



## Formula feed preparation: helping reduce the risks; a systematic review

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## ORIGINAL ARTICLE

## Formula feed preparation: helping reduce the risks; a systematic review

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**Aims:** To assess what is known about the risks associated with errors in reconstituting the present generation of infant formula feeds, and to examine which methods are likely to be safest.

**Methods:** Systematic review, and examination of the range of infant formula products currently on sale in the UK. Studies from developed countries conducted after 1977 were included. All studies investigating the reconstitution of formula feeds for full term, healthy babies were eligible. Parameters studied were: measures of accuracy of feed reconstitution including fat, protein, total solids, energy content, and osmolality of feed; weight of powder in scoop; and reported method of preparing feed and measuring powder. Formula products were collected from one large UK supermarket in 2002. Number of different types of infant formula preparations available for sale were determined, together with scoop sizes for powdered preparations.

**Results:** Only five studies were identified, none of adequate quality or size. All found errors in reconstitution, with a tendency to over-concentrate feeds; under-concentration also occurred. Thirty one different formula preparations were available for sale in one UK supermarket, with a range of scoop sizes. Some preparations had never been tested.

**Conclusions:** There is a paucity of evidence available to inform the proper use of breast milk substitutes, and a large array of different preparations for sale. Given the impact incorrect reconstitution of formula feeds can have on the health of large numbers of babies, there is an important and urgent need to examine ways of minimising the risks of feed preparation.

Breast feeding is the safest way to feed babies. For the majority of babies in all countries it is a perfect source of nutrition<sup>1</sup> and is available, ready-to-feed, via a clean delivery system. Breast feeding protects against infection,<sup>2–4</sup> and has benefits for health in childhood and beyond.<sup>5–7</sup> National and international agencies recognise the superiority of breast feeding and support it unequivocally.<sup>1 8</sup> However, many babies in many countries are not breast fed.

In the UK, in spite of initiatives to encourage more women to breast feed their babies, and to do so for longer,<sup>9–11</sup> over the past 20 years there has been no real change in the proportion of babies who are breast fed at birth.<sup>12</sup> In 2000, by 4–10 weeks of age (the first stage of the most recent national survey), 75% of babies were either exclusively fed on formula milks, or were receiving a combination of breast and formula feeds.<sup>12</sup> These figures, which reflect infant feeding patterns in many westernised populations, highlight the fact that most babies in the UK are fed, wholly or in part, on breast milk substitutes. It is, therefore, important that while attempting to increase the prevalence and duration of breast feeding,<sup>9 13–15</sup> attempts should also be made to minimise the risks associated with artificial feeding.

The most common breast milk substitutes are formula feeds manufactured as dried powders, reconstituted by adding water. Wrongly reconstituted feeds may have serious consequences for babies and during the 1970s there was concern about the apparently high incidence of hypernatraemic dehydration complicating acute gastroenteritis.<sup>16–19</sup> These and other reports<sup>20–25</sup> suggested the problem was due to babies receiving dangerously high solute feeds, in large part a consequence of mothers preparing over-concentrated feeds. Since these studies were carried out, however, there have been changes in the composition of formula milks. National Dried Milk was withdrawn in 1977 and the use of similar formulae based on unmodified dried or evaporated milk is no longer recommended.<sup>26</sup> All infant formulae marketed in the UK now

have to comply with compositional guidelines published by the Department of Health, drawn up to ensure artificial feeds are as close in formulation as possible to human milk.<sup>27</sup> There have also been developments in the ways in which formulae are marketed and sold. For example, parents can now buy formula milk as ready-to-feed preparations and in premeasured sachets.

In contrast to the attention received by hypernatraemic dehydration associated with unsuccessful breast feeding,<sup>28 29</sup> there appears to have been no further investigation of this issue in developed countries in the past two decades, although the problem continues to receive attention in developing countries.<sup>30</sup>

The aim of this review is to assess and update what is known about the risks associated with errors in reconstituting the present generation of infant formula feeds, and to examine which methods are likely to be safest.

## METHODS

A systematic review was carried out in which relevant studies were identified, analysed, and summarised. To establish the context for the review, we also examined the range of products on sale in one large UK supermarket.

