CLINICAL OBSERVATION

Limiting Bacterial Contamination of Enteral Nutrient Solutions: 6-Year History With Reduction of Contamination at Two Institutions

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ABSTRACT: Running enteral nutrient solution (ENS) bacterial contamination logs that were collected over a 6-year time frame are presented. At hospital A, reconstituted ENS were prepared by the pharmacy department in bulk and were frozen in the final container. These solutions were cultured and counted after 12 hours of storage at room temperature to stimulate this institution's hang time. Major reductions in ENS bacterial counts occurred after improvements in sanitation, a reduction in solution hang time, the conversion to the use of sterile water for dilution and reconstitution of ENS, and most dramatically, after the incorporation of a preservative (potassium sorbate) to reconstituted ENS. At hospital B, ENS usage consisted of canned feedings that were prepared by nursing personnel and were transferred to the feeding container at the bedside. Reductions in final counts of contamination of ENS occurred after procedural changes, which included container changes every 24 hours, use of sterile water for dilution, cleansing of can lids with alcohol swabs before use, rinsing and air drying of intermittent feeding containers between feedings, and limiting feeding container fills to 4-hour hang time quantities. At both institutions, the value of an ongoing three-class enteral quality control program with a defined acceptance/rejection criteria was demonstrated in that ENS contamination was reduced to acceptable levels comparable with federal standards for milk and dairy products.

Heavy bacterial contamination of enteral nutrient solutions (ENS) in the institutional setting has been extensively documented over a number of years and occurs with considerable frequency.[1-7] Total bacterial counts as high as 10^8 organisms/mL have been documented in ENS.[8] Sepsis, infectious syndromes, and diarrhea have been noted as a result.[9-13] Despite this knowledge, relatively little progress has been made in the institutional setting to monitor, enumerate, and control bacterial contamination. Further complicating this situation is the widely varying sanitary protocols and feeding techniques used at various institutions. The purpose of this article is to describe the effect of enteral quality control (QC) programs on bacterial levels within ENS in two institutional settings and to suggest the implementation of ENS QC programs at all institutions.

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BACKGROUND

The complications such as sepsis, diarrhea, and infection, associated with contaminated ENS and the aforementioned documented contamination would seem reasons enough to institute enteral QC programs. There are, however, more fundamental reasons why enteral QC is needed. These are the same reasons why QC is instituted in any business or other institutional area—to control and ensure the quality of the final product. It is a basic human failing that, under pressure to produce, quality will suffer. In regard to ENS, other investigators have made this observation and have noted that compliance with tube feeding protocols is often lacking or followed only when personnel are aware that contamination is being monitored.[14,15] For this reason, even the most stringent enteral sanitary protocols will not produce the desired result if not monitored and modified as needed.

In the following tables and figures, the monitored bacterial levels in ENS at two institutions are presented. Hospital A is a teaching tertiary-care facility with over 500 beds. Hospital B is a primary-care referring hospital with over 100 beds. Two QC approaches are outlined. In hospital A, efforts focused on a reconstituted bulk pharmacy-produced feeding solution that was prospectively monitored. In hospital

B, efforts focused on sterile canned feedings, which were mixed and transferred to the final feeding container at the bedside by the nursing staff and were monitored retrospectively. In both instances, ENS QC programs that used defined acceptance/rejection criteria (three-class plan) were established.[16] These criteria were applied to ENS samples obtained from feedings at the end of stimulated or actual usage cycles.

ENS QC samples were cultured and identified by the hospital microbiology departments by standard clinical microbiological techniques. Serial dilutions were made with normal saline as noted for plating of maximum total count. Tryptic soy agar was used as a plating medium. Batch samples were obtained at hospital A directly from the bulk mixing tank and were frozen and transferred to the microbiology department for counting and identification at the timed intervals as noted. At hospital B, QC samples were obtained directly from the patient feeding bag at the end of the infusion and container usage cycle. This was accomplished by the following technique. First, the side of the plastic feeding container was swabbed with alcohol and allowed to air dry. Then, the container was punctured with a needle and a sample of the remaining ENS was aspirated by syringe and immediately transferred to a sterile specimen cup and to the microbiology department for counting and identification.

QC RECORDS

Hospital A—Prospective QC Program History. The data in Table 1 represent samples taken from production runs of reconstituted feedings that were bulk produced, mechanically transferred to the final container, frozen, and later dispensed on demand from a centralized pharmacy (Fig. 1).[17-19] Production time studies of this system have demonstrated a 56% labor savings versus traditional blender methods.[17] Additional benefits from the use of this system include more efficient use of labor during nonpeak hours, reduction of waste, and prospective lot quality testing before releasing for use.

