

Cleaning and sterilisation of infant feeding equipment: a systematic review

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Submitted 3 August 2007: Accepted 14 December 2007: First published online 26 February 2008

Abstract

Aim: To assess the clinical and cost-effectiveness of different methods of cleaning and sterilisation of infant feeding equipment used in the home.

Design: Systematic review of studies from developed countries on the effectiveness of methods of cleaning and sterilisation of infant feeding equipment used in the home. A brief telephone survey of UK-based manufacturers of infant feeding equipment and formula to ascertain the evidence base used for their recommendations, and a comparison of current relevant guidelines in developed countries, informed the work.

Results: National guidelines from six countries demonstrated variation and lack of evidence to support current guidance. Manufacturers did not report evidence of effectiveness to support their recommendations. Nine studies were identified; eight conducted between 1962 and 1985 and one in 1997. All had methodological weaknesses. Hand-washing was identified as fundamentally important. Health professionals were reported as not providing appropriate education on the importance and methods of cleaning and sterilisation. Mothers of subsequent babies and women from lower socio-economic groups were less likely to follow recommended procedures.

Conclusion: There is a lack of good-quality evidence on effective ways of cleaning and sterilising infant feeding equipment in the home. The evidence base does not answer the question about which of the methods in common use is most effective or most likely to be used by parents. Hand-washing before handling feeding equipment remains important. Further research on the range of methods used in the home environment, including assessment of the views of parents and carers, is required.

Keywords
Bottle feeding
Infant nutrition
Infant formula
Infection
Sterilisation
Systematic review

In the UK and many other Western countries, breast-feeding rates fell throughout the first half of the 20th century and remain at low levels. Over the past decades, work conducted to raise the rates of breast-feeding has met with some success^(1,2), but serious problems remain internationally as highlighted in the second Innocenti Declaration on the protection, promotion and support of breast-feeding⁽³⁾. In the UK around 24% of babies will be formula-fed from birth, and by 6 weeks following birth 79% of babies will be fed exclusively or partially on infant formula⁽²⁾, with the highest rates of formula feeding among women of lower socio-economic status. The situation is similar in other Western countries including the USA⁽⁴⁾, while in other countries, including China, previously high breast-feeding rates are declining rapidly⁽⁵⁾. Worldwide, many millions of babies will be fed breast milk substitutes, usually by use of a plastic bottle

and teat. The health consequences of this are enormous, and result in increased mortality and morbidity in both developed and developing countries^(6,7).

Risks to the baby from formula feeding not only include the intrinsic nutritional and immunological deficiencies of formula compared with breast milk. They also include risks that could potentially be reduced, such as errors in the manufacturing process, contamination during storage and transport⁽⁸⁾, errors in reconstitution of infant formula in the home⁽⁹⁾, and ensuring effective cleaning and sterilisation of the equipment used.

Article 1 of the WHO Code on the Marketing of Breastmilk Substitutes endorses 'the proper use of breastmilk substitutes, when these are necessary, on the basis of adequate information'⁽¹⁰⁾. What are the evidence-based ways of ensuring the 'proper use' of such substitutes? Unlike the evidence base for the promotion and

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support of breast-feeding, which has been strengthened considerably in recent decades⁽¹¹⁻¹³⁾, the evidence base for reducing the risks of formula feeding seems to be scanty. It is not clear from the epidemiological literature what proportion of common diseases such as gastro-enteritis is an inevitable consequence of the use of a product of lower quality than breast milk and what proportion could be prevented by improved practice. One recent study⁽⁷⁾ has suggested that, in formula-fed infants, there was significantly more diarrhoeal disease in those infants whose carer did not sterilise bottles and teats with steam or chemicals, particularly in infants under 6 months of age (adjusted OR = 9.13; 95% CI 1.17, 71.39; $P = 0.012$). No information was available, however, on the relative effectiveness of the different methods being used.

Milk is the perfect medium for growth of bacteria, and therefore poorly cleaned feeding equipment can be a potent source of infection for babies⁽¹⁴⁾. The organisms of most concern are reported to be *Salmonella*⁽⁸⁾ and *Enterobacter sakazakii*^(8,15). To reduce contamination with these organisms, the Food Standards Agency and Department of Health in England have recently recommended that formula feeds are made up using boiled water that is $>70^{\circ}\text{C}$ (water that has been boiled and left to cool for no more than 30 min) and that formula is made up fresh for each feed⁽¹⁶⁾. A report by the European Food Safety Authority (EFSA)⁽⁸⁾ concluded that cleaning and sterilisation of equipment in the home is a critical part of the avoidance of infection; recommendations include the use of 'sterile bottles, achieved by heating and chemical methods', although no evidence is provided on the relative effectiveness of these methods. The recent WHO guidelines published in 2006 and updated in 2007⁽¹⁷⁾ are consistent with the EFSA recommendations and suggest that manufacturer's instructions should be followed for chemical or steam sterilisation procedures. These guidelines are stated (p. 2) to be 'largely based on the findings of a quantitative microbiological risk assessment for *Enterobacter sakazakii*'. Effective cleaning and sterilisation of infant feeding equipment offers the opportunity to minimise risks to the baby and could result in significant clinical and cost benefits⁽¹⁸⁾.