### Systematic review

#### Inclusion criteria

Studies carried out in developed countries for which data were collected after 1977 were included. All studies investigating the reconstitution of formula feeds for full term, healthy babies were eligible for inclusion, regardless of study design. No quality criteria were introduced as so few studies were identified. Non-English citations were included, but studies carried out in developing countries were excluded, as the issues are different in such dissimilar settings.

**Table 1** Studies fulfilling the criteria\* for this review

Study	Design	Setting	Participants	Samples analysed	Outcome measures
Jacob, 1985 <sup>31</sup>	Interview	UK	30 mothers living in catchment area of five CHCs	–	Reported method of preparing feed and measuring powder
McJunkin <i>et al</i> , 1987 <sup>32</sup>	Interview; reconstituted milk samples analysed	USA	175 mothers attending one urban CHC	133 reconstituted feeds provided by mothers	Fat, protein, and total solids content of feed
Lilburne <i>et al</i> , 1988 <sup>33</sup>	Interview; reconstituted milk samples analysed	Australia	272 mothers attending 19 CHCs	34 reconstituted feeds provided by mothers and unknown number of reconstituted feeds prepared in hospital kitchen	Reported method of preparing feed and measuring powder; osmolality of feeds
Jeffs, 1989 <sup>34</sup>	Dry milk powder measured from an open packet with product's own scoop	UK	28 mothers attending two CHCs	84 scoops of dry powder measured by mothers	Weight of powder
Lucas <i>et al</i> , 1991 <sup>35</sup>	Reconstituted milk samples analysed	UK	19 mothers included in a randomised trial of ready-to-feed and powdered formula	Median of 5 (range 3–6) reconstituted feeds provided by each mother	Energy content of feed

\*Eligibility criteria given in text.  
CHC, child health clinic.

### Literature search

Two authors (KLM and PA) independently searched for articles from Medline (1966 to April 2002), Cinhal (1966 to April 2002), Web of Science, and the Cochrane Database of Systematic Reviews, with identical results. A broad search strategy was used, initially for the mesh word "bottle feeding" and its variants, which identified 2268 references; 150 of these were broadly related to bottle feeding and formula preparation, and a further 83 were subsequently identified from the reference lists of relevant studies. It was possible to exclude a number of papers by reviewing the abstracts; all those that could not be clearly excluded were retrieved and reviewed, together with all studies that appeared eligible.

As this strategy produced only three eligible studies, further searches were carried out in Medline using the key words "feed\*", "fed", "artificial" "formula\*", "milk\*", "infant", "baby", "reconstituted\*", "scoop\*", "dehydration", "hypernatraemia", and "gastroenteritis". This yielded one additional paper, plus a letter reporting findings on the reconstitution of powdered formula from the pilot phase of an investigation of formula feeding and infant growth. Table 1 summarises key attributes of the papers.

### RESULTS

The five studies fulfilling our review criteria were published between 1985 and 1991.<sup>31–35</sup> No eligible studies published later than 1991 were found. An additional nine investigations published between 1972 and 1979<sup>17–25</sup> were identified, plus 138 articles that were either commentaries on the subject or were studies of related topics.

#### Quality of the included studies

Participants in four of the eligible studies were mothers of artificially fed babies who had been selected or identified through routine child health or welfare clinics<sup>31–34</sup>; those in the fifth<sup>35</sup> were bottle feeding mothers recruited from a postnatal ward for a randomised trial of ready-to-feed and powdered formula.<sup>36</sup> The numbers of participants in each study varied considerably (table 1). The three smallest studies were from the UK and had only 30, 28, and 19 participants respectively.<sup>31 34 35</sup> Of the two larger studies, that by Lilburne and colleagues<sup>33</sup> was most representative of the wider population of mothers with young babies. It recruited and interviewed 272 mothers from 19 clinics in two areas of Australia, selected because of their different characteristics (one area described as predominantly working class, the other as middle class), although unfortunately only 34 samples of

reconstituted feed were obtained for analysis.<sup>33</sup> The remaining study, by McJunkin *et al* in the USA,<sup>32</sup> enrolled 175 urban mothers and obtained 133 feed samples: 95% of the mothers included were black and on low incomes, with more than half entitled to free infant formula or receiving food stamps.