Table 1 lists the progress made over 4 years and representing 6000 ENS feedings as various control measures were implemented. After identification of

Table 1. Hospital A—prospective QC program history[a]

Date	Count/mL	Organisms	Sampling (timing/conditions)	Modifications
12/80	10^5	*Serratia* sp	Immediate	
12/80	10^4–10^6	*Enterobacter cloacae*	Immediate	
1/81	No growth		Time zero	Sanitation improved
	10^4	*E. cloacae*	24-h count (1/81 sample)	
2/81	No growth		Time zero	
	10^4–10^5	*E. cloacae*	24-h count (2/81 sample)	
4/81	No growth		Time zero	
	10^4–10^5	*E. cloacae*; enterococci	24-h count (4/81 sample)	
9/81	10^3	*Klebsiella* sp	12-h count	Hang times reduced
10/81	5×10^4	Enterococci	12-h count	
10/81	10^5	*E. cloacae*	12-h count	
11/81	5×10^4	*E. cloacae*	12-h count	
1/82	5×10^4	*E. cloacae*	12-h count	
6/82	$>10^4$	*Citrobacter* sp; *Streptococcus* sp	12-h count	
9/82	2×10^3	*Klebsiella pneumoniae*	12-h count	Sterile water used for mixing
10/82	$<10^3$	*Staphylococcus epidermidis*; *Bacillus* sp; *K. pneumoniae*	12-h count	Sterile water used for mixing
	2.8×10^4	*S. epidermidis*	12-h count	Sterile water used for mixing
	5×10^3	*S. epidermidis*	12-h count	Sterile water used for mixing
12/82	10^5	*K. pneumoniae*	12-h count	Sterile water used for mixing
3/83	10^4	*Pseudomonas aeruginosa*	12-h count	Sterile water used for mixing
4/83	50	*E. cloacae*	12-h count	Preserved feedings
6/83	100 × 3	*E. cloacae*	12-h count	Preserved feedings
	No growth ×3		12-h count	Preserved feedings
8/83	No growth ×4		12-h count	Preserved feedings
1984	No growth ×17		12-h count	Preserved feedings
	10–1000 range for 1984	Various	12-h count	Preserved feedings

[a] Selected samples from over 100 ENS batch cultures collected over 4 years representing over 6000 feedings.

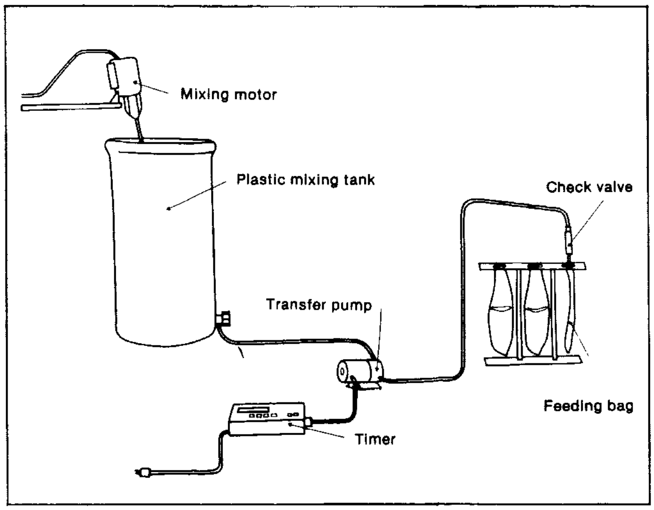

Figure 1. Enteral bulk production system. Reprinted with permission from *Nutritional Support Services*, Volume 3, Number 4, April 1983.

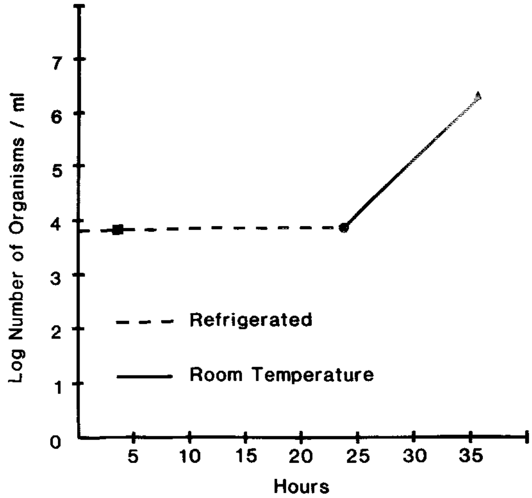

Figure 2. Growth pattern of *E. cloacae* in a selected ENS product. Note suppression of growth at refrigerated temperature and logarithmic growth at room temperature.

