INFORMATION NOTE

Clarification on the classification of follow-up formulas for children 6-36 months as breastmilk substitutes

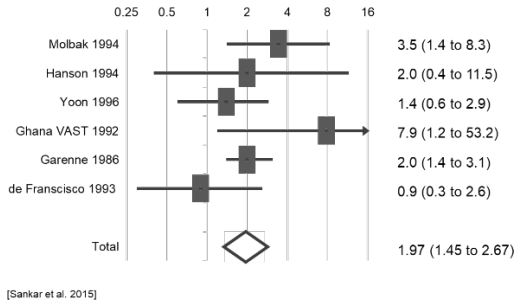
The International Code of Marketing of Breast-milk Substitutes[1] was adopted by the World Health Assembly to protect and promote breastfeeding by ensuring the appropriate marketing and distribution of breast-milk substitutes. The Code did not specify an age range for products that should be considered breast-milk substitutes, but it did indicate that infant formula was only one type of breast-milk substitute. In 2016, the WHO published guidance[2] to clarify that breast-milk substitutes "should be understood to include any milks (or products that could be used to replace milk, such as fortified soy milk), in either liquid or powdered form, that are specifically marketed for feeding infants and young children up to the age of 3 years (including follow-up formula and growing-up milks)." This Information Note describes the rationale for this interpretation.

Breastfeeding for at least two years improves child survival and the health of mothers and babies

The aim of the International Code is to protect breastfeeding from the influences of inappropriate marketing of breast-milk substitutes. WHO and UNICEF recommend breastfeeding be continued for up to two years or beyond[3]. There are a number of reasons breastfeeding in the second year of life is important:

Reduced mortality. Continued breastfeeding in the second year of life protects against mortality. In a 2015 meta-analysis[4], Sankar et al. identified six studies that examined the mortality effect of breastfeeding vs. not breastfeeding at 12-23 months of age (Figure 1). The pooled relative risk was 1.97 (1.45-2.67) times higher mortality in the non-breastfed children (total n=17,761). This means that children who are not breastfed at 12-23 months of age are about twice as likely to die as those who are breastfed in the second year of life.

Figure 1. Relative risk of all-cause child mortality for breastfeeding vs. not breastfeeding at 12-23 months of age



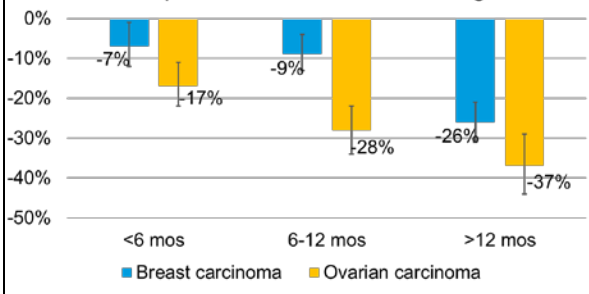
Improved nutrition. Breastmilk makes important and unique contributions to the dietary intake of young children in the

second year of life. In low- and middle-income countries, the average breastmilk intake at 12-23 months has been estimated to be 550 g/day, contributing approximately 35-40% of the young child's energy needs.[5] Breastmilk is a key source of essential fatty acids. It provides 70% of vitamin A requirements, 40% of calcium and 37% of riboflavin at 15-18 months of age.[6] During illness, breastmilk intake is maintained even when appetite for other foods decreases.[7,8] Clinical studies have confirmed that continued feeding during infections reduces the duration of illness and improves nutritional status.[9,10]

Protection against childhood overweight. The protection of breastfeeding against childhood overweight is strongest for those breastfed for more than one year. In a large study among low-income children in the United States, those breastfed for at least 12 months were 28% less likely to be overweight at four years of age than those never breastfed (AOR 0.72, CI: 0.65-0.80).[11] In a meta-analysis of 17 studies conducted in seven countries,[12] Harder et al. found that each additional month of breastfeeding reduced the risk of childhood obesity by 4%.

Improved maternal health. Mothers who breastfeed benefit from longer durations of breastfeeding. Continued breastfeeding delays the return to fertility, contributing to longer birth intervals in the absence of contraceptive use. Breastfeeding for more than 12 months reduces breast cancer by 26%, based on a meta-analysis of 50 published studies (Figure 2).[13] In the same paper, the reduction in ovarian cancer for breastfeeding longer than 12 months was 37%, based on 29 studies. Each additional year of lifetime duration of breastfeeding was associated with a 9% protection against type 2 diabetes (RR 0.91, 95% CI: 0.86–0.96).[14]

Figure 2. Percent reduction in risk of breast and ovarian cancer, by duration of breastfeeding compared to never breastfeeding



[Chowdhury et al. 2015]

Breastfeeding is frequently continued for at least two years in low- and middle-income countries

Breastfeeding through the second year of life is common practice in many countries. A majority of children (>50%) continue breastfeeding for at least two years in 41 out of the 130 countries with data in the UNICEF IYCF database.[15] It is important to protect continued breastfeeding from the competitive marketing pressure of milk products targeted at this age range.

Research shows that artificial milk feedings replace the intake of breast milk rather than add to it

Distinguishing between a breastmilk substitute and a complementary food hinges on whether the food directly reduces breastmilk consumption or adds to it. Complementary foods are consumed in addition to breastmilk when breastmilk becomes insufficient to meet nutritional requirements. Breast-milk substitutes, on the other hand, replace the intake of

breastmilk in young children. In 2013, WHO published a statement on the use and marketing of follow-up formula,[16] stating "where follow-up formula is otherwise represented in a manner which results in such product being perceived or used as a partial or total replacement for breast milk, such product also falls within the scope of the Code." The 2016 Guidance is consistent with this statement, but goes further to clarify that, in actual practice, follow-up formula is used as a partial or total replacement for breast milk. When follow-up formula is introduced, breastfeeding mothers either reduce the number of breastmilk feedings a day or stop breastfeeding altogether[17]. Thus, milks targeted specifically to young children less than 3 years of age replace the intake of breastmilk and are *de facto* substituting for breastmilk.

Classification of milks as breast-milk substitutes depends on their function, not their composition

Whether a food is a breast-milk substitute is not dependent on whether that food is suitable as a breast-milk substitute. The International Code of Marketing of Breast-milk Substitutes was explicit on this point in defining breastmilk substitutes (Article 3): "Breast-milk substitute means any food being marketed or otherwise presented as a partial or total replacement for breast milk, whether or not suitable for that purpose."[1] As a result, the different compositional requirements of follow up formulas for children 6-36 months from that of infant formula would not prevent them from being considered breastmilk substitutes.

Global recommendations on breastfeeding apply equally to infants and young children

The PAHO/WHO Guiding Principles on Complementary Feeding of the Breastfed Child apply to all children under 24 months of age[18]. WHO/UNICEF recommendations make no distinctions on breastfeeding before or after 12 months of age. Furthermore, the Code of Marketing of Breastmilk Substitutes does not have a separate provision for children older than 12 months of age. Therefore, milk products intended for children 12-36 months of age would naturally be classified in the same way as infant formula or follow-up formula for infants 6-12 months of age, intended for younger children.

In summary, the International Code aims to safeguard breastfeeding by ending inappropriate marketing and distribution of breast-milk substitutes. Because continued breastfeeding to two years and beyond saves lives and promotes the health of both the mother and baby, it is important that this protection include follow-up formula. Follow-up formula has been shown to replace the intake of breast milk and therefore acts as a breast-milk substitute. Classification of follow-up formulas for children 6-36 months as breastmilk substitutes is fully consistent with the Code and other WHO policies and recommendations.

References:

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