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POSITION STATEMENT

Nutrition

World Health Organization (WHO) guideline on the complementary feeding of infants and young children aged 6–23 months 2023: A multisociety response

European Society for Paediatric Gastroenterology, Hepatology & Nutrition (ESPGHAN) | European Academy of Paediatrics (EAP) | European Society for Paediatric Research (ESPR) | European Academy for Allergy and Clinical Immunology (EAACI) | Federation of International Societies for Paediatric Gastroenterology, Hepatology & Nutrition (FISPGHAN) | Latin American Society for Pediatric Gastroenterology, Hepatology & Nutrition (LASPGHAN) | Pan Arab Society for Pediatric Gastroenterology and Nutrition (PASPGHAN) | Asian Pan-Pacific Society for Pediatric Gastroenterology, Hepatology and Nutrition (AAPSGHAN) | North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) | World Allergy Organization (WAO) | Asia Pacific Academy of Pediatric Allergy, Respirology & Immunology (APAPARI)

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Abstract

The recent World Health Organization (WHO) guideline aims to provide evidence-based recommendations on complementary feeding (CF) of healthy term infants and young children 6–23 months living in low-, middle-, and high-income countries, including both breastfed and non-breastfed children. Like WHO, our organizations aim to promote optimal infant and young child nutrition and health, with a focus on promoting breastfeeding as well as appropriate and timely CF. In this paper, we share our concerns about aspects of the guideline, some of which may have the potential to cause unintended harm in infants and young children and suggest alternative or modified proposals.

KEYWORDS

animal milk, breastfeeding, complementary foods, food allergy, recommendation

Abbreviations: AAPSGHAN, Asian Pan-Pacific Society for Pediatric Gastroenterology, Hepatology and Nutrition ; APAPARI, Asia Pacific Academy of Pediatric Allergy, Respirology & Immunology; EAACI, European Academy for Allergy and Clinical Immunology; EAP, European Academy of Paediatrics; ESPGHAN, European Society for Paediatric Gastroenterology, Hepatology & Nutrition; ESPR, European Society for Paediatric Research; FISPGHAN, Federation of International Societies for Paediatric Gastroenterology, Hepatology & Nutrition; LASPGHAN, Latin American Society for Pediatric Gastroenterology, Hepatology & Nutrition; NASPGHAN, North American Society for Pediatric Gastroenterology, Hepatology and Nutrition; PASPGHAN, Pan Arab Society for Pediatric Gastroenterology and Nutrition; WAO, World Allergy Organization; WHO, World Health Organization.

Contributors: A list of individual contributors from each Society, along with declaration of interest statements are provided in the Supporting Information: Appendix.

1 | INTRODUCTION

The new World Health Organization (WHO) guideline[1] aims to provide evidence-based recommendations on complementary feeding (CF) of healthy term infants and young children 6–23 months living in low-, middle-, and high-income countries, including both breastfed and non-breastfed children. We acknowledge and appreciate the comprehensive work of the Guideline Development Group (GDG) and WHO colleagues in developing the guideline, which is likely to have a wide-reaching impact on policy and practice and to influence the feeding and nutrition of every infant and child on the planet. Like WHO, our organizations aim to promote optimal infant and young child nutrition and health, with a focus on promoting breastfeeding as well as appropriate and timely CF. We agree with the recommendations made by WHO on dietary diversity, unhealthy foods and beverages, nutrient supplements, fortified food products, and responsive feeding. We also welcome the decision to define complementary foods as foods other than milk, whether breast milk or formula milk. However, we would like to share our concerns about other aspects of the guideline, some of which may have the potential to cause unintended harm in infants and young children and to suggest alternative or modified proposals.

We also have some concerns and questions about the process used to develop the guideline. Given that the guideline is intended to apply to all (healthy term) infants globally, we find it surprising that there was apparently no wider stakeholder involvement nor an open consultation process. This would be considered an essential part of good practice by most public bodies. The lack of stakeholder involvement and consultation meant that the opportunity for wider input was missed. Indeed, many of the comments we now raise could have been addressed during such a process, and some factual inaccuracies would most likely have been spotted.

