastfed for between 4 and 6 mo before the introduction of complementary foods (2). On 18 May 2001, the World Health Assembly urged Member States to promote breastfeeding for 6 mo as a global public health recommendation (3). This resolution followed a 2001 report by a WHO Expert Consultation on the optimal duration of exclusive breastfeeding (4).

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Following the 2001 Expert Consultation and the 2002 publication of a WHO-commissioned systematic review (5), the global recommendation was modified and exclusive breastfeeding is now recommended for the first 6 mo of life with the introduction of CF thereafter and continued breastfeeding for the first 2 y (6).

This topic has become one of the most debated areas of infant nutrition in the past few years. The optimal duration of exclusive breastfeeding is often equated with the optimal age for introduction of solid foods. However, because CFs are defined by the WHO as any fluid or food other than breast milk, breast milk substitutes are regarded as CFs, and formula-fed infants are deemed to have received CF from the point at which they receive formula. Current WHO recommendations focusing on the introduction of CF in the context of the optimal duration of exclusive breastfeeding are therefore difficult to apply to formula-fed infants, yet this group constitutes a significant proportion of healthy term infants in many industrialized countries. The debate has become highly politicized.

In this review, we first discuss the available scientific evidence relevant to the question of whether exclusive breastfeeding for ≥ 6 mo results in benefits to mother and infant compared with exclusive breastfeeding for between 4 and 6 mo. We will also discuss available data relating to the situation in formula-fed infants. We will then put this in the context of the politics of infant feeding and the development of public health policy.

THE SCIENCE

Duration of exclusive breastfeeding and infant outcome

Before 2001, the WHO recommended that infants be exclusively breastfed for 4–6 mo before the introduction of CF (2). Limited evidence from a prospective study in Dundee (7) suggested that the introduction of solid foods before 12 wk was associated with increased respiratory symptoms and greater fatness at 7 y of age, and 4 mo had been generally adopted as the earliest recommended age for introducing solid foods in most countries. The longstanding debate over the optimal duration of exclusive breastfeeding has centered on the so called “weaning’s dilemma” in developing countries: “the choice between the known protective effect of exclusive breastfeeding against infectious morbidity and the (theoretical) insufficiency of breast milk alone to satisfy the infant’s energy and micronutrient requirements beyond 4 mo of age.” To assess the issue, a systematic review commissioned by the WHO was undertaken by Kramer and Kakuma (5) and subsequently published (8). The aim of the review was to consider whether mother and infant outcomes differed with exclusive breastfeeding for a minimum of 4 mo compared with 6 mo. The authors identified 20 studies comparing exclusive breastfeeding for 6 mo versus 3–4 mo. Only 2 studies were randomized intervention trials of different exclusive breastfeeding recommendations, both of which were conducted in a developing world setting (Honduras). All the trials from the developed world were observational. The authors made the following statements:

“Neither the trials nor the observational studies suggest that infants . . . exclusively breastfed for 6 months show deficits in weight or length gain, although larger sample sizes would be required to rule out small increases in the risk of undernutrition.”

“The data are scarce with respect to iron status but at least in developing country settings where newborn iron stores may be

suboptimal, suggest that exclusive breastfeeding without iron supplementation through 6 mo may compromise hematologic status.”

“Based primarily on an observational analysis of a large randomized trial in Belarus, infants who continue exclusive breastfeeding for 6 mo or more appear to have a significantly reduced risk of one or more episodes of gastrointestinal infection.” This statement came from findings in a subgroup of infants from the PROBIT study, a randomized trial of a breastfeeding intervention in Belarus, which for the purposes of the review was regarded as a developed country. A total of 3483 term infants were included in the analysis: 621 had been exclusively breastfed for 6 mo, and 2862 had been exclusively breastfed for 3 mo. The relative risk of one or more episodes of gastrointestinal infections during the first 12 mo was 0.61 (95% CI: 0.41, 0.93) for infants exclusively breastfed for 6 mo; exclusive breastfeeding was not significantly associated with a lower risk of atopic eczema, respiratory infections, otitis media, or hospitalization for respiratory or gastrointestinal infections (9).

“No significant reduction in risk of atopic eczema, asthma or other atopic outcomes has been demonstrated.”

“Data from the 2 Honduran (randomised) trials suggest that exclusive breastfeeding through 6 mo is associated with delayed resumption of menses and more rapid postpartum weight loss in the mother.”

