**SACN consultation on 'Feeding in the First Year of Life' draft report**

**Response submitted by the Royal College of Paediatrics and Child Health**

**September 2017**

**About RCPCH**

The Royal College of Paediatrics and Child Health (RCPCH) has over 17,000 members worldwide and works to transform child health through knowledge, innovation and expertise. The College is responsible for training and examining paediatricians and plays a major role in advocacy, policy development and in supporting the maintenance of professional standards for its members.

RCPCH updated its position statement on breastfeeding in August 2017 (http://www.rcpch.ac.uk/system/files/protected/news/WEBSITE%20FINAL%20Breastfeeding%20Position%20Statement%20280717_0.pdf)

As can been seen from this statement, RCPCH agrees that recent data from the most robust series of meta-analyses to date, with comprehensive assessment of study quality and sources of potential bias, indicate that breastfeeding is likely to be causally related to reduced risk of gastro-intestinal, respiratory and ear infections and reduced need for hospitalisation for infections, in all settings. This protection is seen whilst the infant is receiving breast-milk, and is greater with exclusive than with partial breastfeeding. The protective benefits are large and the evidence consistent and biologically plausible.

RCPCH strongly supports breastfeeding, the promotion of breastfeeding, the provision of advice and support for women, and national policies, practices, and legislation that are conducive to breastfeeding. We also note that whilst breastfeeding is a natural process, mothers may require support, knowledge and education. With such support, the expectation is that most women will be able to breastfeed.

RCPCH is working with a wide range of organisations to consider how breastfeeding rates in the UK can be increased.

**General points:**

1. The report is called 'Feeding in the first year of life', but the terms of reference are more focussed on complementary feeding, and the health and economic benefits of breastfeeding *per se* (or the adverse consequences of not breastfeeding) are not covered in a comprehensive way. A review of the scientific evidence on this topic from a series of systematic reviews and meta-analyses (recently summarised by Victora et al in the Lancet series) would enable current recommendations and advice to parents on breastfeeding to be updated to reflect recent developments. In addition the issue of the appropriate age for introduction of solids in formula-fed infants is not specifically

discussed, even to highlight the lack of good quality evidence. This is important given that the majority of British infants are currently receiving at least some formula by 4-6 months.

2. The terms of reference of the report states that 'breastfeeding is the physiological norm, based on the fact that 80% of infants are at least initially breastfed'. Whilst footnote 2 explains 'incidence of breastfeeding is defined as the proportion of babies who were breastfed initially. This includes all babies who were put to the breast at all, even if this was on one occasion only. It also includes giving expressed breastmilk to the baby,' this definition ignores the reality of breastfeeding rates in the UK in terms of how long the activity is sustained for. By 6-8 weeks a much smaller percentage of babies are receiving any breastmilk (43.2% in England[1],38.9% in Scotland[2]). Whilst the RCPCH is working to improve breastfeeding rates, these figures show that breastfeeding is not the norm in reality in the UK and the terms of reference of the report should be amended to reflect the norms currently observable. RCPCH believes that a more evidence-based, pragmatic, less dogmatic approach is preferable, focussing on breastfeeding per se rather than on exclusively breastfeeding for a particular period of time, particularly when the evidence supporting the latter in the UK context is not strong.

3. The report states a number of times that 6 months is the age when infants are developmentally ready for complementary foods. Chapter 4 outlines the gastrointestinal, renal and neurological development of infants and provides the evidence for this statement, however the evidence is not appraised and many nuances in the included text (e.g. 'within populations there are considerable inter-individual variation in the attainment of skills,' - paragraph 73, and '20% reached out for food as early as four to five months,' paragraph 75) are not translated into the conclusion.

4. The default position of the report is that infants should be exclusively breastfed for 6 months and that earlier introduction of complementary foods must be justified by proving benefits outweigh the 'risk' of displacing breastmilk. However the few higher quality RCTs (randomised) studies demonstrated no negative effects where infants were randomised to start complementary foods at 4 v 6 months (and in fact, better iron status was found in the earlier introduction groups in two trials).

5. The consultation does not include the accompanying SACN/COT report on the introduction of allergenic foods and the introduction of gluten is not covered. It is therefore not possible for stakeholders to critically review and discuss the evidence on those topics and this hinders a full risk-benefit consideration of the optimal age (or range of ages) for introducing complementary foods.

6. The report structure should be reconsidered in order to reduce repetition and a summary of the recommendations should be included.

