

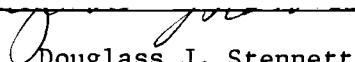
AN ABSTRACT OF THE THESIS OF

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in Pharmacy presented May 1, 1986.

Title: QUALITY ASSURANCE OF HOME AND INPATIENT PARENTERAL
NUTRITION

Redacted for Privacy

Abstract approved:


Douglass J. Stennett

The microbial contamination rate was compared for parenteral nutrition solutions prepared by patients for home use and by pharmacy personnel for inpatient use. The methodology was divided into three phases. Phase I validated the Ivex^R-2 0.22 micron inline filter as a tool for microbiological testing in 5% dextrose injections. Phase II tested a new method of determining microbial contamination of total parenteral nutrition (TPN) solutions. Phase III compared inpatient and home TPN microbial contamination rates using the methodology validated in Phase II.

In Phase I, test organisms were *Candida albicans*, *Escherichia coli*, *Enterobacter cloacae*, *Klebsiella pneumoniae*, *Proteus vulgaris*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, and *Streptococcus pyogenes*. All contaminated 5% dextrose injections showed visual turbidity within 48 hours. Identification of contaminating organisms by subculturing the inoculum of each filter was successful.

Nine TPN solutions were inoculated with test organisms using the methods in Phase I. All contaminated TPN solutions showed visual

turbidity after 96 hours. Subcultures verified the identity of each test organism.

One hundred samples from the TPN solutions were collected randomly and aseptically mixed with Tryptic Soy Broth during the six month Phase III study period. Six patients and two hospitals participated in the study. None of the 44 home parenteral nutrition samples and none of the 56 inpatient TPN samples had any visible turbidity on macroscopic examination. Subcultures of each sample on blood agar were negative for microbial growth.

This methodology offers a means to establish contamination rates of home parenteral nutrition solutions and a method to monitor patient aseptic technique at home.

Quality Assurance of Home and Inpatient
Parenteral Nutrition

by

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A THESIS

submitted to

Oregon State University

in partial fulfillment of
the requirements for the
degree of
Master of Science

Completed May 1, 1986

Commencement June 1986

APPROVED:

Redacted for Privacy

Associate Professor of Pharmacy in charge of major

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Date thesis is presented May 1, 1986

Typed by Cindi Sibert for Michael Henry Bronson

ACKNOWLEDGEMENT

I would like to acknowledge and extend my appreciation to all the people who made it possible for my thesis to be completed. A special gratitude is extended to my wife, June E. Bronson, for her personal support and encouragement during my years of higher education. Without her love and sacrifice, I would not have been able to finish my research. To my children, James and Holly, I thank you for your patience and understanding during the last few years. I love you all very much.

All the gratitude in the world could not acknowledge my appreciation to Dr. Douglass J. Stennett for his assistance and advice throughout my research. When I was frustrated or perplexed, Dr. Stennett would reassure and direct my research in a positive and uplifting manner. I would also like to thank Dr. James W. Ayres for his advice and assistance. Gilbert Boswell, my laboratory assistant, and Donald Johnson, Abbott Laboratories representative, were also most helpful in providing laboratory skills and supplies necessary to complete my research.

No acknowledgement is complete without giving recognition to our Lord, Jesus Christ. He's the way and the light. God has provided our world with many gifts through his son.

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QUALITY ASSURANCE OF HOME AND INPATIENT
PARENTERAL NUTRITION

INTRODUCTION

The growth of the home health care industry is staggering. Home Health Care of America, one of several major home care providers, has grown from a company with total revenues of \$1,040,000 in fiscal year 1980 to \$38,983,000 in fiscal year 1983.¹ Similar growth is expected for the next few years as Diagnosis Related Groups (DRG's) and other third-party requirements change the thrust and nature of health care.

Home care providers and hospitals strive to ensure quality of care for the home parenteral nutrition patient. Subjective assessments of the quality of life of home parenteral nutrition patients have been studied.^{2,3} Extensive quality assurance programs have been developed to ensure the quality of the product delivered to the patient. Sterility and pyrogen testing procedures of home parenteral nutrition solutions prepared by home health care providers are extensive,¹ and studies of catheter complications have been performed.⁴⁻⁸ All have addressed one objective; this is to ensure contamination-free home parenteral nutrition solutions are administered. But the quality of the solution administered in the home is not routinely scrutinized in the same manner.

Catheter related infection remains a paramount concern for the physician and the nutritional support team. Proper training of the

patient and routine follow-up care are essential components for successful home parenteral nutrition. Good aseptic technique and contamination-free I.V. products are an essential part of this treatment.

