

## **Executive Summary**

### **The effectiveness of public health interventions to improve the nutrition of young children aged 6-24 months**

#### **Background**

During the period 6 -12 months, most babies in the UK are in the process of being weaned. The weaning process is the gradual transition from an exclusively milk based diet to a diet based, for the most part, on foods other than milk. Key issues in weaning are: the timing of the first introduction of any solid foods; the timing of the introduction of particular foods/food groups in order to reduce the risk of developing allergies; meeting the infants' nutritional needs through introducing a variety of foods; protecting oral health through choosing appropriate foods and drinks; and the use of vitamin supplements (Department of Health 1994).

In 2001, the World Health Organisation recommended that mothers should breastfeed exclusively for 6 months. This recommendation was adopted by UK Health Departments and the new advice encouraged all mothers, whether they were breast or bottle feeding, to delay introducing solids until 6 months.

After six months, the Department of Health (DH) weaning advice encourages the gradual introduction of a range of foods into the baby's diet, to provide all the nutrients the baby needs and to encourage eating a varied family diet. Potentially allergenic foods can now be introduced one at a time, so that if there is an allergic reaction, it is easy to identify which food may have been the cause. To encourage babies to get used to solid food, purees of meat, poultry, fish and/or pulses can be introduced and full fat cows' milk products such as yoghurt, custards and cheese sauce can be introduced as can well-cooked eggs. The use of homemade foods is encouraged. As time progresses parents and carers are encouraged to move from smooth to lumpier purees and to introduce solid foods at two and then three meals a day, gradually increasing the amount of food offered.

Between 6 and 9 months, solid foods should gradually become a larger part of the baby's diet. At around 9 months it is recommended that foods are mashed so that the baby learns to cope with lumps and starts to learn to chew even if their teeth haven't yet appeared. Finger foods (bread, toast, sticks of vegetables, cheese and peeled fruits) can also be introduced. The importance of red meat as a source of iron is highlighted and it is recommended that babies who do not eat meat have a diet rich in vitamin C in order to enhance the absorption of iron. In particular it is recommended that foods or drinks rich in vitamin C are served at mealtimes (Department of Health 1994).

From the age of six months, the DH recommends the use of supplements of vitamins A and D for babies which are predominantly breastfed. This is not recommended for most babies that are receiving infant or follow-on formula as these products are fortified with these vitamins.

By the time the child has reached its first birthday, it should be eating a varied mixed diet. As this is a period of rapid growth and development, the needs for energy and nutrients are high. Foods that are recommended include full-fat cows milk as a main drink, foods rich in iron each day, especially where meat is not given, and giving vitamin C rich foods or diluted juice at mealtimes. Foods that should be avoided include: sugary foods and drinks in order to protect oral health; low fat and diet products and diets which are too high in fibre; adding salt to foods for children and giving salty snacks; tea and coffee as this reduces iron absorption; and whole nuts until the age of five, because of the risk of choking. Where there is a close family history of asthma, eczema, hay fever or other allergies, peanuts and peanut containing products should be avoided until the age of three.

## **Objectives**

To examine the effectiveness of public health interventions intended to promote safe and healthy feeding practices for infants and young children who are no longer predominantly milk fed.

## **Methods**

This review was carried out by the Mother and Infant Research Unit (MIRU) at the University of York between April and June 2006 and updated in March 2007 by MIRU and NICE.

## **Literature Search**

The Centre for Reviews and Dissemination at the University of York conducted the searches for this rapid review in April 2006, with input from the MIRU review team. Initially, a scoping search was undertaken in order to direct and refine the final search strategy.

All of the searches were conducted using a stepped approach to identify relevant systematic reviews (SRs), randomised controlled trials (RCTs) and non-randomised studies (cohorts, qualitative studies and surveys). A worldwide search of a number of databases was conducted to identify relevant SRs (from 1995 onwards). Secondly, a worldwide search for RCTs was conducted (from 1990 onwards). Finally, the search included any type of study – but this search focused on studies from the UK published from 1990 onwards. Studies not published in English were excluded from the review.

