
Sterilization of Infant Formula: Current Practices and Recommendations

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Home sterilization of infant formula became a standard of well-baby care in the 1940s. Its purpose was to eliminate bacterial pathogens that could contaminate water and bottles. Public water supplies are now rarely contaminated, and studies have confirmed that sterilization is no longer necessary. Connecticut family physicians and Connecticut mothers were polled and it was found that 48 percent of physicians recommend sterilization and that 54 percent of mothers (using public water supplies) sterilize formula. Formula sterilization recommendations by physicians and sterilization practices by mothers need to be updated.

During the 1940s and 1950s home sterilization of infant formula became standard practice in the United States. The purpose of sterilization was to eliminate bacterial pathogens that could contaminate the water, bottles, or nipples used in the preparation and administration of infant formula. Since refrigeration was not always available, bacteria could proliferate in formula. Two methods of sterilization became popular in the United States: terminal sterilization and step-by-step sterilization. By the mid-1950s the necessity for formula sterilization was questioned because commercial water supplies were filtered and chlorinated and because refrigeration was readily available. As a result, a clean tap water method for formula preparation was suggested by some physicians and practiced by many mothers.

At the present time, pediatric textbooks^{1,2} and the instructions from several companies who make infant formula (Enfamil and Similac) recommend

sterilization procedures to be followed when mixing formula from concentrate or powder or when adding ready-to-feed formula to bottles. Family physicians were polled concerning their formula preparation recommendations, and new mothers were polled concerning their formula preparation practices. The results of these polls and a brief review of the literature on formula preparation are the subjects of this report.

DEFINITIONS

Terminal Sterilization Method: Commercial formula (ready-to-feed, concentrate, or powder), plus any needed tap water, is poured into clean bottles with clean nipples and immersed in boiling water for 25 minutes. One day's supply is prepared and refrigerated until use.

Step-by-step Sterilization Method: Tap water, bottles, and nipples are sterilized individually by boiling, then using aseptic technique, commercial formula (ready-to-feed, concentrate, or powder), plus any needed sterilized water, is then poured into the bottles. A day's supply is prepared and refrigerated until use.

Clean Tap Water Method: Commercial formula

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(ready-to-feed, concentrate, or powder), plus any needed tap water, is poured into clean bottles with clean nipples. Bottles are prepared one at a time and used immediately.

METHODS

In January 1983 a brief questionnaire was mailed to the 320 members of the Connecticut Academy of Family Physicians. Physicians were asked their age and whether they took care of infants. Those physicians whose practices included infants were asked whether they recommended formula sterilization and, if so, at what age formula sterilization for the infant should be discontinued.

The State of Connecticut Bureau of Statistics records the names and addresses of new mothers sequentially by date of delivery. Two hundred mothers who gave birth consecutively after July 1, 1983, were sent a brief questionnaire. Mothers whose children died in the first month of life were not polled. Mothers were asked whether (and for how many months) they sterilized tap water, bottles, and nipples. They were also asked whether they used public or well water and where they had learned about sterilization.

RESULTS

Completed questionnaires were returned by 147 of the 320 family physicians (46 percent). The questionnaire was filled out anonymously; thus nonresponders could not be contacted. Of these 147 family physicians, 85 took care of infants. Forty-one of 85 (48 percent) recommended sterilization of water, bottles, and nipples for a mean of 4.7 months. Physicians recommending sterilization were older and had been practicing longer than those not recommending sterilization (Table 1).

Completed questionnaires were returned by 103 of the 200 mothers (52 percent). The questionnaire was filled out anonymously. Eleven mothers breast fed exclusively or used ready-to-use formula in disposable bottles exclusively. Ninety-two mothers used formula and

nondisposable bottles. Sixty-nine mothers used public tap water and 23 mothers used well water. Of the 69 mothers using tap water, 37 mothers (54 percent) sterilized water, bottles, and nipples for approximately seven months. Many of these mothers who sterilized formula had gotten their information from books and pamphlets. In contrast, mothers who did not sterilize formula frequently got their information from physicians, paramedical personnel, and family. Of the 23 mothers using well water, 13 mothers (57 percent) sterilized water, bottles, and nipples for approximately seven and one-half months. Most of these mothers had received their information from family members.

