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Commentary

ESPGHAN's 2008 recommendation for early introduction of complementary foods: how good is the evidence?

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Abstract

Since 2002, the World Health Organization and many governments and professional associations have recommended exclusive breastfeeding for 6 months followed by complementary feeding (giving solid foods alongside breast milk) as optimal infant feeding practice. Several articles have been published challenging this recommendation. Arguably, the most influential has been the 2008 commentary of the European Society for Pediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) Committee on Nutrition, which recommended that complementary foods should be introduced to all infants between 17 and 26 weeks. We challenge the validity of ESPGHAN's position, questioning the adequacy of the literature search, the interpretation and evidence used to reach their conclusions and the balance of an approach that focuses on disease prevention, with scant consideration of growth and neuromotor development. We contend that ESPGHAN's position should be understood as an expert opinion that may be influenced by conflicts of interest. In our view, the ESPGHAN position paper is not evidence based and does not justify a change of the current public health recommendation for 6 months of exclusive breastfeeding. At an individual level, health professionals should understand that developmental readiness for starting solid foods has an age range like other developmental milestones; that fewer infants will probably be ready to start complementary feeding before, rather than after, 6 months; and that their role is to equip parents with the confidence and skills to recognise the signs of developmental readiness. This empowerment process for infants and parents should be preferred over the prescriptive ESPGHAN approach.

Keywords: exclusive breastfeeding, complementary feeding, WHO, public health, policy, evidence-based practice.

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Introduction

A review recently published by the British Medical Journal (BMJ) has once again stirred up a heated discussion on the timing of introduction of complementary foods in exclusively breastfed infants (Fewtrell *et al.* 2011). In 2002, after years of debate, the World Health Organization (WHO) recommended

that 'as a global public health recommendation, infants should be exclusively breastfed for the first six months of life to achieve optimal growth, development and health' (WHO 2002). Much of the world has moved in the same direction since then. In 2003, the UK Department of Health adopted a similar policy (Department of Health 2003) preceded and followed by the governments of most countries in the

European Union (EU) (Cattaneo *et al.* 2010). In 2005, the American Academy of Pediatrics (AAP) stated that 'exclusive breastfeeding is sufficient to support optimal growth and development for approximately the first 6 months of life' (American Academy of Pediatrics Section on Breastfeeding 2005). In Europe, the AAP statement had been anticipated by the recommendations of the Italian Society of Neonatology (Società Italiana di Neonatologia 2002), and was followed by those of many other professional societies, e.g. the Dutch and the Spanish Paediatric Associations (Subcommissie Borstvoeding 2004; Asociación Española de Pediatría 2005).

Were these recommendations followed by a higher prevalence of exclusive breastfeeding in the first 6 months of life or a later introduction of solid foods? In the United States, between 2003 and 2006, the rates of exclusive breastfeeding through 3 and 6 months went up from 29.6% to 33.6% and from 10.3% to 14.1%, respectively (National Center for Chronic Disease Prevention and Health Promotion 2010). In Europe, exclusive breastfeeding at 6 months falls short of what is recommended, but the rates increased between 2002 and 2007 (Cattaneo *et al.* 2010). The lowest values, between 1% and 5%, are reported by Finland, United Kingdom and Italy, the highest, between 25% and 35%, by Denmark, Sweden and Hungary. Increases are reported, for example, by the Netherlands (17–23%), Latvia (24–34%) and the Slovak Republic (30–42%). In the United Kingdom, a comparison of nationally representative survey data gathered in 2000 and 2005, with a change of policy in between (Department of Health 2003), showed that there was a shift towards later introduction of solid

foods. The proportion of mothers introducing solid foods at 4 months fell from 85% (about a third of these before 17 weeks) to 51%, while the proportion introducing solid foods at 3 months more than halved, from 23% to 10%, even though the overall rate of exclusive breastfeeding at 6 months did not change (Scientific Advisory Committee on Nutrition 2008).