One of the recognized difficulties in developing guidelines for infant feeding is that what is optimal, feasible, or acceptable practice may differ depending on factors that are specific to the infant and its environment. Thus, whilst broad principles can be identified, these need to be adapted according to the context. Our concerns about the new guideline mostly arise from the attempt to provide global public health recommendations when there are clear differing environments and health needs. For example, whilst the guideline has the stated aim to include infants and children living in high-income countries, it does not in effect do this as there is no consideration of the potential for excess intake of certain nutrients (e.g., protein) which are considered important contributors to unhealthy growth trajectories and risk of overweight or obesity; or the early introduction of common food allergens aimed at reducing the health burden for countries with a high prevalence of food allergy. CF also poses a particular challenge in settings experiencing double-burden malnutrition (DBM); indeed, it is recognized by WHO as a "double-duty action" in addressing DBM,[2] so we would have expected this topic to be mentioned in the guideline.

2 | RECOMMENDATION ON CONTINUED BREASTFEEDING IN THE SECOND YEAR OF LIFE

> "Breastfeeding should continue up to 2 years or beyond (strong, very low certainty evidence)."[1]

Despite the theoretical benefits of breastfeeding during the second year, the systematic review of the literature conducted to inform this WHO recommendation[3] found evidence of worse outcomes when compared to no breastfeeding during the second year. Although the evidence was considered to be very low certainty, "continued breastfeeding" was associated with higher odds for underweight (OR: 1.25 [95% CI: 1.08–1.46]) and wasting (OR: 2.16 [1.18–3.98]), slightly lower BMI in childhood/adolescence (mean difference: −0.10 [−0.17 to −0.03]) and higher odds for dental caries (OR: 1.52 [1.24–1.88]), with no effect on stunting or infectious morbidity in infants. Yet despite the (albeit low certainty) evidence suggesting poorer outcomes associated with continued breastfeeding, the GDG made a strong recommendation for continued breastfeeding in the second year. This is apparently based on mainly subjective opinion and theory.

Evidence from the systematic review[3] is also wrongly cited in the guideline to state, "two studies found a reduced risk with continued breastfeeding in the second year of life compared to no breastfeeding on acute gastroenteritis (MD: −2.23 [−2.55 to −1.91]." Only one study reported on this outcome, and it was rated as being at serious risk of bias for confounding, departure of intended exposure, and missing data. The authors of the systematic review themselves concluded that "there was no significant association of continued breastfeeding into the second year with childhood morbidity (infectious and noninfectious)."

While continued breastfeeding in the second year can represent the best option to protect child health under some circumstances and should be promoted under such conditions, we disagree with the GDG's strong global recommendation for continued breastfeeding in the second year. In the absence of strong evidence, we would suggest that this decision should be left to the mother and infant. Continued breastfeeding during the second year of life could be a desirable

goal for some families and children, depending on individual factors, personal choice, and environment.

3 | RECOMMENDATION ON THE USE OF ANIMAL MILK IN INFANTS AFTER 6 MONTHS OF AGE

> "For infants 6–11 months of age who are fed milk other than breast milk, either milk formula or animal milk can be fed (conditional, low certainty evidence).[1]
> For young children 12–23 months of age who are fed milk other than breast milk, animal milk should be fed. Follow-up formulas are not recommended (conditional, low certainty evidence).[1]"

This recommendation included evidence from two systematic reviews, assessing outcomes in infants fed either animal milk or formula milk; one covering infants aged 6–12 months[4] and the other young children aged 12–23 months.[5] Although the evidence was considered to be low certainty, both reviews essentially found nutritional benefits for other milk (formula milk) over animal milk. Thus, from 6 to 12 months, infants who received cows' milk had an increased risk of anemia, increased gastrointestinal blood loss, increased risk of IDA, and lower Hb with no significant effects on growth. For infants 12–23 months, receiving at least 250 mL per day of formula or fortified milk during 4–5 months had positive effects for anemia and Hb and improved vitamin D, serum iron and zinc, with no effects on growth.

Although the evidence suggested some benefits of formula or fortified milk over animal milk, after using the Developing and Evaluating Communication Strategies to Support Informed Decisions and Practice Based on Evidence (DECIDE) framework, the GDG made a conditional recommendation that infants older than 6 months who are fed milk other than breast milk should receive animal milk or formula, whereas young children >12 months should receive animal milk (Infants below 6 months should receive breast milk or a breast milk substitute [infant formula]). The main justification for this decision seems to be the lack of resources for using formula milk in lower-income settings. This may be valid in those settings where continued breastfeeding is undoubtedly the optimal practice alongside CF. However, because there is a single recommendation with no mention of context it also seems to be prioritizing the nutritionally "second best" option—that is, animal milk—over formula in all settings. The authors state that there are other options for providing iron. Whilst true, this is recognized to be challenging in practice, especially in settings where access to meat or animal-source foods is limited by cost, availability, or cultural factors. As a result, poor iron status remains a serious global concern.[6]