The overall conclusions of the review were that there was no objective evidence of a “weaning’s dilemma,” that infants who were exclusively breastfed for 6 mo experience less morbidity from gastrointestinal infection, and that no deficits were shown in growth. The authors went on to state (5) that

“Large randomised trials are recommended in both types of setting to rule out small adverse effects on growth and to confirm the reported health benefits of exclusive breastfeeding for 6 months.”

“Exclusive breastfeeding for 6 mo confers several benefits on the infant and mother. However, it can lead to iron deficiency in susceptible infants. In addition, the available data are insufficient to exclude several other potential risks with exclusive breastfeeding for 6 months, including growth faltering and other micronutrient deficiencies in some infants. In all circumstances, these risks must be weighed against the benefits provided by exclusive breastfeeding, especially the potential reduction in morbidity and mortality.”

A second systematic review of the optimal age of weaning (solid feeding) in the United Kingdom concluded that there was no compelling evidence to support a change in the then WHO recommendation to introduce solid foods into the diet at 4–6 mo of age (10). Subgroups in the infant population (eg, low-birth-weight infants) were identified who might benefit from the introduction of appropriate complementary foods sooner than in the majority of the population. No research was identified that had been specifically undertaken to test the appropriateness of 6 mo of exclusive breastfeeding compared with 4–6 mo in a randomized control trial study design on full-term infants in a developed country setting. It is important to note the subtle, but important, differences in emphasis of the 2 systematic reviews. The WHO review (5) evaluated evidence for the appropriateness of the length of exclusive breastfeeding; the Lanigan review was designed to assess evidence for the appropriateness of the optimal age for introduction of solid foods, regardless of the type of milk feeding. The Lanigan review has been criticized on the basis



that the authors received financial support from industry, although the work was in fact carried out independently.

Since the WHO systematic review, few data have been published that add significantly to the scientific basis for the global recommendation. Burdette et al (11) investigated growth and body composition in 5-y-old children by using dual-energy X-ray absorptiometry (DXA) and found no effect of the duration or exclusivity of breastfeeding on fat or lean mass. Chantry et al (12) compared exclusive breastfeeding for >6 mo with 4 to ≤6 mo in a secondary analysis of data from children aged 6 to ≤24 mo from the third National Health and Nutrition Examination Survey. Infants fully breastfed for 4 to ≤6 mo ($n = 223$) were at greater risk of pneumonia than were those who were fully breastfed for >6 mo ($n = 136$; 6.5% compared with 1.6%). After adjustment for demographic variables, childcare, and smoke exposure, children breastfed for 4 to ≤6 mo had a significantly higher risk of pneumonia (OR: 4.27; 95% CI: 1.27, 14.35) and >3 episodes of otitis media (OR: 1.95; 95% CI: 1.06, 3.59) than did children fully breastfed for 6 mo.

Nutritional adequacy of breast milk

Although some mothers succeed in exclusively breastfeeding their infants until 6 mo of age or beyond, many others report introducing other foods before 6 mo. The reason most frequently given for the “early” introduction of solids is that the mother considers the infant to be hungry and not satisfied by breast milk alone. In many developed countries, exclusive breastfeeding for 6 mo remains relatively uncommon. For example, in the United Kingdom in 2000, only 2% of mothers were exclusively breastfeeding at 6 mo (13); the reported figure in the United States is 18% (14). It is possible that mothers who continue to exclusively breastfeed their infants to at least 6 mo differ from those who do not, either in having a slower growing infant with lower energy requirements, higher breast milk volume production, or higher breast milk energy content.

In a separate WHO review, which was commissioned around the same time as that of Kramer and Kakuma, Butte et al (15) investigated whether exclusive breastfeeding for 6 mo would provide sufficient nutrients to meet the requirements of full-term infants and noted a lack of published data for evaluating the nutrient adequacy of exclusive breastfeeding for the first 4–6 mo. She reported that the iron and zinc endowment at birth meets the needs of the (average, full-term [authors’ emphasis]) breastfed infant in the first half of infancy (0–6 mo). However, once prenatal stores are exhausted, exclusively breastfed infants will become deficient unless an exogenous source is provided. In the same review, breast milk vitamin D concentrations were also considered insufficient to meet requirements. Exclusively breastfed infants exposed to inadequate levels of sunlight or those whose mothers have suboptimal vitamin D status are at risk of deficiency. In their summary, Butte et al stated that the inability to estimate the proportion of exclusively breastfed infants at risk of specific deficiencies is a major drawback in terms of developing appropriate public health policies.