Various methods of cleaning and treating infant feeding equipment are used internationally (Table 1). Potential problems in using these methods routinely include cost, the time-consuming and complex nature of some methods, confusion over the length of time equipment should be boiled, left to soak or left in the microwave, whether or not equipment left to soak in hypochlorite should be rinsed, and how equipment immersed in boiling water or hypochlorite should be removed and dried. Such confusion, expense and the time needed may result in a lack of compliance. It is also not clear if basic hygiene measures such as hand-washing are seen by parents and carers as important in the face of more complicated approaches.

Table 1 Methods of cleaning or sterilising infant feeding equipment

Method	Description
Boiling	Placing equipment in a saucepan of boiling water
Chemical sterilisation	Use of a hypochlorite solution into which the feeding equipment is placed
Electric steam steriliser	This is a container with a hotplate set into the base. The equipment is stacked into a designed plastic basket; a small amount of water is added to the base and the unit closed by a lid. The directly heated unit then boils the water until all of it has vaporised, then switches itself off. The items to be sterilised are surrounded by steam, which kills the bacteria only if the equipment has the closed end facing upwards
Microwave steriliser	Feeding equipment is placed in a basket with a lid. Water is added to the base of the unit and placed in the microwave; the water boils by the action of the microwave energy
Dishwasher	Feeding equipment is placed in the rack of the dishwasher and the cycle run as normal

Furthermore, use of dishwashers has been implicated in the release of plasticisers following a relatively small number of washes^(19,20). It is not surprising, therefore, that there is variation in the information and advice given by health professionals. One survey conducted in Scotland found that, before the birth of their baby, only 40% ($n = 25$) of women considering bottle feeding had been given any information on sterilising equipment⁽²¹⁾. It is essential to maximise the opportunities for women to breast-feed, and it is also very important to offer opportunities for parents to learn about minimising the risks of formula feeding.

Preliminary work

Two brief investigations were undertaken to inform this review and to search for unpublished studies. First, UK-based manufacturers of infant feeding equipment and formula who made recommendations for cleaning and sterilising techniques in the literature accompanying their product were identified. The health advisor for each company was contacted by telephone by one of us (M.M.); all agreed to be interviewed. They were asked for information about the evidence base that informed their published recommendations. Responses are summarised in Table 2. Although two infant formula companies and two manufacturers of feeding equipment reported that they based their instructions on Department of Health guidelines or policy, at the time of the interviews (2003) no such guidelines existed on the cleaning and sterilisation of infant feeding equipment. No relevant studies were identified.

Second, we contacted the UNICEF Baby Friendly Initiative Co-ordinator in similar developed countries and requested copies of relevant national guidelines and information about the evidence base used. The results for these six countries are summarised in Table 3 and

Table 2 Responses to the survey of manufacturers of infant feeding formula and infant feeding equipment

Type of company	Evidence used to inform their recommendations	No. of companies
Manufacturers of infant formula (<i>n</i> 3)	Department of Health guidelines	1
	Manufacturers of the sterilisation equipment	1
	UK policy and expert advisor	1
Manufacturers of infant feeding equipment (<i>n</i> 7)	Department of Health guidelines	2
	British Standards	1
	Expert advisor	1
	Company carries out independent tests on the equipment to test the efficacy of sterilisation	3

demonstrate variation in whether sterilisation was recommended for all babies (UK, Ireland)^(22–24), only for those under 3 months of age (New Zealand⁽²⁵⁾, Norway⁽²⁶⁾, USA⁽²⁷⁾), or only on the recommendation of a health professional (Canada)⁽²⁸⁾. In the USA and Norway the use of a dishwasher was recommended as an alternative to sterilisation. There were also variations in the detailed instructions for cleaning teats (i.e. use of salt or not), and in whether bottles and teats sterilised by the chemical method should be rinsed before use. No international respondent was aware of any evidence of effectiveness informing the guidelines from their country.