problem levels of bacterial contamination in December 1980 batch samples (obtained immediately after admixture), changes were instituted in the manner in which the equipment used to produce the feedings was sanitized along with other basic personnel procedures. Personnel were reinstructed in proper handwashing technique and in manipulation methods to minimize touch contamination. A high-volume transfer pump system was developed to eliminate manual transfer of reconstituted product to the final feeding container.

As a result of these efforts, repeat samples (January, February, and April 1981) obtained immediately after admixture were reported as "no growth" by the microbiology lab. These results were dramatic in comparison with the December 1980 levels; these same samples, however, were reported to have levels of 10^4–10^5 organisms/mL[4-5] after 24 hours of storage at room temperature. It was at this time that an appreciation was first gained of the prolific bacterial growth supporting properties of ENS and the effects of time and temperature abuse of ENS. Subsequently, a study of this issue and the growth-supporting characteristics of bacteria in ENS was begun. Final protocol changes of major importance undertaken at this time as a result of these surveillance measures were the reduction of ENS hang time to 12 hours (pharmacy controlled by the volume dispensed in the feeding container) and the monitoring of ENS batch counts after 12 hours of exposure to room temperature.

Figure 2 illustrates the bacterial growth-supporting properties of a selected ENS. Note the suppression of growth at refrigerated temperatures and the logarithmic growth at room temperature. A survey of other commercially available solutions at this time revealed similar growth-supporting characteristics for most ENS.[20] For this reason, an estimate of the final count of bacterial contamination delivered to patients during routine administration can be accurately assessed only by culturing and counting ENS at the end of the container/ENS usage cycle. This can be accomplished either by simulating hang time usage and culturing for final count, as in hospital A, or by actually sampling from the patient's feeding container at the end of the usage cycle, as in hospital B.

In 1982, because of continued concerns and an inability to further reduce final counts (September 1981 to June 1982), a conversion to the use of sterile water for the dilution and reconstitution of ENS was made. This produced erratic reductions of counts (Table 1 and Fig 3) and a shift away from the predominant contaminate, *Enterobacter cloacae*. Interestingly, the probable reason for this decrease in counts and bacteriological shift became apparent 8 months later when the public health department unexpectedly issued a warning not to consume the city tap water because of coliform contamination (*E. cloacae*). This warning, during which the public was advised to boil all water before consumption, continued for the next 3 months while major repairs were made to the city water treatment facilities. We later reported this event and the need to evaluate municipal water supplies.[21]

In 1983, as a result of the previously mentioned research efforts, a preservative (potassium sorbate) was incorporated into the batch-produced feedings with subsequent major reductions in bacterial counts. Studies of the growth-supporting properties of an ENS product preserved with potassium sorbate at 0.036 and 0.2% and then contaminated with *E. cloacae* demonstrated reductions of 70 and 90%, respectively. Potassium sorbate is "generally recognized as safe" (GRAS) by the Food and Drug Administration and is a reliable and inexpensive technique for reduction of ENS bacterial counts.[20] In fact, after this change, most of the batches produced were reported as sterile after 12 hours of storage at room temperature. It was concluded that the final count of bacteria in ENS is dependent on the following three factors: the size of the initial bacterial inoculum, the growth-supporting properties of the formula, and the amount of time the product is held at room temperature.[20] It was also at this time that a prospective QC program that used food science principles[16] was developed and implemented (Table 2). This application was prospective in that the frozen batch-produced feedings were isolated or held after production until "cleared" for use after the receipt of a 12-hour room temperature bacterial count (institution's hang time) and organism identification by the microbiology laboratory. If the total bacterial count and identified organisms met the established criteria (n = 5; c = 2; m = 10^3; M = 5×10^4; no food pathogens), the ENS batch was then cleared for use and released.

