



“We are producing a generation of pale, food-phobic kids”—  
Des Spence on weaning, p 234

# When to wean? How good is the evidence for six months' exclusive breastfeeding

The recommendation that UK mothers should exclusively breast feed for six months is a controversial area in infant nutrition. **Mary Fewtrell and colleagues** review the evidence and ask if the time is right for reappraisal of this advice

In 2001, the World Health Organization announced for the consideration of member states its global recommendation that infants should be exclusively breast fed for six months.<sup>1</sup> Many Western countries, including 65% of European member states<sup>2</sup> and the United States, elected not to follow this recommendation fully, or at all. However, in 2003 the health minister announced that the United Kingdom would comply.<sup>3</sup> Substantial evidence indicates that early nutrition has profound implications for long term health, by programming aspects of subsequent cognitive function, obesity, risk of cardiovascular disease, cancer, and atopy.<sup>4</sup> However, the evidence base supporting a major, population-wide change in public health policy underwent surprisingly little scrutiny. Indeed, the Department of Health's Scientific Advisory Committee on Nutrition (SACN) was not asked to formally consider the scientific evidence. A reappraisal of the evidence is timely in view of new data and a recent expert review for the European Food Safety Authority (EFSA), concluding that for infants across the EU complementary foods may be introduced safely between four and six months.<sup>5</sup>

## Basis of the current recommendation

It is important not to confuse the evidence for promoting six months' exclusive breast feeding with that for breast feeding itself, which is extensive and is not considered here. WHO

defines exclusive breast feeding as excluding solids or any other fluids (including infant formulas) except medicines, vitamins, and minerals.<sup>6</sup> In the United Kingdom and other countries where early formula feeding is prevalent, the timing of introduction of solid foods in all infants (often called weaning) is useful to consider,<sup>7</sup> and evidence on this subject is also included here.

The WHO recommendation rested largely on Kramer and Kakuma's systematic review<sup>8</sup> of infant and maternal health effects of exclusive breast feeding for six months versus three to four months. The review included 16 eligible studies, seven of which were from developing countries. Apart from two randomised trials in Honduras, the studies were observational, precluding proof of causation for the outcomes examined, since residual or unidentified confounding may remain even after adjusting for potential confounders. The study's conclusions (box 1) included evidence for the efficacy of six months' exclusive breast feeding (notably reduced infection rate)

but also potential risk (iron deficiency anaemia, with its associated adverse neurodevelopmental outcomes). The health benefit for infants in developed countries, from an observational analysis in the Belarus promotion of breast



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feeding intervention trial (PROBIT) cohort, was a significantly reduced risk of gastroenteritis (adjusted odds ratio 0.61; 95% confidence interval 0.41 to 0.93).<sup>9</sup> By contrast, Lanigan and colleagues,<sup>10</sup> in a concurrent systematic review of 33 studies on the health effects of the timing of the introduction of solids in breastfed and formula fed infants, found no compelling evidence to support change from the then existing recommendation to introduce solids at four to six months.

## Evidence published since the 2001 WHO recommendation

As with most of the evidence considered in the WHO review, these studies are observational and the same caveats regarding proof of causation therefore apply.

## Infection

Four observational studies in developed countries have provided further evidence on exclusive breast feeding and risk of infection. Questionnaire based data from the National Health and Nutrition Examination Survey III (NHANES III) cohort<sup>11</sup> showed that US infants who were exclusively breast fed for more than six months had lower risk of pneumonia and recurrent otitis media than those breast fed for four to six months. A Spanish study found risk of hospital admission for all infant infections was decreased with longer exclusive breast feeding; this advantage, however, was seen principally before three months, with little

## Infants exclusively breast fed for six months represent, globally, a small, potentially biased subgroup

benefit thereafter.<sup>12</sup> A German study<sup>13</sup> found infants exclusively breast fed for six months, compared with less than four months, had less gastroenteritis. The large representative UK Millennium cohort study suggested 53% of admissions for gastroenteritis and 27% of those for chest infection could be prevented each month by exclusive breast feeding<sup>14</sup>; but, importantly for practice, it was the introduction of infant formula, not solid foods, that predicted increased hospital admission.<sup>15</sup>

### Nutritional adequacy

A key safety issue is whether six months' exclusive breast feeding reliably supports adequate growth—a traditional measure of overall nutritional status. A systematic review commissioned by WHO to address this question<sup>16</sup> showed that this approach was nutritionally adequate for infants up to six months, although data were limited. Yet infants exclusively breast fed for six months represent, globally, a small, potentially biased subgroup (for example, under 1% of UK infants in the 2005 UK Infant Feeding Survey<sup>17</sup>), that presumably excludes those perceived by their parents as signalling hunger and so requiring weaning foods earlier. Generalisation from this subgroup must therefore be questioned. Indeed, Wells and Reilly,<sup>18</sup> following a systematic review of infant energy requirements, breast milk output, and energy content, calculated that many mothers who exclusively breast fed would not support their infant's energy requirements to six months<sup>19</sup>; an important matter under further investigation.