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[1] Public Health England. Official Statistics Breastfeeding prevalence at 6-8 weeks after birth (Experimental Statistics). Available from https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/563003/2015_16_Annual_Breastfeeding_Statistical_Commentary.pdf

[2] Information Services Division Scotland. Breastfeeding statistics Scotland Financial year 2015/16. Available from https://www.isdscotland.org/Health-Topics/Child-Health/Publications/2016-10-25/2016-10-25-Breastfeeding-Report.pdf

7. The description of the methodological approach used to identify relevant studies is imprecise and inadequate.

8. There are frequent statements along the lines of 'a study shows,' or 'studies show' without references and this is unsatisfactory, for example in paragraphs 510, 511 and 514.

9. Given the increasing popularity of vegetarian and vegan diets, it would be helpful for the Committee to consider their role in complementary feeding in order to formulate recommendations and provide advice.

**Specific comments**

***Chapter 1 Introduction***

Paragraph 2. Recommendations by international expert committees: The report on complementary feeding by EFSA (2009) could be cited here (*EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA). Scientific opinion on the appropriate age for introduction of complementary feeding of infants. EFSA J 2009;7:1423*). Also the ESPGHAN Position paper on complementary feeding (*Complementary Feeding: A Position Paper by the European Society for Paediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN) Committee on Nutrition. JPGN 2017;64(1):119-132*).

Paragraph 4a. It would be helpful to include the definition of 'complementary feeding' used in this report early on in the document, to make it clear whether this includes 'anything except milk (breast milk or formula)' or 'anything except breast milk'.

Paragraph 6. The report states 'breastfeeding is the physiological norm and in the UK 80% of babies are breastfed initially'. A reference is required for this figure. The RCPCH agrees with the first element of the statement but disputes the accuracy of the 80% figure when applied to the whole of infanthood. The percentage of babies receiving breastmilk at 6-8 weeks is substantially lower than the initiation rate(43.2% in England and 38.9% in Scotland) which indicates that breastfeeding is not the norm in practice after the first few days/ weeks of infancy.

It is stated that 'the role, timing and type of complementary food can only be considered within the context of their potential benefits balanced against the risk of displacing breast milk'. This is not accurate, since the purpose of a complementary food is to 'complement' the nutrients provided from breast milk at a point where they cannot alone support growth and development. From a nutritional perspective, the issue is to identify the age at which this occurs, and to identify the nutrient gaps which need to be filled by the complementary foods which will differ for breast versus formula-fed infants. Complementary foods are also required for behavioural and developmental reasons, so that infants progress onto the family diet.

The emphasis on the need to balance risks and benefits when drawing conclusions highlights the importance of considering the whole range of relevant outcomes – including allergy and celiac disease. The decision to keep the detailed consideration of evidence on the age at introduction of allergenic foods or gluten to separate documents which are not part of the current consultation, with only a summary in the current report, is therefore unsatisfactory.

Paragraph 8. Growth is not the only outcome of importance related to nutritional adequacy; micronutrient status, especially iron status, is also important.

Paragraph 14. The introduction of gluten should be mentioned here or elsewhere. Along with the introduction of allergenic foods, this is one of the few areas for which the evidence base has improved in recent years with the publication of 2 large RCTs in the NEJM.

Paragraph 25. The systematic review and meta-analysis by Kramer & Kakuma plus the update from 2012 (Cochrane Database Syst Rev. 2012 Aug 15;(8):CD003517) which, along with a separate paper on nutritional adequacy and developmental readiness (Butte et al, 2002) , formed the basis of the WHO recommendation, could be included here. This section could also mention the EFSA opinion of 2009 (see above).

Paragraph 31. It is not correct to state that the purpose of introducing foods other than breast milk is to 'diversify the diet whilst breastfeeding continues'. Whilst dietary diversification is one aspect, the main purpose of complementary foods in a breast fed infant is to complement the nutrients provided from breast milk at the point they can no longer support the infant's requirements for growth and development.

***Chapter 4 Infant feeding, growth and health***

Paragraph 62. RCPCH is not aware of evidence to support the statement that healthy infants are capable of absorbing sufficient amounts of micronutrients from complementary foods 'by six months' as opposed to 'by 4 or 5 months'. Indeed, the fact that infants have for many years thrived whilst receiving other foods considerably earlier than 6 months would suggest that this capability is achieved before 6 months.