The guideline fails to consider the risk of excess protein intake (combined with poor iron intake) from cows' milk in higher income settings or settings with DBM where overweight and obesity and associated diet-related noncommunicable diseases are significant public health issues. There is increasing evidence linking high protein intakes during infancy, especially from dairy foods, with excess weight gain and increased risk of overweight and obesity, including data from a randomized trial comparing infant formulas with different protein contents.[7,8] The GDG only reviewed evidence from studies that compared groups fed animal milk versus formula milk and therefore did not consider evidence from cohort studies (e.g., from the UK,[9] Iceland[10,11]), which shows associations between the amount of cows' milk consumed and both iron deficiency and higher weight gain/adiposity measures in childhood. Furthermore, infants who participated in the included studies were largely born in the 1980s and 1990s and likely had lower exposure to an obesogenic food environment than contemporary infants and young children. In populations where overweight and obesity are prevalent, a recommendation to use cows' milk must consider these potential risks as has already been done by authorities in many countries which recommend that cows' milk is not used as the main drink before 12 months and that it should be limited in quantity to around 500 mL per day after 12 months to ensure a balanced and diverse diet.

The lack of consideration of the potential risks from excess intake of certain nutrients was compounded by the use of Optifood linear programming, which focuses on optimizing diet to avoid inadequate nutrient intakes. Optifood is not intended to identify excessive intakes of nutrients that could increase the risk of later obesity and related diseases. We also note that the Optifood modeling in the Guideline did not include the very common scenario (for high-income countries) of infants who receive infant formulas alongside CFs and, therefore, was unable to inform on the nutritional superiority of either animal milk or formula milk.

In the section discussing this recommendation, the GDG states that "these milks" (referring to follow-on formula but also, by implication, young child formulas since they reference the ESPGHAN position paper on that topic)[12] "*are considered unnecessary by WHO and many paediatric societies*." Here, they reference the ESPGHAN position paper on CF,[13] which makes no statement about these milks. We presume that the GDG may have intended to cite the ESPGHAN position paper on young child formulas[12]—but that paper does not say these milk are unnecessary; it concludes that "based on the evidence, there is no necessity for routine use of Young Child Formulas in those aged 1–3 years but they can be used as part of a strategy to

increase the intake of iron, vitamin D, and n-3 PUFA whilst decreasing the intake of protein compared with unfortified cows' milk'. The paper continues "follow-on formula could be used for the same purpose" and that "other strategies for optimizing nutritional intake include promotion of a healthy varied diet, use of fortified foods and use of supplements."

Thus, in summary, and based on the evidence, we consider that the recommendation to use animal milk in infants and young children, especially those aged 6–12 months, could unintentionally contribute to an increase in the risk of overweight and obesity, including DBM. To avoid this, we propose that recommendations on the use of animal milk in infants >6 months should be context-specific.

In infants aged 6–12 months:

- Breastfeeding should ideally be continued alongside complementary foods.
- If breast milk is not available
  - In settings where infant formulas are available, affordable, and can be safely prepared, they should be used alongside complementary foods to reduce the risk of nutrient deficiencies (providing a nutrient profile more adapted to human infants than unmodified milk from other mammals). To further reduce later obesity risk, the protein content should be limited as recommended by the European Food Safety Authority. In these settings, high protein intake from cows' milk used as the main drink poses a higher risk of excess weight gain than infant formula and could potentially contribute to increasing the risk of double-burden malnutrition in some settings.
  - In settings where infant formulas are not available, affordable or cannot be safely prepared, full-fat animal milk should be used. In these settings, especially where undernutrition is the greater concern, animal milk, which generally has high protein content compared to formula milk, may be beneficial, but it is important not to give excessive amounts of animal milk, which can displace iron and increase gastrointestinal blood loss, and to also provide good sources of iron.

After 12 months:

- Breastfeeding should be continued as part of a healthy diet if mutually desired by mother and child.
- In general, animal milk is safe and can be used alongside other strategies for optimizing nutritional intake, including the promotion of a healthy varied diet, the use of fortified foods, and the use of supplements.
- There is no necessity for the use of Young Child Formulas or fortified milk in children aged 1–3 years. However, they can be used as part of a strategy to increase the intake of iron, vitamin D, and n-3 PUFA whilst decreasing the intake of protein compared with unfortified cows' milk in settings where they are available and affordable and where overweight/obesity is a concern. A follow-on formula could be used for the same purpose.

