

## INFANT FORMULA INSPECTION PROGRAM AS AN AID IN THE PREVENTION OF DIARRHEA OF THE NEWBORN

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Eight neonatal deaths occurring in an average size general hospital in Rensselaer County, N.Y., during 1954 were caused by an epidemic of diarrhea of the newborn.

During the investigation, samples of baby formula prepared at the hospital were obtained and tested according to state laboratory procedures<sup>1</sup>. The formulae so tested were found to be bacteriologically unsatisfactory. However there was never any clear evidence that contaminated baby formulae had caused the epidemic. In searching for a reason for the unsatisfactory samples, a number of "breaks" in accepted techniques were observed.

On the basis of the preliminary investigation, a baby formulae inspection program was organized in Rensselaer County utilizing a team consisting of personnel from hospital administration, the health department nursing division, the sanitation division and laboratory.

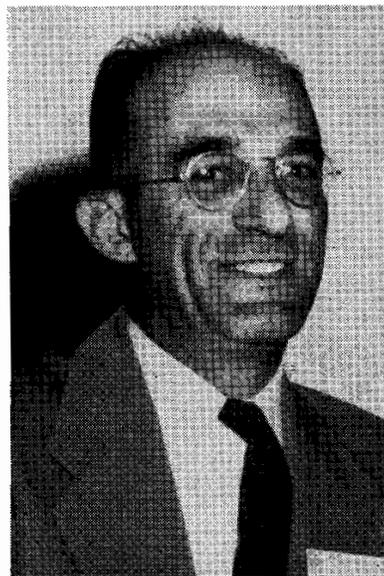
The objectives of the program in the initial planning stage were:

1. Establish appropriate lines of communication between the hospital personnel and the health department to insure continuing supervision and consultation service as required by the New York State Sanitary Code.
2. Assist in establishing procedures to minimize contamination of baby formulae, bottles and nipples during the handling and bottling processes.
3. Assist in establishing procedures designed to insure that terminal sterilization is adequately carried out.
4. Assist in establishing procedures to insure proper handling of the terminally sterilized product until time of consumption by the infants.

### ORIENTATION AND COMMUNICATION

The program was started by making an initial orientation visit at each of the hospitals by health department representatives. The objectives of the new program were explained to the hospital administrators and the staff members responsible for formulae preparation. Emphasis was placed on the fact that the health department and hospital had the common ob-

<sup>1</sup>Methods for Examinations Concerned with Sanitation, N.Y. State Dept. of Health, Division of Laboratories and Research, Form 18-a, Oct. 8, 1954.



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jective of providing a safe and satisfactory formula for each infant. Likewise the new program was characterized as a consultation service to aid the hospital rather than an inspection service. Ultimately the hospitals would carry the inspection program themselves and would utilize health department personnel whenever they had a problem. This approach was well received.

Emphasis was placed on the sanitary survey, and bacteriological testing was deemphasized as being only ancillary and confirmatory to the techniques followed and equipment provided. However, routine bacteriological testing was to be performed weekly by the health department on one bottle from among fifty bottles of each product prepared. The test specimen was to be selected and collected by health department personnel.

Administrators for the respective hospitals con-



FIGURE 1. Formula preparation and terminal sterilization.

cerned accompanied the team on its initial inspection. The new control program included special study of the baby formula preparation room and the collection of process samples. Formula preparation techniques and operation procedures were observed (Figure 1). Following the joint inspection, a letter reporting findings and suggested recommendations, signed by the Health Commissioner, was forwarded to the administrator of each respective hospital.

#### IMPROVEMENT OF HANDLING AND BOTTLING PROCESSES

Acting on the premise that formulae should have a minimum of contamination prior to terminal autoclaving, an extensive investigation of the handling and bottling process was carried out.

Under the routine sampling procedure, a representative sample of each formula and each liquid was collected by a sanitarian from the Division of Environmental Hygiene at least once a week. A standard plate count and coliform count was made on each sample to check on the formula preparation. In addition to the collection of formulae, bottle and nipple rinses were taken to determine the effectiveness of the cleansing operation (Figure 2). A report of laboratory examinations on the formulae and rinses was delivered by the sanitarian each week to the supervisor in charge of the nurseries. The results were inter-

preted in her presence and needed improvements discussed.

The routine reinspections of the formulae preparation rooms disclosed that the following conditions were generally prevalent in the hospitals.

#### 1. Equipment cleansing.

a. Bottle brushes used for manual cleansing showed mineral deposits and grease at the base of the brush bristles. Brushes were also matted. Some poorly designed brushes caused scratching and chipping of the inside surface and lips of the formula bottles.

b. One mechanical bottle-washer found in use was not designed to clean 8-ounce bottles. All bottles cleaned with this portable washer had black scuffmarks at the necks of the bottles caused by grinding action of the revolving metal brush arm against the narrow-neck bottles during the washing operation. The brushes were difficult to remove and were not disassembled daily for cleaning. Cultures taken from these brushes showed heavy growths of *Staphylococcus aureus* and *Staphylococcus albus*.

c. Water pressures at the counter-type bottle spray rinsers were set too high to insure a thorough rinse of the bottles. The inside spray



FIGURE 2. Bottle washing — swab test in background.

