COMMITTEE ON FETUS AND NEWBORN

RECOMMENDATIONS ON FORMULA SUPPLY
IN THE HOSPITAL

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N THE process of preparing a new revi-
sion of the manual, Standards and Rec-
ommendations for Hospital Care of New-
born Infants, the Committee on Fetus and
Newborn established a new set of standards
concerning preparation and handling of for-
mula supply in the hospital.

Because of the current interest in formula
supply, brought about by recent techno-
logical changes, the Committee decided to
issue the standards as a separate statement.
It will later appear as a section in the re-
vised edition of Standards and Recommend-
ations of Hospital Care of Newborn In-
fants.

Responsibility for the policies regarding
feeding of infants in nurseries must be as-
signed to designated members of the med-
ical staff. They make all decisions about
prescription, acceptability, preparation, and
distribution of formula. They also set up
control and review procedures.

Three principal methods for providing
formula to nursery infants are currently
available in the United States. Their rela-
tive efficacies cannot be evaluated at this
time, but all should meet basic standardized
requirements.

The three methods are: (1) preparation
of the formula entirely in the hospital for-
mula room; (2) final preparation of formula
in the hospital from components, pre-steri-
lized, packaged, and delivered by an out-
side source; (3) use of individually pack-
aged pre-sterilized formula delivered by an
outside source.

In providing formula for infants, atten-
tion must be given to the following:
Facilities
Personnel and their responsibilities
Formula preparation
Safety standards and quality control

A. Facilities
Facilities necessary for the preparation of
formula depend on the method used in pro-
viding the formula.

1. Formula Room
A formula room is essential when the for-
mula is prepared entirely in the hospital.

a) Function
All feedings for all infants—newborn, low-
birth weight, and sick—must be prepared in
the hospital formula room. No other use
should be made of the room.

b) Location
The room should be situated where dan-
ger of contamination is minimal, distribu-
tion problems limited, communication easy,
and control procedures readily instituted.

c) Construction and Facilities
Recommendations for the construction
and facilities of a formula room may be
found in a publication of the American Hos-
pital Association, Procedures and Layout
for the Infant Formula Room. The book is
currently being revised; the new edition
will be available in a few months from the
AHA, 840 North Lake Shore Drive, Chi-
cago 11, Illinois.

2. Area for Final Preparation of Formula
A separate formula room may not be nec-
essary when using formula prepared outside
the hospital.

Pre-sterilized bottled formula may be
capped or components may be transferred
to pre-sterilized nursing bottles in a clean
area associated with the nurseries. The
area, however, must not be used for any
other purpose.

3. Facilities for Outside Formula Services
Individually packaged formula from out-
side sources is ready for use in the hospital nursery. No special area is needed.

Recommendations regarding standards for the facilities of formula services outside the hospital are presently under consideration by the Academy's Committee on Formula Services.

B. Personnel and Their Responsibilities

1. When Formula Is Prepared Entirely in the Hospital

The formula room should be continuously supervised by a qualified dietitian and/or nurse. She should have specialized training in formula preparation and terminal heating procedures and should understand the general nature, requirements, and practice of infant feeding.

The supervisor is responsible for training and directing all formula room personnel. She must submit frequent, standardized, periodic reports concerning formula room operations, equipment, supplies, and personnel to those responsible for nursery services.

Workers in the formula room should have no contact with infectious conditions. Employees who develop an infection should be reassigned to other areas at the discretion of the physician-in-charge.

Formula room personnel should wear scrub gowns and caps.

In hospitals where formula preparation does not require the full time of a nurse or dietitian, she may spend the remainder of her time working in a clean area, such as central supply, the regular newborn nursery, or the diet kitchen.

2. When Formula Is Assembled from Components

The hospital administrator, with the advice of the medical staff, should assign the responsibilities for handling pre-sterilized bulk or bottled formula to specific individuals.

Their responsibilities include the receipt of the bulk formula; mixing; bottling when necessary; quality and safety control of the formula; and distribution of the ready-to-use formula to the infants.

C. Formula Preparation

Procedures for preparing formula in the hospital are outlined below. Techniques of initial preparation used by outside suppliers must meet standards comparable to those followed in the hospital.

Hospital procedures for final preparation of formula from outside sources vary; explicit practices cannot be outlined. But formula from outside sources should not be given further heat treatment in the hospital.

Limitations on the number of permissible formula variations must be determined by the medical staff. Use of highly specialized formulas in extraordinary circumstances should require approval by the medical staff member responsible for the nursery.