The aim of the systematic review described in the present paper was to assess the clinical and cost-effectiveness of different methods of cleaning and sterilisation of infant feeding equipment used in the home.

Methods

Literature search

The first search was conducted in 2003 on the following databases: Medline, Embase, CINAHL, Psycinfo, British Nursing Index (BNI), Allied and Complementary Medicine, Premedline, Health Management Information Consortium (HMIC), EBM reviews, SIGLE and the Cochrane library database (which included CDSR, ACP Journal Club, CCTR and DARE). Electronic database searches were supplemented with hand searches of the references of selected papers, relevant policy documents and consultation with the key professionals and companies in this field. Grey literature and unpublished studies not recorded on SIGLE were identified by searching the National Research Register and the NHS Centre for Reviews and Dissemination database. A broad search strategy was used to identify all relevant literature, using the following keywords and Mesh terms: bottle\$, artificial feed\$, formula feed\$, infant feed\$, teat\$, sterili?\$, clean\$, wash\$, prepar\$, disinfect\$, saniti\$, hygien\$, breastfeeding, breast pump, germ free,

spotless, infection, uncontaminated. A second, structured search was run on Medline in 2006 which identified only one additional paper; the full search strategy is shown in Table 4.

Inclusion/exclusion criteria

No date limits were set on either search. The review included research studies from developed countries that examined methods of cleaning and/or sterilisation of infant feeding equipment, either in the home or applicable to home conditions, regardless of the research design used. Studies from developing countries were excluded, as the sterilisation and infection issues are different in such dissimilar settings.

Outcomes

Outcomes of interest included clinical outcomes in infants; results of microbiological tests of bottles and teats; behavioural outcomes for carers; and costs.

Data extraction

Data were systematically extracted by one reviewer (M.M. or A.M.) using pre-designed data extraction forms, and were checked by a second reviewer (M.J.R.). Included studies were assessed for quality using criteria published by the Centre for Reviews and Dissemination⁽²⁹⁾.

Results

Published literature

Of the 1520 references identified, only nine studies published in eight papers^(18,30–36) met the inclusion criteria; all but one⁽¹⁸⁾ were identified in the early search. The majority of the other citations were not research studies. No systematic reviews were identified. Details of the nine included studies are given in Table 5 and the quality of the included studies is summarised in Table 6. Eight were conducted between 1962 and 1987^(30–36) and one in 1998⁽¹⁸⁾. Three were conducted in the USA^(33,34,36) and six in the UK^(18,30–32,35). One was a randomised controlled trial⁽³⁴⁾, four were non-randomised controlled trials^(18,32,33,36), and four were surveys^(30–32,35). The number of participants ranged from twenty-six to 758 (median, sixty-three). No studies examined cost-effectiveness. All studies had serious methodological weaknesses.

Two studies examined infant morbidity related to the cleaning method used^(32,33). No significant difference in the incidence of infections or illness was identified, although no studies were of appropriate design or sufficient quality or size to answer these important questions.

The largest study⁽³⁰⁾, conducted in 1970, took place across four different geographical areas in the UK, each selected because of proximity to a public health

Table 3 Comparison of national guidelines for cleaning and sterilising infant feeding equipment