All five were descriptive studies but they varied in many other respects, with different designs and different outcome measures (table 1). Of the four main studies, one interviewed mothers about their feeding practices<sup>31</sup>; one interviewed mothers and analysed samples of reconstituted feed provided by the mothers<sup>32</sup>; one interviewed mothers and analysed and compared samples of feed provided by mothers and prepared in a hospital kitchen<sup>33</sup>; and one weighed dried milk powder measured by mothers with a scoop supplied with the product.<sup>34</sup> All these studies were concerned with the reconstitution of dried milk powder, measured with the product's own scoop; only the study by McJunkin and colleagues<sup>32</sup> included ready-to-feed and concentrated liquid preparations. The fifth study<sup>35</sup> was part of the pilot phase of a small, randomised trial comparing ready-to-feed and powdered formula, the outcomes of the main study being measures of infant growth such as body weight and head circumference.<sup>36</sup> Only mothers of babies given powdered formula were included in the investigation of formula preparation: it measured the energy content of reconstituted milk samples using potassium content as a marker of feed strength.<sup>35 36</sup>

#### Findings of the review

It is difficult to interpret the results of any of these studies with confidence as a result of their methodological problems and small size. However, they all found errors in reconstitution with a tendency to over-concentrate feeds, although under-concentration also occurred.

#### Products available to parents

An extensive array of infant formula feeds is available in the UK. Table 2 lists those currently sold (April 2002) in one major supermarket as suitable for normal newborns. Of the 14 products, 11 were cows' milk formulae (five whey dominant, five casein dominant, one 100% whey protein) and three were soya based products. Many of these formulae come as ready-to-feed preparations and/or in premeasured sachets, as well as in traditional powder and scoop formulations, leaving parents, and their advisers, to choose between 31 different preparations. Of the 11 cows' milk preparations in powder and scoop form, there were seven different scoop sizes, ranging from 4.0 to 5.0 grams (table 3). In three cases, the same brand had three different scoop sizes.

**Table 2** Infant formulae on sale in one large supermarket chain in the UK, April 2002

Formulae	Type of formulation			
	Ready to feed*	Simplified system†	Premeasured sachets‡	Powder and scoop§
Cows' milk, whey dominant				
Aptamil First	✓	—	—	✓
Cow & Gate Premium	✓	—	—	✓
Farley's First	✓	✓	✓	✓
Hipp Organic Infant	—	—	✓	✓
SMA Gold	✓	—	✓	✓
Cows' milk, casein dominant				
Aptamil Extra	✓	—	—	✓
Cow & Gate Plus	✓	—	—	✓
Farley's Second	✓	✓	✓	✓
Milumil	✓	—	—	✓
SMA White	✓	—	✓	✓
Cows' milk, 100% whey protein				
Cow & Gate Omneo Comfort 1	—	—	—	✓
Soya based				
Farley's Soya Formula	—	—	—	✓
Infasoy (Cow & Gate)	—	—	—	✓
SMA Wysoy	✓	—	—	✓

\*0.5–1 litre cartons and/or individual ready made feeds.

†Mixing equipment plus premeasured sachets of dry powder to make up around one pint (0.56 litre) of reconstituted formula.

‡Each sachet of dry powder sufficient to make up one feed—feed size varies between brands.

§Large carton of dry powder and measuring scoop—scoop size varies within and between brands.

## DISCUSSION

The most striking finding from this review is the paucity of information on a topic important to the health of large numbers of babies worldwide. In the UK alone, 31% of babies are fed breast milk substitutes from birth, and this number increases to around 79% by the time babies are 6 weeks old.<sup>12</sup> Hundreds of thousands of babies each year in the UK, and many more worldwide, are completely dependent on the proper use of these products, yet we found no previous reviews on the reconstitution of feeds and only five relevant studies. All found that errors were made when reconstituting feeds, although none considered the wide range of products currently available.