Despite the almost universal adoption of the WHO recommendation, a series of papers and documents that challenge the 6-month policy have been and continue to be published (Prescott 2008; Prescott *et al.* 2008; EFSA Panel on Dietetic Products Nutrition and Allergies 2009; More *et al.* 2010), the latest being the BMJ review (Fewtrell *et al.* 2011). The arguments used in all these papers are similar and can be seen in the most influential among them, the commentary on complementary feeding published in 2008 by the European Society for Pediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) Committee on Nutrition (CoN) (Agostoni *et al.* 2008). ESPGHAN recommends that 'complementary feeding should not be introduced to any infant before 17 weeks, and all infants should start complementary feeding by 26 weeks'. As far as we know, there was no official reaction to the ESPGHAN commentary from WHO or from other governmental and professional bodies that had endorsed the 6-month policy, except for a document posted in a blog administered by the Spanish Association of Paediatrics (Pallás-Alonso 2009). It was only after the debate stirred up by the BMJ review this year that WHO and the UK Scientific Advisory Committee on Nutrition issued statements to confirm the 6-month recommendation

Key messages

- Since 2002, the World Health Organization, many governments and many professional associations recommend exclusive breastfeeding for 6 months.
- In 2008, the European Society for Pediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) recommended that all infants should start complementary feeding between 17 and 26 weeks of age.
- The ESPGHAN recommendation is based on weak evidence and does not consider infant feeding from a broad social, cultural, health and developmental perspective.
- A change of the current public health recommendation for 6 months of exclusive breastfeeding is not justified; for individual infants, readiness for the introduction of complementary foods has an age range like other developmental milestones.

(Scientific Advisory Committee on Nutrition & Committee on Toxicity 2011; WHO 2011). The objective of this paper is to examine the evidence base of the ESPGHAN recommendation about the optimal timing for introduction of complementary foods.

Strength of the evidence

The ESPGHAN commentary has important flaws in the use and interpretation of available evidence. First, none of the nine ESPGHAN recommendations has a statement on the level of evidence or the strength of the recommendation, as readers familiar with evidence-based guidelines would expect (Atkins *et al.* 2004; Atkins *et al.* 2005). The words used are 'the Committee suggests' or 'the Committee considers', yet the recommendations are categorical: 'Complementary feeding should not be introduced in any infant . . .' Second, the commentary does not describe the methods used to search the literature, what criteria were used to select the articles, how the quality of the studies referred to was rated or how the data used to support conclusions and recommendations were extracted and analysed. In the section on allergy, ESPGHAN dismisses the evidence that delaying or avoiding the introduction of allergenic foods prevents or delays the development of allergy as not persuasive because it is based almost exclusively on observational studies. Yet, all the ESPGHAN conclusions and recommendations are based on observational studies. Finally, the CoN does not discuss the changes and implications of implementing the recommendation, nor does it indicate that some interdisciplinary and intersectoral consultation with various stakeholders took place, as might be expected in the development of evidence-based guidance these days (AGREE Collaboration 2003). Rather, the ESPGHAN recommendation was developed by a select group of paediatric gastroenterologists and has to be considered, along with similar papers (Prescott 2008; Prescott *et al.* 2008; EFSA Panel on Dietetic Products Nutrition and Allergies 2009; More *et al.* 2010; Fewtrell *et al.* 2011), as an 'opinion of experts'. For modern evidence-based medicine, this single discipline expert opinion represents the weakest level of evidence and strength of recommendation.