Country	Guidelines issued by	Guidelines for	Cleaning	Sterilisation recommended	Recommended methods of sterilisation and specific instructions	Additional recommendations
UK	Department of Health	Public	Clean bottles and teats in hot soapy water using a clean bottle brush. Squirting water through the teat will help remove every trace of milk	Yes	Chemical: follow the manufacturer's instructions. Change the sterilising solution every 24 h, leave equipment in the sterilising solution for at least 30 min, make sure there is no air trapped in the bottles or teats, keep all the equipment under the solution with a floating cover, before making up the feed, shake off any excess solution from the bottle and teat or rinse with cooled boiled water from the kettle Steam steriliser: follow the manufacturer's instructions, make sure the openings of the bottles and teats are face down in the steriliser, any equipment not used straight away should be re-sterilised before use	
USA	Department of Agriculture (USDA)	Health professionals	Equipment should be thoroughly cleaned using soap, hot water and bottle and nipple brushes	Sterilisation or dishwasher for babies <3 months old	Boiling: boiling water for 5 min Dishwasher: wash in a properly functioning dishwasher machine	After 3 months, unless otherwise indicated by a health-care provider, bottles should be thoroughly washed using soap, hot water and bottle and nipple brushes or cleaned in a dishwasher
Canada	Canadian Medical Association	Public	All feeding-related items should be washed in hot soapy water and thoroughly rinsed	All feeding equipment should be sterilised before first use, then check with a doctor	Boiling: items should be fully submerged, for five consecutive minutes, in water that is at a rolling boil	Use dishwasher-proof nipples (teats), when nipples are to be cleaned in a dishwasher
New Zealand	National Government Health Department	Public and health professionals	Clean bottles with a bottle brush in warm soapy water. Clean teats in warm soapy water and rub salt inside the teat and through holes to remove milk residue. Rinse bottles and teats well with running cold water, ensuring this is squirted through holes in teats	Yes, for babies <3 months	Boiling: boil the feeding and mixing utensils in a pot of water big enough to cover everything for 5 min. Use clean tongs to lift everything out and drain well and store in a clean dry place until required Chemical: completely immerse all items in a large plastic container with a lid. Make the sterilising solution according to the directions. Equipment must be fully immersed for 1 h. Drain bottles and teats well but do not rinse before use. Sterilising solution must be renewed every 24 h Follow the manufacturer's instructions if you use any of the following methods: Microwave – with a special microwave sterilising unit Steam steriliser	When the baby is older, thorough washing is enough
Norway	National Government Health Department	Public	Rinse and fill bottles/cups with cold water. Wash well, with a brush used only for bottles, in hot water with detergent. Rinse with as hot water as possible. Teats should be carefully cleaned	Yes, 'in first weeks'	Boiling: boil bottles and teats. Let the bottles/cups air-dry. Teats should also be boiled Dishwasher: use dishwasher if you have one	

Table 3 Continued

Country	Guidelines issued by	Guidelines for	Cleaning	Sterilisation recommended	Recommended methods of sterilisation and specific instructions	Additional recommendations
Ireland	UNICEF UK guidelines	Public (widely used by health professionals)	Wash all bottles and other equipment thoroughly in hot soapy water using a bottle brush. Scrub inside and outside the bottle. Pay particular attention to the rim. Use small teat brush to clean inside teat or turn inside out and wash in hot soapy water. If salt used, always rinse off completely. Rinse all washed equipment before sterilising	Yes, up to 1 year	Boiling: put equipment into pan filled with water. Make sure no air is trapped. Cover with lid and bring to boil. Boil for at least 10 min. Keep pan covered until equipment is needed Chemical: make up solution following manufacturer's instructions. Submerge equipment in the solution, making sure no air is trapped. Use plunger to keep equipment under water. Leave in solution for at least 30 min. If you rinse before using, use water that has been boiled and allowed to cool. Always wash hands before removing equipment from steriliser Steam or microwave: always follow the manufacturer's instructions Sterilise up to 1 year	
	Department of Health and Children, Health Promotion Unit	Public	Bottles and teats should be thoroughly washed after use	Yes, up to 1 year		

Table 4 Structured search strategy, 2006

1	bottle feeding/
2	(bottle\$ adj8 feed\$).ti.
3	(bottle\$ adj8 feed\$).ab.
4	(nursing adj2 bottle\$).ti.
5	(milk adj2 bottle\$).ti.
6	(teat or teats).ti,ab.
7	animal/
8	6 not 7
9	nipples.ti,ab.
10	(bottle\$ adj4 nipple\$).ti,ab.
11	10 not 7
12	bottle\$.ti,ab.
13	exp infant/ or infant, newborn/
14	exp infant/
15	12 and 14
16	feeding equipment.ti,ab.
17	1 or 2 or 3 or 4 or 5 or 8 or 11 or 16
18	(editorial or letter or comment).pt.
19	17 not 18
20	*dental caries/
21	19 not 20
22	disinfection/
24	microwaves/
25	sterilization/
26	clean\$.ti,ab.
27	(sterilis\$ or steriliz\$).ti,ab.
28	hygiene.ti,ab.
29	disinfect\$.ti,ab.
30	22 or 24 or 25 or 26 or 27 or 28 or 29
31	21 and 30
33	from 31 keep 1-38

laboratory. Methods used in the home differed across the four areas; these included the hypochlorite method alone (48%), boiling (30%), hypochlorite and boiling together (11%), and the remainder either used another method (not stated) or nothing (12%). Bottles and teats sterilised using the hypochlorite method had lower colony counts (bacterial count ≤ 5 : 63% (n 475) of bottles; 52% (n 395) of teats) when samples were tested in the laboratory. The majority of mothers who used the hypochlorite method lived in rural areas and also spent more time washing and sterilising the equipment. The majority did not carry out sterilisation procedures as recommended, in spite of the fact they had received health education in this field. Clegg *et al.*'s study in England in 1977⁽³¹⁾ found similar results.