Paragraph 79. If the mean age at introducing complimentary food was 5.4 months then it would be more accurate to state this rather than generalising to 'around 6 months' or indeed 'around 5 months', which is closer to the mean average.

***Breastfeeding and infant health***

Paragraph 83. 'Exclusive breastfeeding during the first half of infancy' implies up to 6 months. The supporting evidence is not that specific. 'First months of infancy' would be more appropriate.

Paragraphs 85-102. We agree that the evidence for a protective effect of breastfeeding *per se* against infectious outcomes is convincing, certainly over the first 6 months. Few studies have investigated the impact of longer periods of breastfeeding in higher income settings, although the recent analysis from the Norwegian Mother and Baby cohort suggested that the risk of hospitalisation for infection was similar for infants with any breastfeeding for 6-11 v >12months (Størdal JPGN 2017 Aug;65(2):225-231).

Fewer studies have specifically addressed the effect of exclusive breastfeeding duration or the age at introduction of solid foods on infectious disease in high income settings, and the findings are difficult to compare due to differences in definitions and categorization of breast-feeding/ exclusive breastfeeding, classification and definitions of infection, and methods of ascertainment for both exposure and outcome variables. We agree that collectively these observational studies suggest that

more prolonged exclusive breastfeeding may protect against infection and hospitalization for infection in infants in high-income settings with access to clean water supplies and safe complementary foods, such as the UK. It should be noted however, that most of these studies are looking at 'longer' versus 'shorter' durations of exclusive breastfeeding rather than 6 months v 4-6 months specifically, because in many cohorts only a relatively small proportion of mothers exclusive breastfeeding for 6 months. The following additional relevant studies could be cited in this section and the table at Appendix 1 contains a summary of their main findings:

*1. Chantry CJ, Howard CR, Auinger P. Full breastfeeding duration and associated decrease in respiratory tract infection in US children. Pediatrics 2006;117:425–32.*

*2. Rebhan B, Kohlhuber M, Fromme H, et al. Breastfeeding duration and exclusivity associated with infants' health and growth: data from a prospective cohort study in Bavaria, Germany. Acta Paediatrica 2009;98:974.*

*3. Ladomenou F, Moschandreas J, Kafatos A, et al. Protective effect of exclusive breastfeeding against infections during infancy: a prospective study. Arch Dis Child 2010;95:1004–8.*

*4. Li R, Dee D, Li C, et al. Breastfeeding and risk of infections at 6 years. Pediatrics 2014;134(suppl 1):S13–20.*

*5. Størdal K, Lundeby KM, Brantsæter AL, Haugen M, Nakstad B, Lund-Blix NA, Stene LC. Breast-feeding and Infant Hospitalization for Infections: Large Cohort and Sibling Analysis. J Pediatr Gastroenterol Nutr. 2017 Aug;65(2):225-231.*

RCPCH think it is important to emphasise the findings from the UK Millennium Birth Cohort Study (Quigley 2009), in which it was shown that it was the introduction of infant formula, not solid foods, that predicted an increased likelihood of hospital admission. As summarised in the SACN report appendix, (table 4.1), but not currently mentioned in the text, the monthly risk of hospitalization was not significantly higher in those who had received solids compared with those not on solids (for diarrhoea, adjusted OR 1.39, 95% CI 0.75–2.59; for lower respiratory tract infection, adjusted OR 1.14, 95% CI 0.76–1.70), and the risk did not vary significantly according to the age of starting solids. Thus, it appeared to be the introduction of formula feeding alongside breastfeeding that was problematic.

More recently, the EAT RCT, in which the median duration of exclusive breastfeeding was 16 weeks in the intervention group and 24 weeks in the control group, reported that, whilst parent-reported upper respiratory tract infection in the 4-to-6 month period was significantly higher in the intervention group, there was no significant difference for parent-reported lower respiratory tract infection, bronchiolitis, or other infections, nor in parent-reported diarrhoea between groups (mean [SE] days affected between 4 and 6 months 0.62 [0.06] for the intervention group vs 0.66 [0.08] for controls, P=0.7). Infants in the intervention group in this study consumed most of their complementary foods as solid foods and the use of infant formula was low with only 10.5% consuming >300 mL/day by 6 months (Perkin 2016 (NEJM and JACI)). Thus these findings are consistent with the results from the Millennium Birth Cohort Study in suggesting that the introduction of solids alongside breast-feeding may not result in an increase in infection risk, with

the exception of upper respiratory tract infection. These findings have potential practical importance for breastfeeding mothers and could also be mentioned as a topic for future research.