The evidence itself

The ESPGHAN recommendation on the age of introduction of complementary foods is based mainly on the effects on allergy, celiac disease and type I diabetes mellitus. All the evidence on these effects derives from observational studies. Regarding allergy, the commentary reports briefly and without any detailed analysis the conclusions of five articles from prospective birth cohort studies with a follow-up of 2 to 5 years. Three of these articles looked at all types of foods, split into eight or nine groups (Zutavern *et al.* 2004; Zutavern *et al.* 2006; Filipiak *et al.* 2007). None found an association between the timing of introduction of foods and allergy, except for an increased risk when eggs were introduced at 8 months or later (Zutavern *et al.* 2004). The authors of the three papers conclude that there is no reason to support a delayed introduction of solid foods beyond 6 (Zutavern *et al.* 2004; Zutavern *et al.* 2006) or 4 months (Filipiak *et al.* 2007). Yet, if there is no association between timing of introduction and development of allergy, one may also conclude that there is no reason for solids to be introduced before 6 months. A fourth study looked only at the association between time of introduction of fish and fish allergy (Kull *et al.* 2006). The authors state in their conclusions that regular fish consumption before 1 year is associated with a reduced risk of allergic disease. This conclusion, however, is based on 18 out of 2614 children with specific immunoglobulin E (IgE) antibodies at 4 years who had been introduced to fish at a mean age of 10 months, as opposed to 8.4 months for the non-sensitised children. The fifth study looked at the timing of introduction of cereal grains and its association with the development of wheat allergy (Poole *et al.* 2006). Only 16 out of 1612 children (1%) reported wheat allergy after a follow-up of about 4 years, and only four were IgE positive. The authors report that the risk of wheat allergy increased with exposure after 6 months; however, these children were from groups at risk for diabetes type 1 or celiac disease when they were enrolled at birth. In summary, all these studies are inconclusive and the evidence on the association between age of introduction of solid foods and allergy appears weak.

In relation to celiac disease, the ESPGHAN commentary reports, once again briefly and without any detailed analysis, the conclusions of three articles on the association between the timing of introduction of gluten and the development of celiac disease. The first is a prospective cohort study of 1560 US children, 1307 enrolled at birth and 253 at age 2–3 years, all of them from groups at increased risk of celiac disease, with a mean follow-up of 4.8 years (Norris *et al.* 2005). The outcome the authors looked at, however, was not celiac disease but celiac disease autoimmunity (CDA), i.e. being positive for autoantibody without necessarily suffering from the disease. Overall, 51 children (3.3%) developed CDA; 25 of them (1.6%) also had a positive intestinal biopsy. The authors conclude that in children at increased risk of celiac disease, timing of gluten introduction is associated with a risk of CDA. They prudently warn readers that their results apply only to children at increased risk for celiac disease, that the possibility that earlier exposure to gluten simply leads to earlier appearance of CDA cannot be excluded and that these results should be confirmed by other studies before any interventions are implemented. The other two studies are from Sweden. One is an analysis of data from unconnected national registers of celiac disease cases, breastfeeding rates and the amount of gluten-containing follow-on formula sold by manufacturers as a proxy for intake by children (Ivarsson *et al.* 2000). The data cover a long period of time, 1973–1997, and show a striking rise and fall in the incidence of celiac disease apparently associated with changes in breastfeeding rates and in the amount of gluten-containing formula presumably consumed by children. As the study is not based on individual data, it is difficult to exclude an ecological fallacy or the contribution of other factors to the observed changes in the incidence of celiac disease. The other study compares two age-matched samples of children aged 2.5 to 4.2 years. Of these, 690 were born before, and 679 after, the national recommendation for the introduction of gluten was changed from 6 to 4 months in 1996 (Carlsson *et al.* 2006). The authors report that the prevalence of symptomatic celiac disease declined after the 4-month recommendation was introduced. However, no difference was found in the incidence of undiag-

nosed celiac disease among children born before or after 1996. Also, a careful reading of this study shows that the higher prevalence of celiac disease was found in children who were not being breastfed at the age of gluten introduction. In summary, even the studies on celiac disease are inconclusive as far as timing of introduction of solid foods is concerned, and point to the need for further research.