DISCUSSION

In the 17th and 18th centuries very high infant mortality was associated with feeding infants cows' milk. By the end of the 19th century the technology for artificial feeding had been developed. Cows' milk could be pasteurized and modified for infant feeding, canned sterile condensed milk could be used for infant feeding, and reusable bottles with breast-shaped nipples were being manufactured.^{3,4} In 1908 infant mortality in the first year of life was 6,418 per 10,000 births among artificially fed infants vs 272 deaths per 10,000 births among breast-fed infants.⁴ By 1935 infant deaths from two to nine months of life had fallen to 878 deaths per 10,000 among artificially fed infants vs 13 deaths per 10,000 among breast-fed infants.⁵ Unfortunately, the cause of the high mortality among artificially fed infants was never carefully studied, and the role of bacterial contamination of formula or other variables was never defined.

During the early 1900s unmonitored public water supplies were potentially contaminated, and thus, formula made with tap water might contain bacterial pathogens. Because formula was frequently made in batches and not refrigerated, pathogens could multiply easily. As a result, home preparation of infant formula using the terminal sterilization method or the step-by-step sterilization method became standard well-baby care. In the late 1950s, when public water supplies were

kept free of pathogenic bacterial contamination, the necessity of infant formula sterilization was questioned.^{6,7} Since then there has been disagreement among physicians regarding the need for home sterilization of formula.⁸

Home prepared formula is not sterilized. Sterilization of formula is a misnomer because boiling for 30 minutes does not kill heat-resistant spores. A practical definition of sterilization is the elimination of potential bacterial pathogens including staphylococci, streptococci, and pathogenic enteric bacteria.^{9,10} In one of the first studies of home sterilization, Lathrop⁶ found that contamination could occur when powdered formula was added to sterilized bottles with water. Fomon and others¹¹ reported that nonpathogenic bacteria commonly contaminated formula prepared by the terminal sterilization method, and pathogenic enteric bacteria contaminated formula prepared with unsterilized bottles or finger leveling of powdered formula. In 1971 Kendall and others¹² reported that contamination with low numbers of staphylococci, streptococci, and coliform bacteria occurred with both the terminal sterilization method and the clean tap water method of formula preparation. Thus, home sterilization of formula decreases, but does not eliminate, the likelihood of pathogenic contamination.

Home sterilization became accepted practice in the 1940s and 1950s without controlled studies demonstrating its clinical efficacy. Infant mortality from gastrointestinal illnesses began decreasing before sterilization of home formula became a standard practice, and it has continued to decrease.⁸ The role formula sterilization played in this decrease is unknown. In 1959, when public water supplies were treated to remove pathogens, Fischer and Whitman⁷ reported no difference in the incidence of gastroenteritis between 30 infants who were fed formula prepared by the clean tap water method and 30 infants who were fed sterilized formula. Other limited experience suggests that the clean tap water method and the terminal sterilization method of formula preparation do not differ with respect to an incidence of gastrointestinal illness.¹³⁻¹⁵ In developing countries, the benefit of formula sterilization is a different matter. Elegbe and others¹⁶ reported that in Nigeria formula is frequently contaminated with enteric

TABLE 1. INFANT FORMULA STERILIZATION POLL OF FAMILY PHYSICIANS

	Not Taking Care of Infants	Take Care of Infants and Recommend Sterilization	Take Care of Infants and Do Not Recommend Sterilization
Number	62	41	44
Mean age (years)	61.8	51.0	41.4
Mean years in practice	31.2	21.4	12.1

pathogens and that the incidence of infant gastrointestinal illness decreases with sterilization of bottles and formula.

In the early 1950s formula sterilization was a standard physician recommendation and parental practice.¹⁷ In 1958 Gibson¹³ sent questionnaires to mothers in Texas and found that 96 of 144 (66 percent) were not sterilizing formula. Because physicians and mothers had begun to question the need for sterilization, the Academy of Pediatrics Committee on the Fetus and Newborn made a 1961 recommendation of formula sterilization by the terminal heating method.¹⁸ In a 1962 Georgia study, Vaughan et al¹⁹ reported that although physicians were recommending sterilization of formula, only 11 percent of inner-city mothers were actually sterilizing formula. Most mothers were preparing batches of formula by the clean tap water method and refrigerating bottles until used. In 1971 Kendall et al¹⁴ made 155 surprise home visits and found that 90 families (58 percent) sterilized formula. In the present study, 50 of 92 mothers (54 percent) sterilize formula and 41 of 85 family physicians (48 percent) recommend sterilization. Thus, formula sterilization remains common.

The purpose of infant formula sterilization was to eliminate bacterial pathogens that could contaminate the water used in the home preparation of formula. After formula sterilization became popularized, treatment of public water supplies has made contamination a rarity. It is, therefore, not surprising that formula prepared with treated tap water is as safe as sterilized formula.^{7,8,13,15} Pediatric textbooks and formula companies continue to recommend sterilization as the only

method of formula preparation. These recommendations should be updated to include the simpler clean tap water method of formula preparation.

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