More recent data from 2007 raise further concerns on whether six months' exclusive breast feeding would reliably meet iron requirements. US infants exclusively breast fed for six months, versus four to five months, were more

likely to develop anaemia and low serum ferritin, which is of concern given irreversible long term adverse effects on motor, mental, and social development after iron deficiency.<sup>20-22</sup> Such risks might be reduced by improving iron status in pregnancy, delaying umbilical cord clamping, and supplementing infants at risk (for example, those with low birth weight). However, any residual adverse effects on sub-optimal iron status of six months' exclusive breast feeding are likely to be missed in the United Kingdom, which has no screening policy for iron deficiency.

### Allergy and coeliac disease

Kramer and Kakuma's original review did not find a link between exclusive breast feeding duration and allergic disease (box 1). Important new data are now emerging with implications for practice.

Paradoxically, many developed countries have rising rates of food allergy, despite increasing advice to restrict and delay exposure to potentially allergenic foods, including cows' milk, egg, fish, gluten, peanut, and seeds. Moreover, countries where peanuts are commonly used as weaning foods have low incidences of peanut allergy (Israel, for example<sup>23</sup>). These observations have prompted further work on immune tolerance to foods.

The development of immune tolerance to an antigen may require repeated exposure, perhaps during a critical early window, and perhaps modulated by other dietary factors including breast feeding. A 2008 review<sup>24</sup> found an increased risk of allergy if solids were introduced before three to four months. After four months, the evidence was weak, but suggested an increased risk with delayed introduction of certain allergens. For example, the incidence of early onset coeliac

disease increased in Sweden following advice to delay introduction of gluten until age six months, and it fell to previous levels after the recommendation reverted to four months. Subsequent analyses suggest that gluten should ideally be introduced in small quantities alongside continued breast feeding.<sup>25</sup> A more recent study in infants at risk (with a first degree relative with type 1 diabetes or carriage of certain HLA types), showed that introduction of gluten before three months and after six months was associated with increased risk of biopsy proved coeliac disease<sup>26</sup> and islet cell autoantibodies.<sup>27</sup> This finding suggests that gluten may best be introduced during a critical window of three to six months. In the same cohort, introduction of wheat after six months predicted increased risk of wheat allergy at age four years.<sup>28</sup> Two UK randomised trials are now investigating early introduction of allergenic foods: the Learning Early About Peanut Allergy (LEAP) study (<http://clinicaltrials.gov/ct2/show/NCT00329784>) and the Enquiring About Tolerance (EAT) trial (<http://www.controlled-trials.com/ISRCTN14254740>).

### Outcomes in the longer term

A 6.5 year follow-up of the Belarus PROBIT cohort<sup>29</sup> showed no effect of exclusive breast feeding for six months (versus three months) on blood pressure, cognition, atopy, and dental caries. However, the six month group had higher indices of fatness. The authors speculated that faster growing infants, destined to be fatter children, might be breast fed longer because of mothers' confidence in their milk supply, although contrary evidence suggests faster growing infants receive solids earlier. Thus, the study could suggest that more prolonged exclusive breast feeding predicts later fatness. However, in a Danish birth cohort,<sup>30</sup> earlier introduction of solids was associated with late emergence of a higher risk of overweight at 42 years. Both studies were observational, and randomised trials will help resolve this issue.

### Overview

Exclusive breast feeding for six months is readily defensible in resource poor countries with high morbidity and mortality from infections.

In the UK 2005 Infant Feeding Survey (two years after the altered Department of Health advice), less than 1% of parents<sup>17</sup> were following the recommendation to exclusively



**Breast milk alone for six months is readily defensible in resource poor countries**

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breast feed for six months. However, evidence already existed of altered behaviour with a delay in the introduction of solids. Successive surveys since the 1970s showed that nearly all infants received solids by four months (for example, 85% in the 2000 survey), but in 2005 the figure dropped to 51%<sup>17</sup> and the mean age of introduction of solids was 19 weeks, a rise from 15 weeks in 2000. The trend towards later introduction of solids was mainly attributable to a shift in the proportion of mothers starting weaning between four and five months (31% of 2005 mothers introduced solids in this period, compared with 13% in 2000). In view of the higher reported rates of exclusive breast feeding to six months elsewhere in the West (more than 30% in Hungary and Portugal, for example<sup>2</sup>), it seems likely that the impact of the UK recommendation will be greater in 2010 than in 2005. It is timely to consider whether such trends could influence health outcomes.

In the West, exclusive breast feeding for six months is linked to reduced risk of infection. Nevertheless, the studies are observational and some evidence suggests that introducing solids (rather than formula) before six months may not significantly affect risk of infection. By contrast, exclusive breast feeding to six months raises concerns shown in box 2.