Paragraph 105. In addition to the RCT by Cohen et al in Honduras, there are data on iron status from the Icelandic RCT comparing 4 v 6 months exclusive breastfeeding; and observational data from the US and Germany. References:

*Jonsdottir OH, Thorsdottir I, Hibberd PL, et al. Timing of the introduction of complementary foods in infancy: a randomized controlled trial. Pediatrics 2012;130:1038–45.*

*Dube K, Schwartz J, Mueller MJ, et al. Iron intake and iron status in breastfed infants during the first year of life. Clin Nutr 2010;29:773–8.*

*Dube K, Schwartz J, Mueller MJ, et al. Complementary food with low (8%) or high (12%) meat content as source of dietary iron: a double blinded randomized controlled trial. Eur J Nutr 2010;49:11–8.*

*Chantry CJ, Howard CR, Auinger P. Full breastfeeding duration and risk for iron deficiency in US infants. Breastfeed Med 2007;2:63–73.*

In the Icelandic study, infants randomised to receive complementary foods from 4 months had significantly higher serum ferritin at age 6 months than those still exclusive breastfeeding, across the range of serum ferritin. Although all infants had serum ferritin within the expected range for age in this population, the finding is consistent with higher iron stores in those who received complementary foods from 4 months which would be considered a positive rather than a negative outcome, even though the later significance of this for iron status and anaemia was not tested in the trial. It is also consistent with the findings from the Cohen RCT in Honduras and with observational data suggesting that infants with more prolonged EBF who are not supplemented are at greater risk of iron deficiency later in infancy. It is possible that these results would differ if the studies were repeated in a population where systematic delayed clamping of the umbilical cord is practiced. However, currently no such studies are available to our knowledge.

Paragraph 106. It is not clear why these studies on infectious outcomes are in a section separate from the ones discussed previously. All of the studies in some way address the introduction of solid foods or formula at different ages before 6 months of age.

Paragraph 107. It is not clear how the statement 'exclusive breastfeeding during the first 6 months of life, as opposed to the first four with mixed feeding thereafter, is advantageous for infant health and does not adversely affect infant growth' follows from the data presented and discussed earlier in the chapter. Furthermore, without the additional consideration of allergenic foods and gluten, it is not possible to consider the full balance of risks and benefits for infant health.

Paragraph 108. The recently published study from the Norwegian Mother and Baby cohort is relevant here and suggested that the risk of hospitalisation for infection was similar for infants with any breastfeeding for 6-11 v >12mo (Størdal JPGN 2017 Aug;65(2):225-231).

Paragraph 120. It is really not possible from the available data to make a statement that 'on average, infants attain neurological maturity to participate in diversification of the diet through active acceptance of solid foods at around six months of age' as opposed to 4 or 5 months of age. It also

depends on what type of foods are to be provided (puree v semi-solid for example), and what is meant by 'active acceptance' or 'participation'. It would be preferable either to avoid citing a single age, or to acknowledge that the age at which the necessary skills are obtained depends on the type of food, method of feeding to be employed etc.

***Chapter 5 Energy requirements***

Paragraph 135. The hypothesis raised in the cited papers was that there was insufficient evidence to be certain that exclusive breastfeeding for 6 months would meet the energy requirements of all healthy term infants. The same authors then conducted the study cited in Paragraph 138 (Nielsen et al) to investigate this hypothesis further. In that observational study, it was shown that milk intake increased significantly between 15 and 25 weeks in mothers who chose to and were successful in exclusively breastfeeding their infant for 6 months, without evidence of 'strain' in the breastfeeding process, and without compromising infant growth. Whilst this demonstrates that mothers who exclusive breast feed for 6 months adapt physiologically to provide sufficient breast milk, these mothers were a highly selected minority and certainly not representative of all mothers in the study population in Glasgow. Hence, the same questions about generalisability of findings applies to this study, as is the case with all data used to establish the adequacy of exclusive breastfeeding for 6 months. Namely, all data come from a minority of the population and should be generalised to the whole population with some caution.

Paragraph 146. The recent systematic review by Redsell et al considered RCTs that aim to reduce the risk, either directly or indirectly, of overweight and obesity in infancy and early childhood. It concluded that the most promising obesity prevention interventions for children younger than 2 years of age are those that focus on diet and responsive feeding, including education for carers on recognising infant hunger and satiety cues and non-food management of infant behaviour.