TABLE 1 — INFLUENCE OF IMPROVED WASHING TECHNIQUES ON BACTERIOLOGICAL CONDITION OF TERMINALLY STERILIZED FORMULAE

Sequence	Standard plate count of samples					
	3 or less per ml.		4 to 10 per ml.		more than 10 per ml.	
	(No.)	(%)	(No.)	(%)	(No.)	(%)
Before change in washing operation	132	93	9	6	1	0.7
After change in washing operation	364	98	9	2	0	0

Note: Coliform organisms were not found.

“bounced off” the bottom of the bottle without actually rinsing the bottle.

2. Liquid soap was used to clean bottles and utensils.

3. Wire racks used for storage of clean bottles were rusted and greasy. The majority of the racks in use were galvanized wire. Cultures taken of the rusted racks by a hospital laboratory produced growths of *Staphylococcus albus* and non-hemolytic streptococci.

4. Formula bottles and nipples were in poor sanitary condition. The inside surfaces of many bottles were scratched, pitted or chipped. Some nipples were old and porous.

5. Utensils used in formula preparation were not in good condition. Funnels were dented, strainers rusted, and surfaces of mixing spoons and measuring spoons difficult to clean because of poor constructive features.

6. Heavy mineral deposits which could not be removed by normal washing procedure were found in most of the formula bottles and on utensils. Bottle rinses of cleaned bottles revealed extremely high total bacterial and coliform counts.

7. Daily records were not kept of the temperature of the maximum registering thermometer, pressure during terminal heating, number and type of formulae, and related data for each batch sterilized. In some instances there was no maximum registering thermometer on hand. Measurements of formulae temperatures and air space temperatures at about one-half the distance between the liquid and the nipple, showed the air space temperature to be 2° F. less than the temperature of the liquid.

8. Divided responsibility for the processed formulae was found to make possible delay in placing formula under refrigeration. Likewise no records were kept of refrigerator temperatures as a control measure.

RESULTS OF ANALYSES

The laboratory results on examination of formulae, fluids, and bottle and nipple rinses from three hospitals since the commencement of the new program are summarized in Tables 1 and 2. Process samples were collected to determine the presence of any weak links in the practices being followed.

Table 1 gives the results of standard plate counts of 515 samples. The difference in the plate counts, before and after changing the washing procedures, are significant. Application of the Chi-square test revealed that a difference as large or larger than that obtained will occur by chance only between 1 and 2 times in 100 trials. For statistical analysis, the groups were combined into standard plate counts per milliliter of 3 or less and 4 or more. Study of the table will show that a bacteria count of less than 10 per ml. in baby formula subject to terminal heating is easily obtainable. Actually a count of 3 or less is practical. Regulation 35, Chapter II, of the *New York State Sanitary Code* requires that the standard plate count of formulae which has been subjected to terminal heating be less than 25 organisms per ml., with members of the coliform group absent. *Control of Communicable Disease in Man*, Eighth Edition published by the Ameri-

TABLE 2 — INFLUENCE OF IMPROVED BOTTLE WASHING TECHNIQUES AS DETERMINED BY A BOTTLE RINSE STUDY

	Plate count* per bottle				Coliform count* per bottle					
	Less than 300		300 to 1000		1000 or more		Less than 1		1 or more	
	(No.)	(%)	(No.)	(%)	(No.)	(%)	(No.)	(%)	(No.)	(%)
Before change in washing operation	28	27	13	12	64	61	83	79	22	21
After change in washing operation	59	91	2	3	4	6	62	95	3	5

\*Plate and coliform counts on rinse samples made in accordance with Form 18-a (see footnote 1 in text).

can Public Health Association, 1790 Broadway, New York 19, N.Y. states (under epidemic diarrhea of the newborn) that coliform organisms should be absent and the total plate count should not exceed 10 organisms per ml.

Table 2 summarizes 170 plate and coliform counts of bottle rinses made to determine the effectiveness of bottle and nipple washing. The improved technique resulted in 91 percent of the rinse samples examined showing less than 300 bacteria per bottle as compared to 27 percent before, and 95 percent of the rinse samples showing no coliform organisms as compared to 79 percent before the new procedures were adopted. A proper washing procedure should result in plate counts of less than 300 with no coliform organisms present in 8-ounce bottle rinses. The differences in the plate and coliform counts, before and after changing the washing procedures, are highly significant. Application of the Chi-square test revealed that a difference as large or larger than that obtained will occur by chance less than 5 times in 1000 trials.

#### WASHING TECHNIQUE MODIFIED

The modified washing operation that was instituted in each hospital consisted of the following:

1. All scratched and chipped bottles as well as old and porous nipples were discarded.

2. All bottles and nipples were thoroughly rinsed in lukewarm water immediately after use to simplify and make more effective the subsequent cleansing operation.

3. All bottles and nipples were initially pre-soaked in a 5 percent organic acid milkstone remover for 15 minutes to remove heavy mineral deposits which were evident in most of the bottles and nipples.