### Future implications

In the West, any proposed beneficial effects of exclusive breast feeding to six months on infection risk would need to be weighed against plausible, or at least suggestive, evidence for adverse effects (box 2). This analysis is hampered by a paucity of randomised trials, although at least

#### Box 2 | Areas of clinical concern over recommendation to breast feed exclusively for six months

Evidence challenging the adequacy of breast milk as a reliable sole source of nutrition to six months

- Higher risk of iron deficiency anaemia (identified in data from the developing and developed worlds) known to be linked to irreversible adverse mental, motor, and psychosocial outcomes. The lack of a screening programme in the United Kingdom to detect such adverse population effects is a further concern
- Concerns over a higher incidence of food allergies
- Higher risk of coeliac disease, with concomitant long term complications

one is now under way. Nevertheless, available data raise concerns about longer term influences on immune health, neurodevelopment, behaviour, and body fatness. These concerns are given plausibility by numerous animal and human studies showing brief early dietary manipulation can programme these outcomes.<sup>4</sup> There are also relatively unexplored concerns about the potential for prolonged exclusive breast feeding to reduce the window for introducing new tastes. Bitter tastes, in particular, may be important in the later acceptance of green leafy vegetables, which may potentially affect later food preferences with influence on health outcomes such as obesity. This breadth of possible adverse effects was not envisaged when the current WHO policy was endorsed in the United Kingdom.

We suggest three prerequisites for devising such a pervasive public health recommendation in nutrition; similar to those adopted, for example, in the development of policies in other areas such as immunisation.

- 1) An evidence based approach to appraisal of the available scientific data, after prior assessment of the adequacy of these data to support change in practice.
- 2) A synthesis balancing the risks and benefits of the proposed intervention, accounting for a range of plausible outcomes.
- 3) An auditing mechanism in place for detecting any adverse population effects of the recommendation once implemented.

In the United Kingdom, it would be the brief of the Scientific Advisory Committee on Nutrition (SACN) to advise the Department of Health on the first two prerequisites. Ideally, this should be supported by a broad professional consultation process, helpful also here for the third. Doubt must exist whether any of these prerequisites were met in the United Kingdom when the recommendation was announced. Certainly, it was acknowledged by SACN that no data were available on which to



Most infants in the 1970s started solids by four months

base the extension of the recommendation to delay the introduction of solids to formula fed infants until six months.<sup>31</sup>

The critical question is whether the United Kingdom should alter its advice on the introduction of complementary foods while new evidence is assembled. At one extreme, it has been suggested<sup>32</sup> that there is insufficient scientific evidence for any lower age for weaning and that “infants should be weaned

on demand, which is what most infants and their parents actually do in practice.” It can be argued that, from a biological perspective, the point when breast milk ceases to be an adequate sole source of nutrition would not be expected to be fixed, but to vary according to the infant’s size, activity, growth rate, and sex, and the quality and volume of the breast milk supply. Signalling of hunger by the infant is probably an evolved mechanism that individualises timing of weaning for a mother-infant pair.<sup>19</sup> However, others would adopt a more cautious approach, based on data suggesting that the introduction of solid foods before three to four months may be associated with increased fatness and wheeze later in childhood,<sup>33</sup> with an increased risk of allergy, and with higher rates of coeliac disease and type 1 diabetes in infants at risk.<sup>26 27</sup> Recently, after a detailed review commissioned by the European Commission, the European Food Safety Authority’s panel on dietetic products, nutrition, and allergies concluded that for infants across the EU, complementary foods may be introduced safely between four to six months, and six months of exclusive breast feeding may not always provide sufficient nutrition for optimal growth and development.<sup>5</sup> This is similar to recent guidance issued by the British Dietetic Association Paediatric Group.<sup>34</sup> Perhaps the Department of Health might conclude similarly were it to commission an objective, independent review of the evidence that has accumulated since WHO commissioned Kramer and Kakuma’s review a decade ago.



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**Competing interests:** All authors have completed the Unified Competing Interest form at [http://www.icmje.org/coi\\_disclosure.pdf](http://www.icmje.org/coi_disclosure.pdf) (available on request from the corresponding author) and declare that no external funding was received in connection with the preparation of this manuscript; MF, AL, and DCW have performed consultancy work and/or received research funding from companies manufacturing infant formulas and baby foods within the past 3 years; their spouses, partners, or children have no relationships that may be relevant to the submitted work; and the authors have no non-financial interests that may be relevant to the submitted work.

**Provenance and peer review:** Not commissioned; externally peer reviewed.

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Cite this as: *BMJ* 2010;341:c5955

## ANSWERS TO ENDGAMES, p 235. For long answers go to the Education channel on [bmj.com](http://bmj.com)

### CASE REPORT A rare cause of thunderclap headache

- Cerebral venous thrombosis is the most likely diagnosis.
- Magnetic resonance venography or computed tomography venography will confirm the diagnosis.
- Ulcerative colitis, prednisolone use, oral contraceptive use, and female gender are all risk factors for cerebral venous thrombosis in this patient.
- A patient with cerebral venous thrombosis should be managed with a therapeutic dose of heparin (unfractionated or low molecular weight).

### STATISTICAL QUESTION Meta-analyses II

Answers *a* and *e* are true, whereas *b*, *c*, and *d* are false.

### ON EXAMINATION QUIZ

#### Managing a high international normalised ratio

Answer D is correct.