*Redsell SA, Edmonds B, Swift JA, et al. Systematic review of randomised controlled trials of interventions that aim to reduce the risk, either directly or indirectly, of overweight and obesity in infancy and early childhood. Matern Child Nutr 2016;12:24–38.*

Paragraph 149. Follow-up data from the Icelandic RCT also suggest that there was no effect of the intervention on anthropometric measurements up to pre-school age *(Jonsdottir OH, Kleinman RE, Wells JC, et al. Exclusive breastfeeding for 4 versus 6 months and growth in early childhood. Acta Paediatr 2014;103:105–11)* or developmental screening tests over the same period *(Jonsdottir OH, Thorsdottir I, Gunnlaugsson G, et al. Exclusive breastfeeding and developmental and behavioral status in early childhood. Nutrients 2013;5:4414–2).*

Paragraph 153. It is important to add that this finding was in self-selected mother-infant dyads who successfully undertook exclusive breastfeeding for 6 months, and generalisability to the wider population is uncertain.

Paragraph 154. It is inappropriate to say that the intervention 'compromised' breast milk intake; that is a subjective assessment. Objectively, the intervention decreased milk intake by a small amount without affecting total energy intake or growth, and overall there were no adverse effects of the intervention on any measured outcome. In fact, the only potentially 'beneficial' effect seen in the trial – on iron status (serum ferritin) - was seen in the intervention group who had solids

introduced alongside breastfeeding from 4 months rather than in the 6 months exclusive breastfeeding group.

Paragraph 157. This is similarly inaccurate. There have not been a 'succession' of RCTs showing that giving complementary feeding to breast fed infants before 6 months is associated with other negative health outcomes. It is objectively true that complementary foods will replace an equivalent amount of breast milk with no effect on anthropometric outcomes, but the 'negative' outcomes, if any, have actually been found in groups of infants exclusive breastfeeding for 6 months: poorer iron status in the Honduras RCT, lower serum ferritin in the Icelandic RCT, with no reported effect on infectious diseases in any of the trials, including the recent EAT RCT. If negative outcomes are mentioned in this way, they should be specified and the references cited.

***Chapter 6 Infant feeding, body composition and health.***

Paragraph 161-3.The additional systematic review by Daniels et al could also be cited: *Daniels L, Mallan KM, Fildes A, et al. The timing of solid introduction in an 'obesogenic' environment: a narrative review of the evidence and methodological issues. Aust NZ J Public Health 2015;39:366–73,* although the conclusions are similar to those in the reviews by Moorcroft and by Pearce.

Paragraph 165 (and 196 of conclusions). The Icelandic RCT has also reported growth data beyond infancy, using data from the computerised child health records system up to pre-school age, showing no effect of 4 v 6mo exclusive breastfeeding on the anthropometric outcomes (*Jonsdottir OH, Kleinman RE, Wells JC, et al. Exclusive breastfeeding for 4 versus 6 months and growth in early childhood. Acta Paediatr 2014;103:105–11).*

*Quality of the complementary feeding diet*

Additional references which could be considered relating to protein intake during complementary feeding (from milk and solid foods):

*Hornell A, Lagstro¨m H, Lande B, et al. Protein intake from 0 to 18 years of age and its relation to health: a systematic literature review for the 5th Nordic Nutrition Recommendations. Food Nutr Res 2013:57.*

*Pimpin L, Jebb S, Johnson L, et al. Dietary protein intake is associated with body mass index and weight up to 5 y of age in a prospective cohort of twins. Am J Clin Nutr 2016;103:389–97.*

*Inostroza J, Haschke F, Steenhout P, et al. Low-protein formula slows weight gain in infants of overweight mothers. J Pediatr Gastroenterol Nutr 2014;59:70–7.*

*Ziegler EE, Fields DA, Chernausek SD, et al. Adequacy of infant formula with protein content of 1.6 g/100 kcal for infants between 3 and 12 months. J Pediatr Gastroenterol Nutr 2015;61:596–603.*

***Chapter 7 Micronutrients***

Iron: RCPCH suggest it would be relevant to consider the effectiveness of different sources of iron to inform recommendations. This is particularly relevant to populations for whom meat is not acceptable, including vegetarian and vegan families. Given the current popularity of plant-based

diets, it would be helpful to have an opinion on the role of such diets during the complementary feeding period.