The most recent study⁽¹⁸⁾ examined the effectiveness of commonly used cleaning and disinfecting procedures on the removal of enterotoxigenic *Bacillus cereus* from feeding bottles. This non-randomised experimental study was conducted in the laboratory, but included subjecting bottles to storage conditions which may occur in the home. The results showed that thorough cleaning reduced, but did not completely eliminate, all microbes. All of the three disinfection procedures tested (one chemical and two thermal) eliminated the organism at low levels of contamination ($<10^5$ organisms/ml) but the chemical method failed to eliminate *B. cereus* at potentially hazardous levels ($\geq 10^5$ organisms/ml) which may occur with improper use in the home.

Table 5 Summary of studies included in the present review

Study	Setting	Participants	Methods of preparation of infant feeding equipment	Data collection methods	Main findings
Hargrove <i>et al.</i> (1974) ⁽³³⁾ : non-randomised controlled trial	USA	26 babies selected from a hospital nursery representing a wide range of socio-economic levels	Intervention group (<i>n</i> 13): babies were fed formula prepared by the clean method – bottles and nipples (teats) were washed with hot soapy water and rinsed with hot running water. Bottles were filled immediately before each feed Control group (<i>n</i> 13): babies were fed formula prepared by terminal (not defined) sterilisation	Mothers recorded signs of illness in their baby; home visits to assess infant well-being, cleanliness of the home and preparation time; lab analysis of samples of unused formula	Clinical: no differences occurred in frequency of illness in the 2 groups Microbiology: 70% of each set of formula samples grew aerobic bacteria, whether prepared by the clean or sterilisation technique; 6 samples from the clean group and 5 from the sterilised group showed growth of coliform organisms High incidence of positive cultures occurred regardless of socio-economic background, housekeeping habits or method of preparation used Behaviour: women from the clean method group spent on average 10 min a day on preparation v. 30–45 min spent by the control group
Hughes <i>et al.</i> (1987) ⁽³⁴⁾ : randomised controlled trial	USA	284 bottle-fed infants and their mothers who delivered in a regional hospital; babies were full term	Group 1: mothers were individually taught the terminal method of formula preparation according to written guidelines (no further details given; the discussion indicates this is similar to 'traditional sterilisation') Group 2: mothers were individually taught the clean method of formula preparation according to written guidelines (no further details given: the discussion indicates is based on washing with hot water and soap) Number of participants assigned to each group not reported	Accident and emergency records reviewed for cases of gastroenteritis	Clinical: 11 (3.9%) cases of gastroenteritis were documented, 5 in the 'terminal' group and 6 in the 'clean' group No significant difference found between the method of formula preparation taught to mothers and incidence of gastroenteritis in their infants
Jacob (1985) ⁽³⁵⁾ : survey	UK	30 mothers with babies aged 5 months; 6 mothers were randomly selected from each of 5 child health clinics in catchment area	28 mothers sterilised bottles and teats using cold method ('soaking in a hypochlorite solution'); 1 used boiling technique; 1 did not use any method	Interviews with mothers	Behaviour: 14 (46.6%) mothers were sterilising 'correctly' and 16 (53.3%) were not Of those not sterilising 'correctly', 14 did not use salt to clean the teats, 5 did not use detergent, 3 did not sterilise if another fluid was used instead of milk, 1 did not sterilise the teats, 1 did not sterilise at all and 1 did not soak the equipment for minimum recommended time 81% of mothers who were not sterilising 'correctly' were from social classes 4 & 5 v. 17% from social classes 1 & 2 Majority of the mothers who were not sterilising correctly were multiparous ($P < 0.02$) Women reported learning how to sterilise equipment from manufacturers' instructions (<i>n</i> 24, 80%) and from instructions during their postnatal stay in hospital (<i>n</i> 15, 50%) as well as family and friends (<i>n</i> 11, 36%)