## **Selection criteria**

Studies were included if participants were infants and young children (approximately 6 to 24 months of age) who were no longer predominantly milk fed. Studies of children with clinical conditions requiring specialist advice, secondary dietary management or clinical therapeutic advice, where normal care would be inappropriate, were excluded (for example, children with established atopic disease). To be included in the rapid review, the studies had to be conducted in developed countries.

The review included public health type interventions that aimed to promote safe and healthy feeding practices. Studies of interventions that began before the infant was 6 months old were included, provided outcomes were reported during the infant's first 24 months of life. Studies of uptake of recommended vitamin and mineral supplementation were included, but not studies of effectiveness or dosage of vitamins, minerals or micronutrients, nor of fortification. Studies of screening

interventions were excluded as were any studies on obesity. The interventions of interest were those promoting: timely introduction of appropriate supplementary feeds/solids; introduction of appropriate family foods; continuation of breastfeeding after 6 months, especially after the mother had returned to paid employment; diet (of the child) to reduce food allergies and intolerance; and dental health

### **Outcomes of interest**

Appropriate outcomes were included depending on the intervention examined. These included: dietary intake; nutrient and micronutrient intake; nutrient status; breastfeeding duration beyond 6 months; appropriate provision of foods by mothers; for example, milk, meat and fruit; uptake of recommended dietary and micronutrient supplements.

### **Data sources**

The following databases were searched to identify relevant systematic reviews: Cochrane Library: Cochrane Database of Systematic Reviews; DARE <http://www.york.ac.uk/inst/crd>; National Research Register (including CRD Ongoing Reviews) [http://www.update-software.com/National/Health Technology Assessment Database](http://www.update-software.com/National/Health%20Technology%20Assessment%20Database) <http://www.york.ac.uk/inst/crd>; SIGN Guidelines <http://www.sign.ac.uk>; National Guideline Clearinghouse <http://www.ahcpr.gov/clinic/assess.htm>; National Coordinating Centre for Health Technology Assessment <http://www.hta.nhsweb.nhs.uk>; NICE web pages (published appraisals) <http://www.nice.org.uk/nice-web/>; HSTAT <http://text.nlm.nih.gov/>; The Department of Health Research Findings electronic Register; TRIP <http://www.tripdatabase.com>; Clinical Evidence <http://www.clinicalevidence.com/cweb/conditions/index.jsp>; Health Evidence Bulletins Wales <<http://www.uwcm.ac.uk/uwcm/lb/pep>>

Where no relevant reviews exist, a search for RCTs was conducted (from 1990 onwards). The following databases were searched: CENTRAL; EMBASE; PsycINFO; CINAHL and MEDLINE

### **Data extraction and quality assessment**

Two reviewers independently screened all titles and abstracts identified in the literature search. Full paper copies of those papers believed to be relevant were obtained and independently assessed by two reviewers. Any disagreements regarding whether or not a paper met the inclusion criteria were resolved in consultation with a third reviewer.

All of the studies that met the inclusion criteria were critically appraised by two reviewers in accordance with criteria described in NICE (2006). A study was given a 1 or 2 based on its design and graded using a code ‘++’, ‘+’ or ‘-’, based on the extent to which the potential sources of bias had been minimised. If there was any discrepancy in a grade given to a study by the two reviewers, the opinion of a third reviewer was sought.

### **Key research questions**

Evidence is presented to answer the following questions:

1. What interventions effectively promote the timely introduction of appropriate solid/family foods?

2. What interventions effectively promote uptake of recommended vitamin and micronutrient supplements?
3. What dietary strategies effectively reduce the risk of food allergies and intolerance?
4. What dietary interventions help prevent diet-related dental caries in infants and young children?
5. What interventions effectively help mothers continue breastfeeding after 6 months, both at home and out of the home, for example, during return to paid employment?