Patient compliance and good aseptic technique become crucial components in the successful therapy once the patient is discharged from the hospital. Parenteral nutrition solutions (TPN) are prepared in the home, by hospitals, or by one of the numerous home parenteral nutrition companies. Procedures previously performed by licensed professionals may now be performed by the patient or the patient's family.

The purpose of this project was to compare the microbial contamination rates of parenteral nutrition solutions prepared and/or administered by patients at home with TPN solutions prepared and administered by hospital personnel in an institutional setting. Quality assurance for the purpose of this study is limited to evaluation of microbial contamination, not quantitative analysis of TPN ingredients.

BACKGROUND OF RESEARCH

Since development of the technique for administering hypertonic glucose and amino acids through a central vein, or total parenteral nutrition, by Dudrick in 1968,⁹ the literature has abounded with related articles. Many of these have dealt with the successful treatment of diseases that previously had a high morbidity. Other articles have discussed complications which limited the usefulness of TPN.^{6,8,10,11}

One such complication has been catheter sepsis. Early reports of catheter sepsis were alarming, but in 1974 Ryan et al., using strict aseptic technique, showed that catheter sepsis could be reduced to 7% in a prospective study of 200 patients.⁴ However, this technique required the patient to have professional assistance. Meanwhile, in Seattle, Washington, Broviac and Scribner introduced a new method of catheter insertion.⁵ This method required a venous cutdown procedure followed by catheter insertion similar to Dudrick's method, but the catheter was then tunneled through subcutaneous tissue down the anterior aspect of the chest wall. The tunneled segment of the catheter has a thicker extravascular segment with an attached dacron felt cuff which becomes fixed to the tissue in two to three weeks. Once the cuff becomes fixed to the tissue, it acts as a mechanical barrier to bacteria ascending the outer surface of the catheter.⁵ This development simplified dressing changes for catheters and has enabled treatment to be continued on an outpatient basis. Home parenteral nutrition (HPN) became feasible with the development of this more reliable means of infusing TPN solutions.⁵⁻⁸

A critical part of a home parenteral nutrition program is a patient education program. The patient and family are taught proper catheter care, mixing and administration procedures, and clinical and laboratory monitoring parameters during the HPN program. While all HPN articles discuss sepsis in relationship to the catheter, none were found which discuss the potential complication of solutions contaminated by the patient or family while being admixed or administered. Also, the benefit of teaching aseptic technique to the patient has not been shown to reduce contamination rates.

METHODOLOGY

The proposed study was conducted in three phases. Phase I validated the in vitro study by Lim using inline 0.22 micron filters as a tool for quality assurance.¹² Phase II validated the Phase I method in TPN solutions.¹² Phase III compared the microbial contamination rate after administration of inpatient TPN and home parenteral nutrition solutions. All equipment and solutions were used as obtained from manufacturers. Aseptic technique was used during the entire study (appendix A).

Phase I

Twelve one liter glass containers of 5% dextrose injection^a (Table 1) were inoculated with micro-organisms. Each I.V. solution was inoculated with either 0.1 ml sodium chloride 0.9%^b as a control, or 0.1 ml sodium chloride 0.9% containing 50-300 test organisms using standard microbiological techniques. Each I.V. bottle was spiked with a pump administration set^c with an inline 0.22 micron filter.^d The administration set was primed with the 5% dextrose injection and the pump cassette attached to the pump^e (appendix B). A needle was attached to the distal end of the tubing. Immediately following this, the needle was aseptically pierced through the rubber stopper of a 1000 ml sterile empty evacuated container^f and solution pumped into the container over 8 to 12 hours. Once the pumping had been completed, the administration set was clamped and aseptically removed. Two milliliters of sterile Tryptic Soy Broth^g (TSB) was introduced into each filter set using a sterile syringe. Turbidity of the culture medium added to each filter set was determined

by a "blinded" research assistant. Turbidity determinations were read at time 0, 12, and 24 hours after the additions of the TSB, and then daily for 10 days. Samples were stored at $22^{\circ} \pm 2^{\circ}$ C. All samples were subcultured on blood agar plates and incubated at $33^{\circ} \pm 4^{\circ}$ C. Subcultures were identified using standard microbial determination procedures.

TABLE 1

Phase I and Phase II Test Organisms

Candida albicans	Pseudomonas aeruginosa
Escherichia coli	Staphylococcus aureus
Enterobacter cloacae	Staphylococcus epidermidis
Klebsiella pneumoniae	Streptococcus pyogenes
Proteus vulgaris	Controls x 3

Isolates were obtained from the Good Samaritan Hospital Clinical Laboratory. Test organisms were identified by bacteriologists from the laboratory staff.