Table 5 Continued

Study	Setting	Participants	Methods of preparation of infant feeding equipment	Data collection methods	Main findings
Vaughan <i>et al.</i> (1962) ⁽³⁶⁾ : non-randomised controlled trial	USA	63 mothers selected 'essentially at random' from a well baby clinic with infants aged 6–16 weeks; alternate mothers allocated to intervention group	Intervention group (<i>n</i> 29): mothers performed the bottle-at-a-time method (at each feed: wash hands, wash bottle and teat with bottle brush, rinse thoroughly; rinse after feeding and leave to dry until next feed) Control group (<i>n</i> 29): mothers continued using their 'usual technique' (no details)	Initial interview; home visits to evaluate home conditions; bacteriological cultures from homes; mothers' reports of illness of the infant	No results presented by intervention/control groups Microbiology: 20% (<i>n</i> 45) of samples from homes designated 'sanitary' showed heavy growth of organisms <i>v.</i> 36% (<i>n</i> 26) from homes designated 'unsanitary' Largest percentage of heavy growth (19/23) and most regular isolation of <i>Escherichia coli</i> (8/28) were from containers in which milk was stored in bulk
Gatherer (1978) ⁽³²⁾ : study was in two parts, (1) survey and (2) non-randomised trial of two products	UK	Part 1: 94 mothers and their babies aged 2–6 months	Cold chemical (hypochlorite solution)	Interview; sample of sterilising fluid from home taken for lab analysis of available chlorine	Bacteriological: results showed nil growth in 91% (<i>n</i> 86) of bottles and 75% (<i>n</i> 71) of teats. Nearly 30% (<i>n</i> 28) of mothers were using a sterilising fluid which gave a low estimation of residual chlorine, 11% (<i>n</i> 10) of these had poor results with either bottles or teats Behaviour: nearly all mothers (no. not reported) were 'correct' in their account of bottle hygiene but not of teats. Many mothers (no. not reported) thought rinsing or using a brush was not necessary, 14 mothers did not sterilise dummies, small feeders and teething rings Of the 36% (<i>n</i> 34) of mothers who did not attend antenatal classes, 5 had poor results with bottles and 17 with teats
	UK	Part 2: 51 mothers divided into 2 groups	Group 1 (<i>n</i> 27): fluid hypochlorite solution Group 2 (<i>n</i> 24): unit dose crystals product Both groups of mothers were given additional instructions and encouragement by midwives and health visitors	Bacteriological assessment of bottles and teats	Microbiology: on bacteriological assessment, all of the feeding bottles gave satisfactory results, as did all but 2 of the teats (no further information given)
Anderson and Gatherer (1970) ⁽³⁰⁾ : survey	UK	1000 homes, with babies aged 2–4 months, were selected in 4 geographical areas which contained a cross-section of socio-economic groups; 758 completed the questionnaire and gave bottles and teats to be tested	94% of mothers reported they sterilised feeding bottles and teats; 48% (<i>n</i> 362) used the hypochlorite method alone; 30% (<i>n</i> 230) relied solely on boiling; 11% used both methods together; the remainder used another method or did nothing Health visitors arrived without prior warning and collected a bottle and teat which were, according to the mother, clean and ready to be filled for the morning feed	Questionnaire; bacteriological assessment of bottles and teats	Microbiology: 63% (<i>n</i> 475) of bottles and 52% (<i>n</i> 395) teats had a bacterial count of ≤ 5 colonies. Area b was significantly worse than the other areas, both for bottles and teats ($P < 0.001$) 78% (<i>n</i> 281) of bottles and 70% (<i>n</i> 253) of teats sterilised by hypochlorite had ≤ 5 colonies <i>v.</i> 46% (<i>n</i> 106) of bottles and 34% (<i>n</i> 77) of teats sterilised by boiling method Behaviour: more mothers using hypochlorite method used a more thorough cleansing routine – more of them used bottle brushes and liquid detergent and more rubbed the teats with salt and turned them inside out (no figures given)