## Results

### **What interventions effectively promote the timely introduction of appropriate solid/family foods?**

There was limited data found to answer this question. Two relevant systematic reviews were identified. The first by Elkan et al (2000) (2+) examined the effectiveness and cost-effectiveness of home visiting by health visitors, and the second by Tedstone et al (1998) (2++) examined interventions designed to promote healthy feeding of infants under one year of age. Unfortunately, many of the studies identified by these reviews were either of little relevance or were of poor quality. Both the Tedstone review and the Elkan review conclude that there are insufficient high quality studies to draw firm conclusions for policy. Nevertheless some relevant evidence can be described. A randomised trial to evaluate home visits in the USA during the first three years was rated 1+ and was suitable for producing an evidence statement (Gutelius et al 1977). In this study the intervention group received intensive home visits: 9, 6 and 4 home visits in the 1st, 2nd and 3rd years of life, respectively. These visits were for a minimum of one hour and were undertaken by a paediatrician or nurse. The study found that these intensive home visits had a positive effect on feeding when compared to a control population that did not receive the intervention. Among the indicators measured, it significantly improved daily milk intake, self feeding and meat intake.

#### **Evidence statement 1**

Of four relevant studies included a 2+ systematic review, only one (a 1+ RCT) was of sufficient quality. It found intensive home visiting by a health professional significantly improved daily milk intake, self-feeding, fruit or fruit juice and meat intake in children under 3 years whose mothers were unmarried, low-income, black school girls (15-18 years).

A second study of health visitors was undertaken in Dublin (Johnson et al 1993). This study has been given a 2+ rating by this review team. The study was considered in the Elkan review and the Tedstone review. The two reviews differed in their assessment of the quality of this study with the Elkan review giving the study a lower quality rating which appeared to be mainly based on the study being curtailed earlier than intended due to lack of funding. In Johnson's study, the study population were first time mothers of disadvantaged infants. The intervention group received monthly visits by non-professional 'community mothers' for the infant's 1st year of life. Each

community mother had 4 weeks' training and worked under the guidance of a family development nurse. The controls got routine care which was a visit at birth, at 6 weeks and then as required by the public health nurse. The two groups were assessed at 1 year using a dietary recall method. The study found that for a number of dietary recommendations, the intake of the intervention group was better than the control group, these included intake of milk, fruit and vegetables and whole foods. In addition infants in the control group were significantly more likely to be given cows milk before 26 weeks.

### **Evidence statement 2**

One 2+ study included in a systematic review by Tedstone et al, found monthly visits by 'community mothers' significantly improved dietary intake of animal protein, non-animal protein, whole foods, milk, fruit and vegetables in infants under one-year of age from low-income families in Dublin.

A large randomised trial undertaken in Finland that was given a 1+ rating was also included in the Tedstone review (Lapinleimu et al 1995). This study used intensive health education with specific counselling to reduce dietary fat. The aim was for participants to obtain 35% of their energy from fat, 15% from protein and 55% from carbohydrates. The study was successful in reducing the total intake of dietary fat but this outcome was noted by Tedstone as not being in line with UK recommendations for infants of this age group.

### **Evidence statement 3**

A large 1+ RCT included in a systematic review by Tedstone et al, found specific dietary counselling and health education conducted in a health clinic reduced serum lipids and cholesterol levels in both boys and girls up to the age 36 months (significant only for boys) and was successful in reducing dietary intake of fat, saturated fat in both girls and boys up to age 36 months.

## **What interventions effectively promote uptake of recommended vitamin and micronutrient supplements?**

No studies were found that specifically addressed this question. Three studies undertaken in the UK were identified that had evaluated ways to improve iron and vitamin C status. The aim of these studies was to evaluate ways to reduce anaemia. The studies varied in size and quality but each were undertaken in communities that were predominantly Asian. In a 1+ RCT 455 completed the study (Childs et al 1997), whereas a 1- RCT had only 69 participants (McEneaney et al 1986), and a 2+ study also had a small number of participants (Griffiths et al 1995).

Each of the studies evaluated health visits and health education classes that were designed to be sensitive to the needs of the participants. The intervention group in the Child's study received home visits from health visitors at 3, 6 and 9 months with the focus being on improving intakes of vitamin C and iron rich foods and the control group received normal current practice. At 18 months of age, the haemoglobin and iron content of the diet was measured in both groups and was found to be similar. The two smaller studies also reported no significant differences.