Growth and neuromotor development

The ESPGHAN CoN states that exclusive or full breastfeeding for about 6 months is a desirable goal, but fails to recognise breastfeeding as the natural and physiological way to feed infants and young children and its strong association with the achievement of normal physical growth and neuromotor development. The recommendation on the timing of introduction of complementary foods is based solely on the prevention of disease, mainly allergy and celiac disease, and of nutrient deficiencies. At the beginning of the commentary, the CoN notes that, 'by around 6 months, most infants can sit without support and can sweep a spoon with their upper lip, rather than merely suck semisolid food off the spoon. By around 8 months, they have developed sufficient tongue flexibility to enable them to chew and swallow more solid lumpier foods in larger portions' (Agostoni *et al.* 2008), followed by a description of the abilities infants develop from 9 to 12 months, and by a discussion on the appropriate window for the introduction of lumpy solid foods. These considerations, however, are disregarded in the rest of the commentary and do not seem to have a bearing on the recommendation about timing.

The WHO Multicentre Growth Reference Study has shown that all stages of motor development have a window of achievement (WHO Multicentre Growth Reference Study Group 2006). If the capacity to consume foods other than breast milk or formula depends on neuromotor development, for example on the appearance at about 6–7 months of the gag reflex that makes the ingestion of solids easier, then there must be a window of normal achievement for this. This window is very likely to coincide with the

period during which the child's immune, digestive and renal systems become mature enough, and breast milk (or infant formula) alone gradually becomes inadequate to sustain adequate growth. However, data on the earliest and latest age of the window of development when this is usually achieved are not available, and will probably never be, because a natural experiment like the one published in 1939 by Clara Davis would not pass ethical approval nowadays (Davis 1939). This does not allow us to act as if it did not exist. Based on the available knowledge about the development of the skills needed to eat complementary foods, as briefly described and discussed in the ESPGHAN commentary and the WHO study, one would expect the ages for developmental readiness to start complementary feeding to be distributed in a sort of asymmetric Bell curve, with a mode at around 6 months and tails that touch the 4-month mark to the left and the 10-month mark to the right. If this is true, some infants would be ready for complementary foods at 5 months, and a tiny minority even at 4 months. Conversely, some infants would become ready for complementary foods at 7, 8 or even 9 months, though in progressively smaller proportions. The developmental readiness for solid foods is unfortunately not taken into account in the ESPGHAN recommendation on timing for complementary foods.

Conflicts of interests

A footnote on the first page of the ESPGHAN commentary states that 'declaration of conflicts of interest of members of the CoN are submitted yearly to the CoN secretary and are available on request' (Agostoni *et al.* 2008). Even in the recent BMJ review, the declaration on conflicts of interests was only available on request from the corresponding author (Fewtrell *et al.* 2011). This is an unusual way of dealing with conflicts of interests. Almost 25 years after the problem was first discussed by the editor of the *New England Journal of Medicine* (Relman 1984), and 7 years after all major medical journals decided to 'routinely require authors to disclose details of their own and the sponsor's role' (Davidoff *et al.* 2001), the disclosure of potential conflicts of interests should be the norm. Making this information available on request is