Paragraph 256. Whilst we agree that EBF provides sufficient iron in the first 6 months for healthy, term, AGA infants with adequate iron stores and delayed clamping of the umbilical cord, the same cannot be said for the many infants who do not meet one or more of these criteria. Hence some flexibility is required since some of these infants may benefit from earlier introduction of iron-rich foods to complement the supply from breast milk.

Paragraph 259. Regarding the possible adverse effects of supplemental iron, especially in iron-replete infants, there are two other potentially relevant references:

*Krebs NF, Sherlock LG, Westcott J, et al. Effects of different complementary feeding regimens on iron status and enteric microbiota in breastfed infants. J Pediatr 2013;163:416–23.* Data from this pilot study conducted within a larger RCT suggested that iron supplements may have adverse effects on the microbiome, raising the hypothesis that providing additional iron in a form which is not easily absorbed could promote dysbiosis.

*Lozoff B, Castillo M, Clark KM, Smith JB. Iron-fortified vs low-iron infant formula: developmental outcome at 10 years. Arch Pediatr Adolesc Med 2012;166(3):208-15.* This was a follow-up of 473 children at age 10 years from a RCT in which 835 healthy Chilean infants with birth weights > 3 kg and no IDA at 6 months were randomized to high iron (12 mg/L) or low iron (2.3 mg/L) formula from 6-12 months. It showed a trend towards a lower IQ in the iron fortified group (91.5 vs 93.3, p=0.06) and the iron fortified group had significantly lower scores for spatial memory (86.8 vs 91.4, p=0.02) and visual-motor integration (97.2 vs 99.8, p=0.046). There was also a significant interaction between initial Hb at 6 months and the intervention effects on all developmental outcomes; children with higher 6-month hemoglobin concentrations (> 128 g/L) showed poorer developmental outcomes if they received iron-fortified formula, whereas whose with low initial hemoglobin levels (<105 g/L) showed better outcome with iron fortified formula. This adds to concerns that providing additional iron to iron-replete infants could have adverse effects.

**Chapter 8 Eating and feeding of solid foods**

Paragraph 347. This conclusion does not seem to follow from the results of experimental studies with extensively hydrolysed protein formulas summarized in Paragraphs 285-288 in which earlier (and longer) exposure to the formula was associated with greater acceptance of this flavour later on, albeit in formula-fed infants. The remaining data on timing of exposure to different flavours is observational and therefore presumably should be considered of lower quality. Additionally, few of the studies include infants exposed to different flavours specifically from 6 months since mothers have generally introduced them earlier.

**Chapter 9 Oral health**

In practical terms, RCPCH suggest that it would be helpful to have a conclusion/recommendation on the importance of tooth-brushing with a fluoride paste from the time the first tooth erupts, regardless of mode of feeding.

***Chapter 10 UK infant feeding practice***

Paragraph 162. The low prevalence of iron deficiency anaemia found in DNSIYC is likely to reflect the high use of infant formula and follow-on formula in the second six months. The impact of higher breastfeeding prevalence and reduced use of formulas during this period is uncertain but this should be an area for future research assuming measures to increase breastfeeding duration in the UK are successful.

***Chapter 12 Risks arising from the infant diet and development of atopic and autoimmune disease***

Paragraph 485 and 486. It is impossible to respond adequately to these statements without the opportunity to comment on the scientific assessment on which they are based. It is stated that 'based on the consequences of reduced breast milk feeding, on the basis that complementary foods displace breast milk, introduction of complementary foods including peanut and hen's egg earlier than around six months of age presents risks that are not outweighed by any potential benefit'. It is not clear which risks are referred to here. In the EAT study itself, there were no apparent risks associated with the introduction of allergenic foods from 3-4 months, including for all types of infection apart from URTI. Furthermore, the statement assumes that nutritionally significant amounts of allergenic foods would be consumed, whereas the beneficial effects of introducing such foods for immune tolerance may be afforded by relatively small quantities which have minimal impact on breast milk intake. Indeed, published data from the EAT study suggested minimal impact on breastfeeding duration since rates in the intervention group were significantly above expected for the UK, and were not significantly different from those in the control group. RCPCH would like a clearer explanation of the risks which were considered in formulating this statement, and an opportunity to respond to them. Without such an opportunity, we suggest it is impossible to conduct a comprehensive assessment.