4. All bottles and nipples were subjected to weekly treatment in a 1 percent organic milkstone remover to prevent further mineral deposits from building up. A milkstone remover used in the dairy industry was effective.

5. A detergent was substituted for soap in washing the bottles and nipples.

6. Finally, the bottles and nipples were thoroughly rinsed after washing. The bottle spray rinsers were readjusted to insure a thorough rinsing.

#### NIPPLES A SPECIAL PROBLEM

The necessity for boiling nipples became apparent when swab tests made on supposedly cleaned nipples showed extremely high plate counts as well as high coliform counts. A swab was moistened in a freshly-opened vial of sterile buffered rinse solution and rubbed slowly and thoroughly four times over the

TABLE 3 — BACTERIOLOGICAL RESULTS ON SWABS FROM BOTTLE NIPPLES

Nipple treatment	Coliform count per swab <sup>a</sup>	Standard plate count per swab <sup>a</sup>
	20	10,000
	9,200	41,000
	0	15
	0	20
Nipples washed in green soap.	1,520	TNTC <sup>b</sup>
Picked at random.	0	31,000
	0	2,500
	0	TNTC
Nipples soaked in a quaternary ammonium solution overnight.	8,200	TNTC
	60	TNTC
	30	TNTC
	540	TNTC
	0	0
	0	10
	0	0
	0	20
	0	5
	0	20
	0	75
	0	10
	0	25
Nipples washed in a detergent and boiled 5 minutes.	0	5
	0	10
	0	0
	0	0
	0	10
	0	0
	0	5
	0	0
	0	15
		5

<sup>a</sup>Swab test made as explained in text.

<sup>b</sup>TNTC = too numerous to count.

TABLE 4 — COMPARISON OF BOTTLE RINSES FROM AUTOCLAVED BOTTLES AND PROPERLY WASHED BOTTLES

Standard plate counts	Number of autoclaved bottles	Number of properly washed bottles
Under 100	16	49
100 and over	2	6

inside surface and ridge of the nipple. The swab was replaced into the vial and the stick was broken off above the cotton by using the edge of the vial as a fulcrum. A single swab was used for each individual nipple. Table 3 summarizes the results of 34 nipple

swabs. The ineffectiveness of ordinary cleaning or soaking in a quaternary ammonium solution, and the superiority of boiling nipples for 5 minutes is shown.

It was also learned, as may be seen by inspection of Table 4, that bottles that had only been properly washed gave counts approximately equal to that of bottles that had been autoclaved. Autoclaved and properly washed bottles were cleansed as explained under "Washing Technique Modified".

#### TERMINAL STERILIZATION

This process should be the final one. If proper handling has occurred prior to terminal sterilization it should be possible to produce a formula with a standard plate count of 3 or less almost 100 percent of the time, with coliform organisms being uniformly absent.

#### SUMMARY

Periodic inspections by the Rensselaer County Health Department on a team basis was found extremely effective in making full use of the combined talents of the resources available in a modern county health department having a properly staffed laboratory. The cooperation given by the personnel in charge of the maternity sections at the respective hospitals helped accomplish in a relatively short time the improvements listed below.

1. The bottle and nipple washing operation was modified. All bottles and nipples are now immediately rinsed with lukewarm water after use to remove milk film and soaked at least once a week in a mild organic acid milkstone remover to remove and prevent mineral deposit build-up. A detergent is used to clean bottles, nipples and utensils instead of a soap.

2. All nipples are being boiled daily.

3. About 100 to 150 scratched, chipped and pitted bottles as well as 50 to 75 old and porous nipples have been discarded.

4. The water pressures at the bottle spray rinsers have been adjusted to insure a thorough bottle rinse.

5. Stainless steel bottle racks are on order to replace rusted racks that are presently being used at two hospitals.

6. The temperature attained by formulae and fluids during terminal heating is being determined by a maximum registering thermometer at all three hospitals.

7. Each hospital is now keeping a daily record of the maximum temperature of the maximum registering thermometer, the pressure indicated during terminal heating, and the number of formulae and fluid bottles for each batch autoclaved. Records are also kept of the temperature of each refrigerator in which formula is stored.

8. Poorly constructed and rusted utensils used in the formula preparation are being replaced with stainless steel types that are easily cleaned and maintained.

9. The metal brush spindles on the mechanical bottle-washer that was causing the black scuffing on the inside necks of the bottles are being replaced by the manufacturers with a plastic type spindle which will eliminate the grinding action causing the scuffing.

#### CONCLUSIONS

Health Department team supervision of maternity hospitals is necessary. Important members of the team are personnel from the laboratory, and sanitarians. Formula preparation may be a causative factor in diarrhea of the newborn epidemics. To deal with this problem emphasis should be placed on the sanitary survey rather than on laboratory tests alone. Proper techniques and procedures in formula preparation are necessary to insure that terminal sterilization will be effective. The Rensselaer County Health Department has developed a baby milk formula program which should aid in the prevention of epidemics of diarrhea of the newborn.

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