**Evidence statement 4**

Two RCTs, a 1+ study and a 1- study, and one 2+ non-RT reported in a systematic review by Tedstone et al (1998), evaluated three different interventions including home visiting by health visitors and health education. The studies found no effect on the incidence of anaemia in children under 18 months of age from predominantly Asian low-income families living in the UK.

**What dietary strategies effectively reduce the risk of food allergies and intolerance?**

Three randomised control trials were identified that were relevant for answering this question. A 1+ study undertaken in Finland with mothers with at least one first degree relative (or partner) with atopic eczema, allergic rhinitis or asthma evaluated the effectiveness of probiotics in preventing early atopic disease (Kalliomaki et al, 2005). Women in the intervention group received 2 capsules of Lactobacillus GG daily for two weeks prior to birth. After delivery, breastfeeding mothers either took the capsules or gave them to their children for 6 months, in which case the capsule contents were diluted with water and given with a spoon. The control population were given a placebo. The children were examined at 3, 6, 12, 18 and 24 months. The proportion of children in the intervention group with atopic eczema was significantly less at 24 months and was also less at four years follow-up than children in the control population. The intervention did not significantly change other indicators of atopic disease.

**Evidence statement 5**

A single RCT (a 1+ study) found giving two capsules of  $10^{10}$  Lactobacillus GG daily for two weeks prior to delivery and postnatally for six months to breastfeeding mothers, or giving infants the capsule contents diluted with water, significantly reduced the incidence of atopic eczema in children up to 4 years of age from atopic families, whether capsules were given to the breastfeeding mother or infant. There were no significant differences in other indicators of atopic disease.

A 1+ RCT undertaken in the UK (Arshad et al 1992, Hide et al 1994) recruited infants from families with a family history of atopic disease and evaluated a multi intervention strategy to reduce allergies. The control group had a normal diet and did not receive any part of the intervention. The intervention group received a dual approach: breastfeeding mothers avoided allergenic foods (milk, egg, fish and nuts) and infants' diets were free of dairy, egg, wheat, unhydrolysed soya, orange, fish and nuts up to 12 months. Up to 9 months, breastfeeds were supplemented if necessary with a soya-based protein hydrolysate. Formula fed infants received this from birth. Cow's milk and soya were introduced at 9 months, wheat at 10 months, and egg at 11 months. A dietitian explained the dietary restriction in detail to all intervention mothers at birth. Written instructions were also given to mothers with a list of foods to take.

In addition, the infants' bedrooms and living rooms were treated with an acaricidal powder and foam (benzyl benzoate, a chemical agent used to kill mites) in the first week of life and then every 3-9 months, and all infants used polyvinyl-covered mattresses with vented head area.

The intervention group and control group were tested by a blinded allergy specialist at 12 and 24 months. At 12 months the control population had significantly more eczema, food intolerance and asthma. At 24 months the control population had significantly more allergic symptoms and eczema but the difference in asthma was no longer statistically significant. In addition to the difference between the two groups two other risk factors for developing allergies were identified. These were parental smoking and low income.

#### **Evidence statement 6**

A single RCT ( a 1+ study) with multiple interventions including, reduced exposure to allergens in food for breastfeeding mothers and infants, and a reduced exposure to house dust, reduced the frequency of allergic disorders in infants at twelve months with a family history of atopy. Parental smoking was a significant risk factor for total allergy at 12 months ( $p < 0.05$ ). Infants from low socio-economic groups had a higher risk of developing allergy than those from a higher socio-economic group ( $p < 0.05$ ).

A 1- RCT which was reviewed and found to be under powered, compared the allergy preventive effect of extensively and partially hydrolysed cows' milk formulas compared with a regular formula (Oldaeus et al 1997). The study recruited pregnant women who were at a high risk of having an infant that would develop significant atopic disease. All participants had no cows' milk during the first nine months of life and no egg or fish up to 12 months of age. Breast feeding mothers avoided the same foods. At weaning, the infants were randomised to one of the formula groups. At 18 months the cumulative incidence of atopic symptoms was found to be 51%, 64%, and 84% in the extensively, partially, and regular groups, respectively. From 6 to 18 months there were significantly less cumulative atopic symptoms in the extensively hydrolysed group compared with the regular group. At 9 months significantly fewer infants in the extensively hydrolysed group (10%) than in the partially hydrolysed group (33%) had a positive skin prick test to eggs. The findings support an allergy preventive effect of an extensively hydrolysed formula, but not of a partially hydrolysed formula, during the first 18 months of life of high risk infants.