Phase II

Twelve one liter TPN solutions were substituted for the 5% dextrose solutions used in Phase I. Formulation of the TPN solutions is listed in Table 2. The same procedure used in Phase I was used in Phase II to ensure the method would detect and identify organisms growing in TPN solutions.

TABLE 2

TPN Solutions Used in Phase II

Crystalline Amino Acid Solution 10% ^h	500 ml
Dextrose 70% ⁱ	500 ml
Sodium Chloride 2.5 mEq/ml ^j	50 mEq
Potassium Chloride 2 mEq/ml ^k	20 mEq
Potassium Phosphate 3 mM/ml ^l	15 mM
Magnesium Sulfate 50% ^m	8 mEq
Calcium Gluconate ⁿ	9.2 mEq
Zinc ^o	4 mg
Copper ^p	0.5 mg
Chromium ^q	10 mcg
Manganese ^r	1 mg
Multivitamins ^s	10 ml

TABLE 3

Code for Determining the Identification of
the Micro-Organisms in Phase I and Phase II

<u>Phase I</u> <u>Sample Number</u>	<u>Phase II</u> <u>Sample Number</u>	<u>Organism</u>
12	1	control
11	2	Streptococcus pyogenes grp. A
10	3	Staphylococcus epidermidis
9	4	Staphylococcus aureus
8	5	control
7	6	Pseudomonas aeruginosa
6	7	Proteus vulgaris
5	8	Klebsiella pneumoniae
4	9	control
3	10	Enterobacter cloacae
2	11	Escherichia coli
1	12	Candida albicans

Phase III

One hundred filter samples were collected after TPN administration from home parenteral nutrition patients and from inpatients receiving TPN at two non-profit community hospitals. Bottles were selected using a table of random numbers.¹³ HPN solutions were prepared by either the patient or a local professional home care provider. All HPN patients participated in a formal training program on the administration of HPN solutions and the care of the catheter. Inpatient TPN solutions were prepared in a laminar flow hood in the respective hospitals by I.V. pharmacists. Administration sets and solutions were prepared and administered following the guidelines in Phase I (appendix A & B). Six patients and two hospitals participated in the study. Informed consent was obtained from each patient's physician and each patient. Hospitals and patients were notified that TPN solutions would be collected after solutions were mixed and administration completed. TSB was introduced aseptically into each filter by the primary author no longer than 60 minutes after the TPN solution was administered. Turbidity of the cultured medium added to each filter set was determined at time 0, 12 hours, and 24 hours after the addition of the TSB, and then daily for 10 days. Samples were subcultured on blood agar plates. Cultures and subcultures were incubated using the same conditions used in Phase I.

Statistics

Statistical significance of Phase III results of the study were to be tested using the Student's T-test.¹⁴ Sample size was determined

using the following statistical formula:

$$n > \frac{2 Z_{\alpha}^2 pq}{t^2}$$

where: n = sample size; p = contamination rate; $Z_{\alpha} = 1.96$ (Z value); q = 1.0 - p; t = tolerance.¹⁵ The contamination rate is expected to be 4-8%.^{4,5,16,17} The tolerance for the study is 0.08. Therefore inserting these figures into the formula, the maximum number of samples needed for the study will be:

$$n > \frac{2(1.96)^2 (0.08) (1.0-0.08)}{(0.08)^2} > 88 \sim 90$$

RESULTS

Twelve inoculated filter samples from the intravenous solutions in Phase I containing 5% dextrose injection were collected. Inoculated samples with the test organisms (Table 1) showed visual turbidity within 48 hours. The intravenous solutions supported significant microbial growth of all the test organisms within 48 hours. Identification of the contaminating organisms by subculturing the inoculum from each filter was successful in all nine test organisms. None of the test solutions contained additional organisms. The three control solutions did not become turbid, and subcultures showed no growth after 10 days.

Similarly, all nine contaminated samples from the TPN solutions in Phase II showed visual turbidity. Eight of the nine contaminated samples showed visual turbidity within 96 hours. Turbidity was not visible in the *Staphylococcus epidermidis* contaminated sample until the sixth day (144 hours). The low pH and relative high osmolarity delayed the growth patterns of all the organisms. Subcultures verified the identity of each test organism. The three control solutions did not become turbid, and subcultures showed no microbial growth after 10 days.

In the final phase of the study, six patients from two hospitals participated in the study. Tables 4 and 5 summarize patient and hospital information. All six patients remained in the study during the entire six month period. Four of the six patients prepared their own solutions. Two of the six patients had their solutions pre-mixed by a local home health care agency. The six TPN patients had a combined total of 9.75 years of TPN preparation and administration experience.