Table 5 Continued

Study	Setting	Participants	Methods of preparation of infant feeding equipment	Data collection methods	Main findings
Clegg <i>et al.</i> (1977) ⁽³¹⁾ : survey	UK	63 mothers, all having babies aged 2–5 months who were being bottle-fed, from wide range of socio-economic groups	3 used the boiling method; 60 used some form of hypochlorite solution (not defined) Mothers were provided with a commercial sample of a stabilised solution of 1% sodium hypochlorite to use for treatment of their babies' feeding utensils; each mother was visited twice by a microbiologist who collected a bottle and a teat which had been immersed for minimum of 30 min in a sterilising unit using the aseptic technique	Bacteriological assessment of bottles and teats	Microbiology: 98.1% of bottles and 90.6% of teats had a residual count of less than 5 colonies/ml. As only 3 mothers were using the boiling method it was impossible to make any significant notes in comparison to the other technique
Rowan and Anderson (1998) ⁽¹⁸⁾ : non-randomised lab-based trial of 3 procedures	UK lab	20 infant feeding bottles	Bottles contaminated with different levels of enterotoxigenic <i>Bacillus cereus</i> were subjected to commonly used cleaning and disinfecting procedures. Uncleaned, partially cleaned and thoroughly cleaned bottles were subjected to the following: Steam sterilisation: bottles automatically steamed at 100°C for 15 min Microwave steam sterilisation: bottles placed in a sterilising unit and steamed at 100°C in a microwave oven for 9 min Chemical sterilisation: bottles immersed in sodium hypochlorite solution for 90 min	Bacteriological assessment of bottles and teats	Microbiology: the greater the level of infant bottle cleaning, the larger the reduction in microbial numbers. Effectiveness of each cleaning stage at removing <i>B. cereus</i> was significant ($P < 0.05$). Thorough cleaning did not remove all spores and potentially hazardous levels remained in more contaminated bottles All methods of disinfection successfully reduced <i>B. cereus</i> to non-detectable level when initial contamination was $\leq 10^5$ colonies/ml. <i>B. cereus</i> emerged earlier (after 14 h) in uncleaned bottles subjected to chemical disinfection. Both thermal disinfection methods did not totally eliminate <i>B. cereus</i> after 18 h. Level of contamination and degree of bottle cleaning affected length of time that <i>B. cereus</i> remained at undetectable levels ($P < 0.05$). Chemical method failed to disinfect uncleaned feeding bottles contaminated with 10^5 colonies/ml. Potentially hazardous levels detected after 14 h storage following thermal disinfection. Both steam disinfection methods equally efficient at removing <i>B. cereus</i> from bottles contaminated with $\leq 10^5$ colonies/ml ($P < 0.05$) and both methods significantly better than chemical method ($P < 0.05$)

Table 6 Design and quality assessment* of the experimental studies included in the present review

Study	Design	Allocation concealment	Comparability of groups	Eligibility	Blinding	Analysis
Hargrove <i>et al.</i> (1974) ⁽³³⁾	Non-randomised controlled trial	Group allocation chosen by mother's preference	No information	Healthy full-term newborns, bottle feeding, from one hospital nursery	Blinding of participants not possible: no evidence of blinding of care providers or outcome assessors	Point estimates/variability not reported; ITT analysis not stated
Hughes <i>et al.</i> (1987) ⁽³⁴⁾	Randomised controlled trial	No information on allocation; concealment not possible	No information	Term babies with stable temperature and blood sugar	Blinding of participants not possible: no evidence of blinding of care providers or outcome assessors	Point estimates/variability not reported; ITT analysis not stated
Jacob (1985) ⁽³⁵⁾	Survey			Not an experimental design – background information only		
Vaughan <i>et al.</i> (1962) ⁽³⁶⁾	Non-randomised controlled trial	Alternate allocation, method not described; concealment not possible	No information	Mothers who attended well baby clinics selected 'at random'	Blinding of participants not possible: no evidence of blinding of care providers or outcome assessors	No results presented by groups as allocated
Gatherer (1978) ⁽³²⁾	Survey			Not an experimental design – background information only		
	Non-randomised trial of two products	No information on allocation; concealment not possible	No information	Informed volunteers, wished to bottle feed	Blinding of participants not possible: no evidence of blinding of care providers or outcome assessors	Point estimates/variability not reported; ITT analysis not stated
Anderson and Gatherer (1970) ⁽³⁰⁾	Survey			Not an experimental design – background information only		
Clegg <i>et al.</i> (1977) ⁽³¹⁾	Survey			Not an experimental design – background information only		
Rowan and Anderson (1998) ⁽¹⁸⁾	Non-randomised lab-based trial of three procedures	All bottles subjected to three procedures in turn	All bottles subjected to three procedures in turn	Bottles prepared to a protocol in lab conditions	Blinding of outcome assessors not described	All results presented for all bottles in groups as treated

ITT, intention to treat.

*Using criteria in Khan *et al.*⁽²⁹⁾.

Authors of several of the included studies^(33,34) suggested that the 'clean' (washed with hot soapy water and rinsed with hot running water) method is a safe alternative to traditional 'sterilisation' techniques, provided the safety of the water is assured. However, three studies^(30,32,35) found higher numbers of organisms on teats, suggesting that they are more difficult to clean effectively than bottles. Gatherer⁽³²⁾ indicated that bacteriology results were excellent using either thorough cleaning or sterilisation; this was attributed to the education provided for mothers. Other studies^(30-32,35) identified a link between the failure to correctly sterilise and prepare formula feeds and a lack of ante- and postnatal education from health professionals, multiparity (mothers with two or more children) and low socio-economic status. Several authors^(18,30,31,37,38) have suggested that improved teaching for mothers and consistent advice from health professionals⁽³⁸⁾ are key factors in improving sterilisation and cleaning of infant feeding equipment.