tantamount to concealing it, because only a tiny minority of meticulous readers will go to the trouble of writing to the CoN secretary or to the authors. Yet, there are plenty of conflicts of interests. The first author of the ESPGHAN commentary, for example, is since 2009 a member of the European Food Safety Authority (EFSA) panel that issued the 4- to 6-month recommendation for complementary foods (EFSA Panel on Dietetic Products Nutrition and Allergies 2009). Not surprisingly, the EFSA recommendation is based on the same arguments used by ESPGHAN. His declaration of interests, dated 17 March 2010, is transparently posted in the EFSA website (<https://doi.efsa.europa.eu/doi/doiweb/doisearch>) and shows that he has worked and written for Ferrero, Danone, Dicoform, Dietetic Metabolic Food, Heinz, Hipp, Humana, Martek, Mead Johnson, Mellin, Milupa, Nestlè, Noos, Ordesa, SHS/Nutricia and for the federation of Infant Food Manufacturers. The third author of the ESPGHAN commentary is the first author of the BMJ review (Fewtrell *et al.* 2011); upon request, she declares that she and two co-authors 'have performed consultancy work and/or received research funding from companies manufacturing infant formulas and baby foods within the past 3 years'. Conflicts of interests are also not disclosed in an article published at almost the same time as the ESPGHAN commentary and using the same arguments to conclude that 'there is a growing case for further revising the recommended age for the introduction of complementary foods to 4 months while breastfeeding is maintained for at least 6 months where possible' (Prescott *et al.* 2008). In another article published in the same year, the first author reveals that she works for Mead Johnson, Nestlè and SHS/Nutricia (Prescott 2008). Finally, the systematic review quoted by the ESPGHAN commentary and by the BMJ review to support the conclusion that 'there was no compelling evidence to support a change in the 1994 UK Department of Health recommendation or the (then current) WHO recommendation (both 4–6 months)' was also supported in part by an educational grant from Nestlè (Lanigan *et al.* 2001). ESPGHAN itself held its meetings at Nestlè headquarters in Switzerland until 2005 (http://www.espghan.med.up.pt/reserved/pdf_files/

agm_minutes_2005.pdf, accessed 28/03/2011) and has its annual congresses sponsored by the infant food industry and by manufacturers of blood test systems for the clinical diagnosis and monitoring of allergy and autoimmune diseases (<http://www.espghan.med.up.pt/>, accessed 18/08/2011). ESPGHAN's own declaration of interests web page has not been updated since 2009 and declares only the conflict of interests of individual members, not the funding sources of ESPGHAN as a group.

Discussion and conclusions

The recommendations of the ESPGHAN commentary and similar papers on the timing of complementary feeding are based on weak evidence and do not justify a change of the current policies for 6 months of exclusive breastfeeding as a public health recommendation. Moreover, any re-evaluation of public health guidance on when and how to start complementary feeding would need to consider infant feeding from a broad perspective, and should take into account wider social, cultural, health, developmental and cognitive outcomes, besides any possible effects on allergy or celiac disease, which were the focus of ESPGHAN as a group of paediatric gastroenterologists. Public health guidance should also consider how recommendations will affect public interpretations and behaviour. As an example, the UK data suggest that more parents would start complementary feeding at, or even before, 4 months, with an overall reduction of the duration of exclusive breastfeeding, if there was any pushing back of the date from 'around 6 months' (Scientific Advisory Committee on Nutrition 2008). This earlier introduction of complementary foods is further encouraged by labels that declare most industrial products 'suitable' from 4 months.

Furthermore, in most European contexts, there is no evidence of disadvantage for starting complementary foods at 6 months, or even later. Concerns about some infants in low-income countries and communities being at risk of low-iron status, if they are exclusively breastfed for 6 months (Kramer & Kakuma 2002), are thus largely irrelevant in Europe, where the majority of women have access to antenatal care and iron supplementation if needed, and preterm or low-

birthweight infants are routinely prescribed iron supplements. Also, iron stores in infancy can be simply improved by delaying cord clamping at birth by about 2 min (Hutton & Hassan 2007). On the other hand, an earlier introduction of complementary foods may bring about significant risks even in high-income countries. It is well known that non-breastfed infants are more likely to suffer from infections, to be hospitalised for severe infections and to have higher neonatal and post-neonatal mortality rates (Bachrach *et al.* 2003; Chen & Rogan 2004; Pardo-Crespo *et al.* 2004; Paricio-Talayero *et al.* 2006; Quigley *et al.* 2007; Duijts *et al.* 2009). It is also known that lack of breastfeeding is associated with higher costs for health services (Ball & Wright 1999; Cattaneo *et al.* 2006; Bartick & Reinhold 2010). Finally, the earlier introduction of solid foods increases the likelihood of premature termination of breastfeeding (Simard *et al.* 2005), which may in turn be associated with a higher risk of obesity later on (Griffiths *et al.* 2009; Chivers *et al.* 2010).