More recently, Reilly et al (16) conducted a systematic review of metabolizable energy consumption and patterns of consumption of exclusively breastfed infants in the developed world. The authors concluded that breast milk metabolizable energy content is probably lower and breast milk transfer slightly higher than usually assumed or quoted in the literature. They also found that longitudinal studies do not support the common assumption that

breast milk transfer increases markedly with age. On the basis of their findings, and consistent with evolutionary considerations, they hypothesized that many mothers do not provide sufficient breast milk to feed a 6-mo-old infant adequately (17). The authors pointed out that this hypothesis is eminently testable in a longitudinal study with the use of stable-isotope techniques to measure energy balance.

Introduction of solid foods in formula-fed infants

Although formula-fed infants receive solid foods earlier than do breastfed infants, few data are available on whether the age at introduction of solid foods in this group of infants influences short- or long-term health outcomes. The reasons for the differences in behavior between breastfeeding and formula-feeding mothers are complex. Some evidence suggests that cultural and economic factors as well as maternal and infant cues are responsible (13, 18). The early introduction of complementary food in term infants has been reported to be associated with low maternal age, formula feeding, and maternal smoking. Kattelman et al (19) performed the only randomized trial of introducing solid foods to formula-fed infants at 4 or 6 mo ($n = 172$) and reported no significant difference in iron or zinc status. Data on other outcomes were not reported. Arguably, formula-fed infants receive higher amounts of dietary iron and zinc than do infants who are breastfed and might not require solid foods until a later age than those who are breastfed.

Overview of scientific evidence

A reasonable interpretation of the available scientific data is that there are currently insufficient grounds to confidently recommend an optimal duration of exclusive breastfeeding of 6 as opposed to 4–6 mo for infants in developed countries. In fact, the data suggest that it is plausible that breast milk may not meet the full requirements for energy and certain micronutrients of the average infant at 6 mo of age. Virtually no data are available to form evidence-based recommendations for the introduction of solids in infants who are receiving predominantly or exclusively infant formula.

SUMMARY: FORMULATING POLICY

Public health policy should ideally be based on scientific evidence. In the case of infant nutrition, this has historically centered on meeting energy and nutrient requirements and on short-term health outcomes, but recent developments have highlighted the need to consider effects on longer-term health. Based on available scientific data, a policy of exclusive breastfeeding for 6 mo appears eminently sensible for countries in which clean water and safe, nutritious first solid foods are scarce. Scientific evidence supporting the same policy for the developed world is less persuasive. However, the WHO recommendation is intentionally a global one, on the basis that what is best for an infant in terms of the duration of breastfeeding should not depend on his or her environment, and concerns that having a different recommendation for the developed world might be seen as undermining breastfeeding. It should be noted, however, that the WHO and other agencies have supported alternatives to breastfeeding in situations such as maternal HIV infection and other scenarios when breastfeeding is not safe or feasible.

This topic was recently reviewed by Foote and Marriott (20), who concluded that the evidence that introducing solids before 6



mo causes harm is weak for infants in developed countries and that infants should be managed according to their individual needs. This view is widely held among health professionals having regular contact with mothers and infants, especially given the fact that it is not consistent with current maternal behavior and choice in many countries. The authors highlighted, for example, the lack of specific recommendations for the introduction of CFs in preterm infants, who have their own specific nutrient requirements that are unlikely to be met by a recommendation designed for healthy full-term infants. Similarly, the data suggest that both early (<3 mo) and late (>6 mo) introduction of gluten-containing cereal may increase the risk of celiac disease or wheat allergy in at-risk infants (21, 22).

Given the increasing evidence that early nutrition and growth can have effects not only in the short term, but also on longer-term health, we believe it is vital that this issue be investigated in high-quality randomized studies, as recommended by Kramer and Kakuma in their systematic review. At the very least, the consequences of the WHO recommendation should be monitored in different settings to assess compliance and to record and act on adverse events. The policy should then be reviewed in the context of new data to formulate evidence-based recommendations.

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