Discussion

The striking finding from the present study is the lack of good-quality information on clinical and cost-effective ways of cleaning and sterilising infant feeding equipment in the home, especially under conditions relevant to families in developed countries in the 21st century. Only two studies examined clinical outcomes for the babies. Design flaws identified included lack of randomisation, inadequate sample size and selection bias. This lack of high-quality evidence probably explains the variation in international guidelines that we identified.

The majority of studies identified were conducted in the 1950s to the 1980s, before the introduction of microwaves and the widespread use of dishwashers in the home. It was during the 1950s that there was a steady improvement in infant mortality rate due to the reduction in deaths from childhood infectious diseases, including gastroenteritis^(30,39,40). This was in part due to the recognition of the dangers of contaminated water and the introduction of chemical sterilisation methods for infant feeding equipment⁽⁴¹⁾, and forms of sterilisation used in the 1950s are still recommended. Only one study⁽¹⁸⁾ tested more recent approaches (electric and microwave steam sterilisation) and found both to be more effective than chemical sterilisation. The contribution of microwaves, with the potential for overheating, and dishwashers, with the possible hazards of salt and detergent residues and the release of plasticisers, remains to be examined.

Our preliminary work found that the evidence base for the current advice given by some infant formula or feeding equipment manufacturers in the UK is unclear. Several respondents stated that they based their advice on Department of Health guidelines, but we were unable to

identify the existence of such guidelines at that time. Since we conducted this preliminary work, limited guidelines have been issued by the Food Standards Agency in the UK⁽¹⁶⁾ and by EFSA⁽⁸⁾ in Europe, in response primarily to recent concern about *E. sakazakii* and *Salmonella*. The recommendation in those guidelines to make up each feed as required is likely to have implications for compliance with complex sterilisation procedures.

In the absence of a secure evidence base, it is not clear what advice health professionals should be giving. Such information as we have from the included papers in this review, however, suggests that input from health professionals does have the potential to make a difference, probably in promoting compliance with whichever method is used.

We found no studies that examined the views and experiences of parents and carers about the problems of cleaning and sterilising in the home environment, or ways in which the process might be simplified and made more efficient and effective.

Unanswered questions remain: what are parents and carers actually doing? Which methods are easier and achieve best compliance? Which methods achieve the best clinical outcomes for the babies? Are basic hygiene measures such as thorough hand-washing, cleaning of equipment and a clean water supply sufficient?

Conclusion

Bottle feeding carries inherent risks for the baby and is a potential source of bacterial contamination. There is scanty of evidence, however, on clinical and cost-effective ways of cleaning and sterilising infant feeding equipment, including both bottles and teats, in the home, and there is a risk that some parents may reject current methods as cumbersome, time-consuming and expensive. Further, the focus on 'sterilisation' procedures could have a paradoxical effect of reducing basic hygiene procedures such as hand-washing and thorough washing and drying of equipment, as it could induce complacency about the possibility of infection. The current evidence base provides little information about effectiveness of the range of old and new methods used, and there is no evidence that either manufacturers or health policy makers have identified the problems parents might face in their own homes. Studies are old, of poor quality and largely irrelevant to circumstances in the home in the early 21st century.

Further research

Research is needed to determine which methods of cleaning or sterilisation of infant feeding equipment are

most effective and efficient, for both bottles and teats. Epidemiological studies could contribute to a more comprehensive assessment of the risks of poor practice and the likely effects of improved procedures in this important public health issue. Further surveys and qualitative studies could provide updated information on what parents and carers actually do in the home environment and what the barriers to good practice are. Such information would inform the design of a randomised controlled trial, adequately powered, of the range of methods in common use, measuring clinical and cost outcomes, as well as the views of parents and carers.

Acknowledgements

None of the authors has any competing interests.

We are grateful for the input of international colleagues in providing and translating their national guidelines: Cindy Turner-Maffei, National Coordinator, Baby Friendly, USA; Julie Stufkens, Executive Officer, New Zealand Breastfeeding Authority, New Zealand; Pat Martz, Project Manager, Population Health Strategies Branch, Alberta Health and Wellness, Canada; Rachel Myr, Staff breastfeeding specialist midwife, Sørlandet Sykehus, Kristiansand, Norway; Elisabeth Tufte, Norwegian Resource Centre for Breastfeeding, Norway; Genevieve Becker, National Coordinator, Baby Friendly, Ireland. We also thank the anonymous respondents from manufacturing companies who provided information.

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