The World Health Organisation Code on the marketing of breast milk substitutes, adopted in 1981,<sup>37</sup> aims to “contribute to the provision of safe and adequate nutrition for infants, by the protection and promotion of breast feeding”, and by “the proper use of breast milk substitutes, when these are necessary ...” (Article 1). However, since then, little attention has been paid to the second part of the Code's aim, either in practice or in research. In the UK in 2000, for example, of first time mothers attending antenatal classes and who intended to fully formula feed, only 9% were taught how to make up a bottle,<sup>12</sup> and the National Audit Office report on the maternity services in 1997 did not consider artificial feeding at all in its examination of antenatal or postnatal care.<sup>38</sup>

Many of the new infant formulae are intended to reduce error although, paradoxically, they could have the opposite

effect—for example, if a parent wishes to prepare a six ounce feed using premeasured four ounce individual sachets, one sachet might be used, plus an estimated half of another, potentially yielding more error than with traditional powder and scoop. The ways in which such sachets are actually used do not appear to have been investigated. Additionally, ready-to-feed preparations are expensive, and could result in a baby being given less feed than needed, or the feed being diluted with water or other liquids such as tea—a suggestion that the latter occurred was found in the study of low income mothers by McJunkin and colleagues.<sup>32</sup> Without studies designed to examine such issues, it is impossible to advise either parents or health professionals on the relative merits of individual products.

The potential for harm resulting from over- or under-concentration of feeds is serious and includes both obesity and failure to thrive, as well as hypernatraemic dehydration.<sup>16–19</sup> Furthermore, babies most likely to be artificially fed in westernised populations are those who come from lower socioeconomic groups<sup>12</sup>; these babies already suffer increased morbidity<sup>39</sup> and their parents are those least likely to be able to afford the expensive ready-to-feed preparations. The price variation between products is considerable, with ready-to-feed preparations two or three times more expensive than powder and scoop (table 4). There is no unbiased source of information to help either parents or their advisers choose between brands, and between different ways of reconstituting

**Table 3** Variation in scoop sizes\* in and between brands of powdered formula milk

Brand	Scoop sizes (g)
Cow & Gate	4.3, 4.4, 5.0
Farleys	4.1, 4.4, 4.5
Hipp	4.5
Milupa	4.3, 4.6, 5.0
SMA	4.0 (assumed)

\*Scoop sizes from products sold in one large supermarket chain in the UK, April 2002.

**Table 4** Price ranges\* of infant cows' milk formulations

Type of formulation†	Price (pence per 100 ml feed)
Powder and scoop	7.9–12.5
Premeasured sachets	9.3–19.5
Simplified system	9.4
Ready-to-feed (largest carton)	19.8–19.9
Ready-to-feed (individual feed)	22.5–29.5

\*Price ranges of products sold in one large supermarket chain in the UK, April 2002.

†See footnotes to table 2.

feeds. Health professionals, like parents, have to rely on information produced by product manufacturers.

This review did not include issues related to the safety of breast milk substitutes in developing countries. Although many issues are similar, in developing countries there are additional risk factors to consider—for example, transport and availability of products, lack of clean water, the cost of artificial substitutes, and a lack of appropriate feeding equipment, manufactured to required standards. These are fundamentally important issues, especially in the light of the potential for HIV transmission through breast feeding,<sup>40</sup> and the numbers of babies who need to be artificially fed as a result of their mother's illness or death. In the search for papers for this review, we identified only one paper related to feed reconstitution in a developing country context, indicating that the lack of evidence base is just as profound as in the western world.<sup>41</sup> A full and proper assessment of the various risks associated with the use of breast milk substitutes is needed to inform this debate.

### Further research

It is important to continue looking at ways to support women in initiating and maintaining breast feeding, enabling mothers to breast feed their babies for as long as they wish.<sup>8,9</sup> In addition, however, it is important to minimise the risks associated with breast milk substitutes. Specifically, parents need to know which ways of giving their babies formula feeds are the simplest, most accurate, and cost effective. It is important to identify the outcomes as well as the sources of error in making up feeds—what contribution do they make to infant mortality and morbidity?

### Recommendations

The range of ways in which manufacturers package and sell breast milk substitutes needs to be examined; they themselves recognise that risks are introduced in the reconstitution of their products.<sup>42</sup> Some consistency in approach would be a step forward, perhaps moving towards uniform instructions and scoop sizes for the reconstitution of all products and brands. This would avoid confusion for parents when changing from one product to another,<sup>12</sup> and help health professionals teach parents how to make up feeds more accurately.

A source of unbiased information is needed to inform parents and health professionals about the differences between the available formulae, including the different forms in which they are sold. In the UK there is an important role in this regard for both the Food Standards Agency and the Department of Health.

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Contributors: The review was initiated by MJR; MJR and PA were involved in all its aspects. KLM contributed to early discussions, the identification and analysis of studies, and drafting of the paper. MJR and PA act as guarantors.

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