#### **Evidence statement 7**

One RCT (a 1- study) compared extensively hydrolysed casein formula, partially hydrolysed whey formula and standard infant formula from the start of weaning to age 9 months in infants with a family history of atopy. Allergy preventive measures were also recommended including discouraging smoking and dietary exclusion of cow's milk, eggs, fish and citrus fruits in both mothers and infants diets. The study found hydrolysed casein formula had a positive allergy-preventive effect during the first 18 months of life but not partially hydrolysed whey formula when compared to standard infant formula.

## What dietary interventions help prevent diet-related dental caries in infants and young children?

The evidence for dietary prevention of dental caries was derived from the evidence used by the Scottish Intercollegiate Guidelines Network to produce their 2005 national guidance for pre-school children in Scotland (SIGN 2005). In the evidence table produced for this review, additional data from the original papers that were not presented in the SIGN document have been added. This was done to enable clear linkage of an evidence statement and the source data.

Dental dietary advice to reduce the consumption of sugar is appropriate for this age group but for infants there is also a specific area of concern. This is the development of early onset dental caries which has also been called 'bottle caries' and 'early childhood caries'. This early onset of caries is thought to occur when sweetened liquids are left to pool inside the infant's mouth. This issue is important when considering breast feeding and the use of drinks in feeding cups.

A systematic review by Valaitis et al (2000) (graded 2+) investigated the relationship between early onset caries and breastfeeding. Of 28 relevant articles identified, none were rated as strong, three were moderate, nine weak and 16 very weak. The authors believed that a lack of methodological consistency and inconsistent definitions of early caries and breastfeeding, make it difficult to draw conclusions. Moderate articles indicate that breastfeeding for over one year and at night beyond eruption of teeth may be associated with early caries but there are conflicting findings in less rigorous research studies. The authors therefore concluded that no definitive time at which an infant should be weaned was determined, and suggest that parents should begin an early and consistent mouth care regime.

### Evidence statement 8

A systematic review (graded 2+) of 28 articles of varying quality, found no consistent high quality evidence of an association between breastfeeding beyond one year and the development of early dental caries.

A systematic review (graded 2+) of early caries which included an evaluation of the literature on bottle use, reports that the evidence of bottle use and caries risk is weak, and suggests that no recommendations can be made about either limiting bottle use to prevent caries or altering current recommendations about prolonged bottle use, or putting a child to bed with a bottle (Reisine and Psoter 2001). The authors note that many of the studies in the literature rely on samples of convenience and retrospective reports of weaning to evaluate the relationship between feeding practices and caries risk. Current advice is to limit bedtime use of feeding bottles and the SIGN review recommends that parents and cares should not put drinks containing free sugars into feeding bottles (SIGN 2005). A large cross sectional survey ( a 2+ study) in Australia examined 3,375 four to six-year-old children in a school based setting using 'decayed missing and filled teeth' indices (dmft's) and gave their parents a self-administered questionnaire to obtain information regarding social background and past infant feeding practice (Hallett et al 2002). The study found significant associations between ethnicity other than Caucasian, language other than English, sweetened bottle contents, going to sleep with the bottle and sipping from the bottle during the day, and the onset of early dental caries.



**Evidence statement 9**

An Australian cross sectional survey ( a 2+ study reported in a 2+ systematic review) of infant feeding including dental examination of 3,375 children analysed using a stepwise regression model found significant associations between reported use of sweetened drinks in bottles, going to sleep with a bottle and sipping from a bottle during the day and early childhood dental caries.

**What interventions effectively help mothers continue breastfeeding after 6 months, both at home and out of the home, for example, during return to paid employment?**

A number of studies have been identified that examine interventions that aim to increase the duration of breastfeeding (these are included in the 0-6 month review). Only one study specifically aimed to support breastfeeding in women who planned to return to paid employment. This study was given a minus rating and no evidence statement was derived (Jones et al 2004)

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