Formula preparation in the hospital formula room includes the following steps:

1. Washing Equipment

In the clean-up section of the formula room all bottles, caps, and nipples should be thoroughly washed, with a detergent solution (not soap) and then thoroughly rinsed. Nipples should be inverted in the cleaning process. Nipples should be rinsed in running water, then boiled for five minutes.

Detergents are superior to soap for cleaning bottles and utensils because soap combines with milk casein to form a gummy residue difficult to remove.

Detergents should be kept in their original containers and stored where there is no danger of their being mistaken for formula ingredients.

3. When Individually Prepackaged Formula Is Used

The administrator, with the advice of the medical staff, should assign the responsibility for receiving and distributing the individually packaged formula.

Special attention must be given to the location and supervision of the delivery area; the mechanics of transporting the delivered formula to areas of use; and to a cross checking system for insuring delivery of the correct formula to each infant.
2. Preparing Milk Mixtures

Milk mixtures are prepared by using clean but not aseptic technique. They are transferred to clean bottles, nipple, capped, and placed in metal racks. The nipple caps may be of glass, metal, plastic, or water-resistant paper, but must not form a tight seal around the shoulder of the nipple or bottle during the terminal heating process.

Special mixtures which cannot be subjected to terminal heating must be prepared with aseptic technique, using all sterilized utensils, sterile water, and insofar as possible, sterile ingredients.

Only materials actually used in the preparation of milk mixtures should be kept in the formula room. All materials should be delivered to the formula room in their original labeled containers.

3. Terminal Heating of Formulas

The racks of filled bottles are placed in sterilizers and terminally heated, either under pressure at 230°F for 10 minutes or by the nonpressure method of steam or water at 212°F for 25 minutes.

Both the pressure and nonpressure methods have their advantages. The pressure method gives a higher percentage of sterile milk mixtures. But the nonpressure method presents fewer dangers of carmelization of the sugar in the formula; of coagulation of milk proteins; of clogged nipples resulting from boiling the formula; and of damage to the sterilizer from milk entering the drain line.

Through carefully planned technique, these methods can be followed in all hospitals, even with very simple and inexpensive equipment. A pressure cooker may substitute for an autoclave. Nonpressure terminal heating may be carried out in the simple sterilizers sold for home use.

4. Cooling Formulas

Upon completion of the terminal heating, the bottles are removed from the sterilizer, cooled at room temperature for one hour, and then placed in a refrigerator maintained at 40°F.

For rapid cooling, special heavy duty refrigerator units are desirable. Cooling in water may introduce the danger of contamination.

Formula should never remain at room temperature for more than one hour.

D. Safety Standards and Quality Control

All formula preparation—inside and outside the hospital—must (1) conform to requirements set by local health agencies and (2) meet standards approved by the hospital medical staff.

Few existing health codes include standards for operation of local formula services outside the hospital. The Academy's Committee on Formula Services was organized specifically to help define standards of operation and facilities for formula services outside the hospital. It is currently working on such standards.

All formulas, regardless of supply source, should meet certain bacteriologic and chemical standards. Hospitals should carry out the following control procedures:

1. Microbiologic Control

The techniques of formula preparation should be checked by frequent bacteriologic examination. A predetermined surveillance plan should be established under which randomly chosen samples of the ready-to-use preparations are submitted for bacteriologic examination.

Sampling should be frequent and comprehensive, occurring at least once a week and involving all nursery units and nursing duty periods in random order.

Plate counts on samples of milk mixtures should not exceed 25 organisms per milliliter. The individual organisms should be identified; if organisms other than spore formers are found, a breakdown in technique is indicated. Responsible hospital and medical authorities should be notified and steps immediately taken to remedy the breakdown.

2. Chemical Control

Formulas used in the hospital should be
periodically and randomly sampled for chemical analysis. Determination should be made of one or more of the following selected formula ingredients: sodium, potassium, chloride, total solutes, nitrogen, and the pH of the formula. The findings should be reported to the person responsible for formula preparation and recorded in a permanent file.

In addition, for premixed formula, chemical control data must be provided by the supplier.

3. Tasting

By simply tasting the formula or other mixture before it is bottled, the worker can easily perceive certain gross mistakes in composition. The occasional container of spoiled processed milk, for example, may be detected this way, as may such uncommon and hazardous errors as substituting salt for sugar.

4. Storage and Use of Ready-to-Use Formula

a) Bottled formula ready to use should not remain at room temperature for more than one hour.

b) Additional bottles of formula should not be made by transferring formula from previously bottled units. The composition of formula, after bottling, should not be altered without specific authorization.

c) Unused formula must be discarded within 24 hours, except formula assembled from pre-sterilized components, which must be used within four hours or discarded. Partially used containers must not be stored for more than four hours; if unused longer, the formula must be discarded.

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