There is also no specific mention of the issue of gluten introduction during complementary feeding. Two large RCTs conducted in European infants have shown that the introduction of gluten at different ages after 4 months does not influence the subsequent development of coeliac disease. Breastfeeding also had no impact on this outcome. These studies have led to the revision of guidelines on introducing gluten which now suggest that it can be introduced at any time between 4 and 11 months of age.

*Vriezinga SL, Auricchio R, Bravi E, et al. Randomized feeding intervention in infants at high risk for celiac disease. N Engl J Med 2014;371:1304–15.*

*Lionetti E, Castellaneta S, Francavilla R, et al. Introduction of gluten, HLA status, and the risk of celiac disease in children. NEJM 2014;371:1295–303.*

*Szajewska H, Shamir R, Mearin L, et al. Gluten introduction and the risk of coeliac disease: a position paper by the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition. J Pediatr Gastroenterol Nutr 2016;62:507–13.*

***Chapter 13 Conclusions and recommendations***

Paragraph 490. Breastfeeding is certainly the physiological norm at birth but there is no evidence that the physiological norm for the duration of exclusive breastfeeding is six months in all infants. It is more likely biologically and physiologically that the optimal period for exclusive breastfeeding is variable between infants. Hence the assertion that the potential benefits of introducing any

complementary food before six months must be balanced against the risk of displacing breast milk is not a reasonable starting point for the analysis. It is also important to consider behavioural aspects and the possibility that infants may indicate or 'signal' to their mother that they are ready for other foods – either from a nutritional or developmental perspective.

Paragraph 506. The 'best estimates' indicating that breast milk production increases between 4 and 6 months and that this would meet the increasing energy demands of the growing infant are all from studies in (highly) selected mother-infant dyads who chose this behavior and are successful. The statement should be qualified to this effect and the issue of generalizability mentioned.

It is not accurate that a 'succession of randomised trials has shown that giving complementary foods to breast fed infant before 6 months compromises breast milk intake without increasing total energy intake or increasing weight gain and is associated with other negative health outcomes'. There have been 4 RCTs; two in Honduras, one in Iceland and one in the UK (EAT). The studies did suggest that some breast milk is displaced by complementary foods without influencing energy intake or infant growth (or growth in early childhood in the Iceland study) but we are not aware of negative health effects. In fact, in both the Honduras and Iceland trials, infants with earlier introduction actually had better iron status.

*Complementary feeding*

Paragraph 507. This statement is not substantiated by evidence – see Paragraph 120.

Paragraph 512. This statement ignores the findings of the research with extensively hydrolysed protein formulas by Menella et al. See Paragraph 347.

Paragraph 520. See Paragraph 162. It seems likely that the relatively low prevalence of IDA in DNSIYC reflects the widespread use of infant formulas and follow-on formulas between 6 and 12 months.

Paragraph 531. See Paragraphs 485 and 486.

Paragraph 533. We cannot agree that the evidence presented (and other evidence so far not included) justifies the statement that 'the evidence reviewed for the report strengthens current guidance to breastfeed exclusively for around the first six months of the infant's life'. Recent evidence from RCTs demonstrates no adverse effects from introducing complementary foods, including gluten and allergenic foods, from 4 months, with better iron status in two trials. The evidence is not sufficient for such a dogmatic statement, and suggests the need for a greater degree of flexibility. RCPCH believes that mothers should be supported to exclusively breast feed their infant for up to 6 months, that complementary foods should not be introduced to any infant before 4 months, and that all infants require complementary foods by 6 months. We favour a greater focus on supporting breastfeeding initiation and maintenance given strong evidence for beneficial effects on infant and maternal health, than on a goal for exclusive breastfeeding which many mothers find unrealistic and for which the evidence is much weaker.

Paragraph 542. This recommendation could also emphasise the importance of regular tooth brushing with fluoride toothpaste once the first tooth erupts.

Paragraph 543. RCPCH suggests this recommendation should emphasise that peanut and hen's egg should not be introduced before 4 months, and after that these foods should be treated in the same way as other complementary foods.

Paragraph 544. What is the evidence for the recommendation that exposure to allergenic foods must continue after initial exposure to avoid the risk of sensitization and food allergy? The follow-up of subjects from the LEAP trial showed no increase in sensitization or allergy after a 1 year period of peanut avoidance in the intervention group. To our knowledge, this issue was not investigated in the other published trials.

Paragraph 545. RCPCH strongly supports the reintroduction of the five yearly Infant Feeding Survey to allow tracking of secular trends and changes in practice consequent to new recommendations.