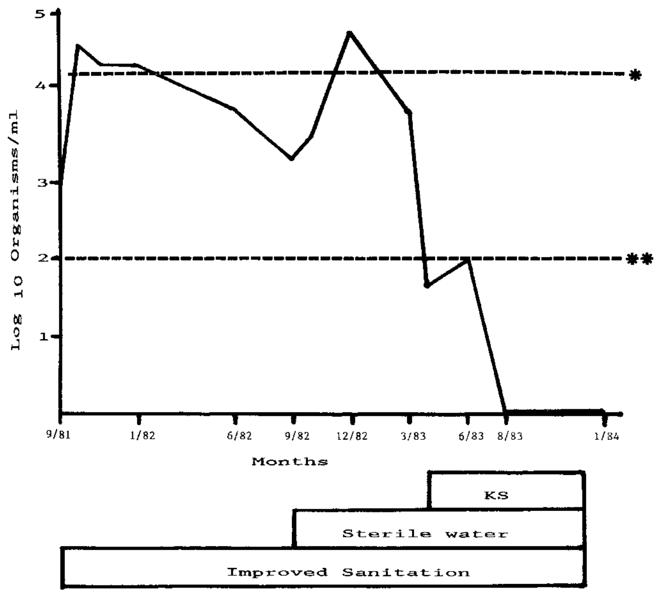

Figure 3. Hospital A peak ENS counts at room temperature. KS, potassium sorbate; * federal limit for milk products; ** coliform limit for milk products.

Hospital B—Retrospective QC Plan History. Data in Table 3 (also presented as Fig. 4) are from a retrospective enteral QC plan collected over a 19-month period. In this QC plan, the ENS samples are taken from random bedside feeding containers at the end of the feeding infusion and container usage cycle. The data collected in March 1985 represent an initial contamination survey authorized by the hospital's infection control committee. Samples were serially diluted to a level allowing a maximum total plate count of 10^5 organisms/mL. Despite the insistence of a number of staff that the feedings were "sufficiently clean," counts at this time revealed cases of gross contamination with culture plates heavily overgrown at this dilution with multiple organisms and yeast. Investigation by the infection control department revealed that a number of key nursing enteral feeding procedures either were not being followed or did not exist. The following major protocol points were then implemented or enforced: feeding containers to be changed every 24 hours (labeled and dated), sterile water to be used for dilution and reconstitution of ENS, can lids swabbed with alcohol pad before opening, bag fill limited to 4-hour hang time quantities, and intermittent feeding bags to be rinsed and dryed between feedings. After these changes and a reeducation effort by the hospital's infection control department, a repeat survey was sanctioned by the hospital's infection

Table 2. Three-class enteral QC plan[a]

Lot/Survey Specifications:	n = 5; c = 2; m = 10x; M = 10y
Lot/Survey Rejection:	Any lot/survey with a value >c and/or a sample with counts >M or identification of food pathogen. (All counts at end of usage cycle).
Definitions:	n, number of samples per lot/survey
	c, maximum number of defectives
	m, maximum number of organism/mL for good quality rating
	M, maximum bacteria/mL. Samples >M are unacceptable. Samples between m and M are rated marginal quality. Lots/surveys with c > 2 are rejected.
	x and y, values set according to established guidelines or degree of stringency desired.

Example of plan:
For c = 2, m = 10^3, M = 2×10^4, and n = 5,

Samples <1,000 organisms/mL are considered good quality, between 1,000 and 20,000 are marginal, and >20,000 are unacceptable.

Quality survey or lot is rejected: of five total samples, any time more than two marginal samples are found, one or more counts >20,000 is returned, or if a food pathogen is identified (regardless of count).

[a] From: Sampling for microbiological analysis: principles and specific applications. In: Ingram M, ed. Micro-organisms in foods. Toronto: University of Toronto Press, 1974:3–55.

Table 3. Hospital B retrospective QC plan history

Date	Count	Organisms	Comments
3/85	>10^5	4 nonfermenting; 1 fermenting GNR;[a] Group D and Alpha streptococci	Initial contamination; survey; random sampling
	>1×10^5	Group D streptococci; GNR[a]	
	2×10^4	Yeast[b]	
8/85	Nursing unit a		
	No Growth ×3		Follow-up survey after infection control review; 24-h bag counts; quality survey accepted
	<500 ×3	*S. epidermidis*; *P. aeruginosa*	
	Nursing unit b		
	22×10^6	*Streptococcus* and *Staphylococcus* sp	Conditions same as above but survey rejected
	3.8×10^6	*P. aeruginosa*	
	10^6	Gamma streptococci mixed; Gram-negative bacilli	
1/86	Nursing units a and b		
	No growth ×5		Quality survey accepted
10/86	5 organisms/mL × 5		Quality survey accepted; quarterly reaudits with three-class criteria approved by QA committee

[a] GNR, Gram-negative rod.
[b] Unidentified yeast.