4 | RECOMMENDATION ON THE AGE AT INTRODUCTION OF CF

> "Infants should be introduced to complementary foods at 6 months (180 days) while continuing to breastfeed (strong, low certainty evidence).[1]"

This recommendation considered nutritional aspects of CF and the impact for some health outcomes but omitted other factors highly relevant in determining the optimal age for introducing complementary foods, notably developmental readiness and the introduction of allergenic foods. The one comment on developmental readiness in the document is not based on evidence: "With respect to developmental readiness to begin consuming foods, the ability to sit without support is considered an important factor as it is associated with other aspects of physiological development, including gastrointestinal, renal and immunological system maturation." The ability to sit without support is certainly important for the infant to consume finger foods, but not for consuming pureed or mashed foods. We are unaware of any demonstrable link between the maturity of the gut or kidneys (which evidence would suggest can handle nonliquid foods from very early in the postnatal period) and an infant's neurodevelopmental readiness.[14]

The guideline does not address the appropriate age for the introduction of allergenic foods. The burden of childhood allergic disease has markedly increased during past decades, reaching 10% in some HICs,[15] and currently it is also rapidly increasing in many LMICs.[16,17] High-quality evidence from several randomized clinical trials demonstrates that earlier introduction of allergenic complementary foods before the age of 6 months, along with continued breastfeeding, can markedly reduce the risk of food allergies.[18–21] A recent European evidence-based guideline on allergy prevention concluded that the most effective time window for introducing peanuts with CF for risk reduction of allergy is 4–6 months of age.[20] Of importance, randomized clinical trial evidence shows that the introduction of CF at about 4–6 months did not reduce the rate and duration of subsequent breastfeeding, as compared to later introduction.[19,22] We note the WHO Geneva has also acknowledged "that some

infants may benefit from earlier introduction of complementary foods" [earlier than the age of 6 months],[1] but unfortunately, further qualification is missing on which specific benefits are to be considered in which infant populations.

We suggest the following recommendations regarding the age at introducing complementary foods:

- Exclusive or full breastfeeding should be promoted for at least 4 months (17 weeks, beginning of the fifth month of life), and exclusive or predominant breastfeeding for approximately 6 months is considered a desirable goal.
- In populations affected by food allergy, complementary foods with high allergenic potential (e.g., well-cooked egg or peanut) may be introduced in an age-appropriate form when CF is commenced any time from 4 months (17 weeks).

5 | OTHER COMMENTS ABOUT THE GUIDELINE DEVELOPMENT PROCESS

In addition to previously mentioned issues about the lack of stakeholder engagement and public consultation, we have some other questions. The process used to obtain consensus by the GDG is not clearly described; for example, it is not clear how many of the GDG agreed with each recommendation or with each of the words used to describe an opinion in the summary tables. There are also some contradictory statements on this: "70% of members needed to vote for the directions and/or strength of the recommendation to be accepted," but then "All decisions were made by consensus with the exception for recommendations on nutrient supplements and fortified food products which were agreed by over 70% of members."

As noted above, the decision to base the systematic reviews on studies comparing groups of infants and children with different exposures and not to consider data on the potential risks of excess protein intake led to the exclusion of potentially relevant literature. This is unfortunate in a field where the evidence was considered to be generally of low or very low quality. We also note that the systematic reviews considered evidence up to the end of 2020 or early 2021 and question why these were not updated before publication.

We find that the strength of recommendations often seems contrary to the (albeit limited quality) evidence (e.g., for continued breastfeeding, use of animal milk; see above). We understand that the process of developing the recommendations and determining their strength relied on the DECIDE framework, but in the end, this gives the appearance of subjectivity, as in most cases, there was no empirical data on the additional factors included in the framework, or they were considered likely by members of the GDG to differ depending on context. In future, the new recommendations are very likely to be cited and used in isolation without mentioning the strength of the recommendation or the level of certainty of the evidence, and this could potentially be misleading.

6 | CONCLUSION

We welcome the updated WHO guideline on CF and support several of the recommendations. However, we question some aspects of the recommendations on continued breastfeeding in the second year, use of animal milk and age at the introduction of CF. We suggest that these recommendations should be context-specific, as outlined above, and follow the approach already used by the GDG in its recommendation on the use of fortified foods. Without such modification, the recommendations have the potential to cause confusion and potential unintended harm. Wider stakeholder involvement and public consultation might prevent such misunderstanding, and we call for all future guidance on infant feeding to follow good scientific practice.

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CONFLICT OF INTEREST STATEMENT

Declarations for individual contributors from each Society is provided in the supporting information.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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