Health professionals should recognise that there is a window of achievement, rather than of opportunity, for the introduction of complementary foods, and that fewer infants will probably be ready to start complementary feeding before, rather than after, 6 months, in terms of neuromotor development. This physiologic window of achievement should be considered a normal developmental milestone, like walking and talking, and health professionals should inform parents of this and help them recognise the three signs that indicate that an infant is ready for complementary foods: (1) staying in a sitting position and holding the head steady; (2) coordinating eyes, hands and mouth to look at the food, pick it up and put it in the mouth; and (3) being able to swallow solid foods; it is rare for these signs to appear together before 6 months. Individual infants achieve these behaviours within a wide age range (Carruth & Skinner 2002). Parents should start offering healthy complementary foods when infants are ready, respecting their physiological development. If the parents misinterpret their infants' signs and infants reject the offered food, it means that they are not ready yet, or that they have not yet 'learned' the taste of the food. Parents will try again later on and will learn by trial and error. It is

well known that infants need to taste foods several times to learn the taste (Birch 1998). It is very unlikely that parents will make mistakes by being excessively prudent, i.e. offering foods too late; their infants will send them very clear signs that they need food. Using key signs of developmental readiness for starting solids foods provides practitioners with an opportunity to further 'responsive parenting', i.e. responding to children's cues, needs and developmental capacities that needs to continue throughout childhood. Such an empowerment process should be preferred to the prescriptive instruction to give solid foods before 26 weeks as recommended by ESPGHAN and others.

The use of readiness for complementary feeding, as opposed to a fixed recommended age or age period, does not conflict with the WHO recommendation for 6 months of exclusive breastfeeding (WHO 2002), because this is 'a global public health recommendation', i.e. a figure to be used for policy guidance and for evaluation and monitoring of population practices, rather than for rigid application to individual infants. The available evidence does not support revising the WHO recommendation, it rather strengthens it.

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Conflicts of interest

- None of the authors has or has had financial relationships with companies manufacturing infant formulae and baby foods.
- AC is employed by IRCCS Burlo Garofolo in Trieste, a maternal and child health hospital of the Italian National Health System, to carry out, among others, research and development activities on infant and young child feeding. He has been in charge of EU-funded projects for the protection, promotion and support of breastfeeding. He is a member of the Italian National Breastfeeding Committee and of IBFAN (International Baby Food Action Network) Italy.

- CW is co-director of international courses on infant feeding at the UCL Institute of Child Health in London and former Director of Baby Milk Action.

- CRPA, MTHA, JLV and LLR are members of the Breastfeeding Committee of the Spanish Paediatric Association, of which MTHA is the coordinator. CRPA, MTHA and JLV are members of the Baby Friendly Hospital Initiative in Spain. LLR is a former member of La Leche League International Health Advisory Council and has participated as co-researcher in research projects at the Department of Nutrition, University of California, Davis.

- ER is a member of the German National Breastfeeding Committee, board member of the Academy of Breastfeeding Medicine and medical adviser of a mother-to-mother breastfeeding support group.

- MP works as a hospital specialist in internal medicine, but is also a lactation consultant, a La Leche League leader and Regional Network Coordinator for Europe of the Academy of Breastfeeding Medicine.

- AV works as a paediatrician with the Italian National Health System and is a trainer in breastfeeding practice.

- AMOM works as a hospital paediatrician and has been a member of the Baby Friendly Hospital Initiative in the Netherlands.

Contributions

AC conceived the paper and wrote the first draft after formal and informal consultation and exchange of opinions with all the other authors. Subsequent drafts were circulated and the feedback from all co-authors, including ideas for more detailed analysis of the ESPGHAN commentary and further references, were used to improve the manuscript up to its final version. AC wrote the final version, which was read and approved by all co-authors. All authors are ready to take public responsibility for the content of the manuscript.

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Additional Supporting Information may be found in the online version of this article:

Supplementary Material: Italian translation of this article.

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