**Appendix 1: Summary of additional studies reporting associations between duration of exclusive breastfeeding and infection in higher income settings**

| *Author* | *Setting & Population* | *Infant feeding exposure classification used* | *Outcome(s)* | *Reported results* |
|---|---|---|---|---|
| Perkin 2016 | RCT. UK infants EBF at 3 mo | Randomised to early exposure to 6 allergenic foods from 3-4mo (EIG) v avoidance until at least 6mo<br>Continued BF both groups<br>Median duration EBF<br>16 v 24 weeks | Parent-reported infection recorded as adverse event: URTI, LRTI, diarrhoea, bronchiolitis, other infections, hospitalisation for period 4-6mo | URTI significantly more common in EIG<br>No significant difference for LRTI, bronchiolitis, other infections, hospitalisations.<br>Diarrhoea days affected:<br>EIG 0.62 (SE0.06) v SIG 0.66 (0.08), p=0.7 |
| Størdal 2017 | Norwegian Mother and Child study (MoBa) prospective birth cohort | Duration any BF categorised as:<br>None, 0.1-3, 4-6, 6.1-8, 9-11, >12mo<br><br>Age at introduction of CF in infants BF>6 months analysed in categories<1, 1 to 3, and 4-5 mo with FBF for 6mo as reference | Parent-reported hospitalization for infections from 0 to 18 months | 7.3% of breast-fed children with CF Introduced 4-6mo v 7.7% of those with CF after 6 months were hospitalized (adjusted RR 0.95, 95% confidence interval 0.88-1.03).<br><br>Higher risk of hospitalization was in those breast-fed 6 months or less (10.0%) compared to ≥12 months (7.6%, adjusted RR 1.22, 95% confidence interval 1.14-1.31), but similar risks for 6 to 11 months versus ≥12 months. |
| Chantry 2006[37] | US NHANESIII<br>Nationally representative cross-sectional<br>Home survey 1988-94<br>Healthy infants | Full FF (n=1149)<br>FBF<1mo (n=426)<br>FBF1-3mo (n=343) | Pneumonia<br>≥3 episodes AOM<br>≥3 episodes cold/influenza<br>Wheezing past 12 mo | Comparing 4-5 v ≥6mo<br>Unadjusted:<br>Pneumonia: 6.5% v 1.6%<br>Adjusted OR: |

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|---|---|---|---|---|
| | | FBF4-<6mo (n=223)<br>FBF≥6mo (n=136) | AOM below 12 mo | Pneumonia 4.27 (1.27,14.35)<br>≥3 AOM 1.95 (1.06,3.59) |
| Rebhan[39]<br>2009 | Bavaria, Germany<br>Healthy term infants born April 2005 | No BF or <4mo (n=619)<br>FBF/EBF 4-<6mo (n=870)<br>EBF≥6mo (n=475) | ≥1 episode gastroenteritis from 0-9mo | aOR for EBF≥6mo v 0/<4moBF 0.6 (0.44,0.82) |
| Ladomenou[41]<br>2010 | Prospective observational cohort<br>Representative sample born in Crete During 2004 | No or partial BF (n=835)<br>EBF 6mo (n=91) | Parent report aOM, ARI, GI thrush, UTI conjunctivitis,0-12mo and hospitalisations | EBF duration negatively correlated with infection episodes (r=-0.07, p=0.02) (r=-0.06, p=0.04)<br>aOR for EBF6mo v rest: ARI 0.58 (0.36,0.92) |
| Li 2014[42] | US IFPSII born 2005-7<br>Follow-up at age 6 years | EBF>0-<4m (n=868)<br>EBF>4-<6mo (n=195)<br>EBF≥ 6mo (n=43) | Infections in the past 12mo: (maternal report) Respiratory, ear, throat, sinus | Trend for fewer ear, throat & sinus infections with more prolonged EBF(p<0.01)<br>aOR for EBF6 v 0-4*: ear 0.37 (0.14,0.98), throat 0.23 (0.07,0.76), sinus 0.13 (0.02,0.97); ≥2 sick visits 0.33 (0.15,0.75) |

All studies included healthy term infants. Abbreviations: EBF Exclusive breastfeeding; FBF full breastfeeding; FF formula feeding; aOR adjusted odds ratio; AOM acute otitis media; GI gastrointestinal infection; URTI upper respiratory tract infection; LRTI lower respiratory tract infection; mo months: *Statistical comparison between 4-<6 v 6mo EBF not made in the paper