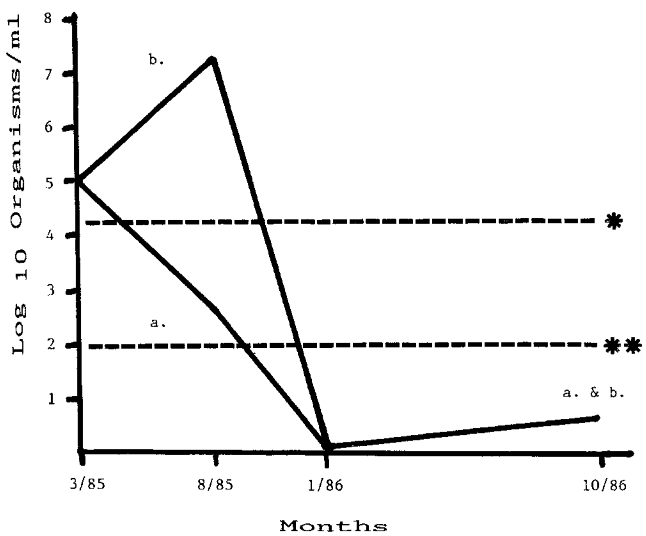

Figure 4. Hospital B peak ENS counts for nursing units a and b. * Federal limit for milk products; ** coliform limit for milk products.

control committee and conducted in August 1985. These samples again were obtained directly from the bedside feeding container and at the end of the 24-hour bag usage cycle and 4-hour feeding infusion. Results at this time (from nursing unit a) clearly showed that enforcement of the existing policies and procedures were sufficient to produce feedings of good to excellent quality when followed as opposed to results from nursing unit b. After corrective action was taken, subsequent ENS follow-up contamination surveys conducted in 1986 continued to demonstrate favorable results and the correction of compliance deficiencies in nursing unit b.

As a result of these efforts and the reductions in total final counts, a recommendation was made by the infection control committee and accepted by the hospital's quality assurance committee to make retrospective enteral bacterial contamination surveys a quarterly quality assurance measure. Acceptance/rejection criteria ($n = 5$; $c = 2$; $m = 10^3$; $M = 2 \times 10^4$; no food pathogens) were established by the infection control committee by use of a three-class plan.

DISCUSSION

The US government limits total bacterial counts to 20,000 organisms/mL and coliform count to 100 organisms/mL for milk and dairy products.[22] The US Centers for Disease Control use a count of 100,000 organisms/g as an incriminating level in complaints regarding foodborne disease outbreaks.[23] In comparison, reported levels in ENS have frequently exceeded these levels with numerous organisms including *Pseudomonas*, *Enterobacter*, and *Klebsiella* species, which have been cited as potential food pathogens for healthy adults and documented as sources of infection and diarrhea in ENS patients. Certainly, it would seem that debilitated patients receiving enteral nutrition would deserve ENS that were at least as "clean" as the food we consume as healthy adults. Although little action has been taken on the issue in the United States, it should be noted that the British Dietetic Association has established microbiological limits for ENS and has endorsed the concept of routine monitoring of ENS. Furthermore, the British guidelines are designed to limit total bacterial counts in ENS at the end of the infusion to not more than 1000 organisms/mL.[24]

It has been my experience during the course of both feeding quality improvement programs that the rate of diarrhea decreased and that patient tolerance to enteral feeding improved dramatically. This observation is consistent with a study by Anderson et al[12] that demonstrated an association between high bacterial counts (>100,000 organisms/mL) and ENS-related diarrhea. Experience has also shown that ENS feedings with microbiological quality equal or superior to that of milk products can be routinely achieved in the institutional setting. This can be accomplished by altering the growth-supporting characteristics and admixture contamination of ENS in a pharmacy distribution system, as in hospital A, or through controlling personnel contamination, as in hospital B.

More important, however, is the end result, rather than the method used to achieve it. Enteral sanitary policies and procedures alone are not enough to ensure ENS quality. At both institutions in this report, personnel were made aware of the ongoing bacterial quality monitoring. The control measures used to reduce counts were presented to the staff as methods by which to help them achieve the desired goals. This, combined with the continuous monitoring, was the reason these programs were successful.

Enteral microbiological QC programs with defined acceptance/rejection criteria can provide performance information and a means of objectively evaluating and monitoring control measures. Because of the great potential for heavy contamination in the institutional setting, enteral microbiological QC programs should be a requirement at all institutions.

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