TABLE 4

Patient Information

<u>Patient</u>	<u>Age</u>	<u>Samples</u>	<u>Diagnosis</u>	<u>No. of infusions per week</u>	<u>self-mix</u>	<u>No. of months on home TPN</u>
HJ	36	9	Crohn's	5	yes	18
IR	35	7	short bowel syn. Gardner's syn.	7	yes	30
PM	80	7	short bowel syn.	5	no	14
SD	64	10	short bowel syn.	7	no	17
WH	67	7	short bowel syn.	2	yes	24
RB	16	6	Crohn's	4-6	yes	14

TABLE 5

Hospital Demographics

<u>Hospital</u>	<u>No. of Samples</u>	<u>Location</u>	<u>No. of Beds</u>	<u>Classification of Hospital Type</u>
Good Samaritan Hospital & Med- ical Center	34	Portland, OR	539	Acute-care, tertiary facility with physician, nursing, and pharmacy training programs
Good Samaritan Hospital	22	Corvallis, OR	165	Acute-care, community facility with nursing and pharmacy training programs

Forty-six samples were collected from the home parenteral nutrition patients (Table 4). Two samples were not included in the study due to delayed injection of the TSB into the filter. Of the forty-four remaining samples, none developed any visual turbidity on macroscopic examination after ten days. Subcultures of each sample on blood agar were also negative for microbial growth.

A total of fifty-six samples were collected from the two hospitals; thirty-four samples from an acute-care tertiary teaching facility and twenty-two samples from an acute-care community hospital (Table 5). Zero out of the fifty-six inpatient TPN samples developed any visual turbidity on macroscopic examination after ten days. Subcultures of each sample were also negative for microbial growth.

The patients and the hospital staff both demonstrated the ability to administer these solutions at a rate of contamination less than or equal to 8% ($p < 0.05$).

DISCUSSION

During the early 1970's, Ryan, et al., described the complications of indwelling catheters,⁴ while in 1986, Scheckelhoff, et al., examined the growth of bacteria and fungi in total nutrient solutions.¹⁷ Such concerns about catheter contamination and septicemia have existed since the advent of TPN and continue today.^{1,4-8,16} The study herein demonstrates the usefulness of Lim's methodology in determining microbial contamination of standard TPN solutions. The results of this study also demonstrate that HPN and TPN can be administered as safely in the home as it can within the hospital ($p < 0.05$). The contamination rate of products mixed and administered by the properly trained HPN patient, and the contamination rate of TPN products mixed and administered by professionals to institutionalized TPN patients are both less than 8%.

Even with small numbers of test organisms (50-300) used as the inoculum, all samples inoculated supported significant microbial growth. A solution with less hostile conditions, such as 5% dextrose injection, supports a more rapid development of contamination. The dextrose solutions developed significant contamination within 48 hours. The more hostile environment of the TPN solution delayed the growth of microbes, but did not kill these organisms. Significant bacterial contamination did not become evident until at least 96 hours after the inoculation of the TPN solutions. *Staphylococcus epidermidis* was not macroscopically visible for 144 hours.

Each patient had at least twelve month's experience in administering HPN solutions (range 14-30 months). The six patients had

9.75 years of HPN experience in all. Each patient should have developed the concepts of aseptic technique before beginning participation in the study, but the possibility exists that the patient's aseptic technique could have deteriorated during the study period. Based on the findings of this study, however, all six patients demonstrated the ability to perform and maintain good aseptic technique.

The two hospitals participating in the study used standardized methods of preparing the inpatient TPN solutions. Training procedures of patients, although slightly different, produced the same results outside the hospital and with inpatient TPN solutions.

The addition of TSB into the inline 0.22 micron filter can be used in the future as a means of monitoring a patient's aseptic technique. Patients can be provided single use containers of sterile TSB on a routine basis and asked to inoculate the TPN filter, bring the tubing to the hospital, and have solution tested for microbial growth. This identification method creates a rational means for selecting patients for retraining. In addition, patient's technique during HPN training can now be monitored objectively as well as subjectively.

CONCLUSION

The methodology presented offers a means to establish contamination rates of HPN solutions and a method to monitor patient aseptic technique at home. By monitoring the patient's aseptic technique, the physician and nutritional support team can monitor the need to reinforce the patient's technical competencies. In the population group studied, the home parenteral nutrition patients were as able to safely administer their I.V. solutions without increasing the threshold microbial contamination rate of 8% when compared to the inpatient TPN solution contamination rate.

ENDNOTES

- a. Abbott Laboratories, North Chicago, IL 60064.
- b. Abbott Laboratories, North Chicago, IL 60064.
- c. Abbott Laboratories, North Chicago, IL 60064.
- d. Abbott Laboratories, North Chicago, IL 60064.
- e. Abbott Laboratories, North Chicago, IL 60064.
- f. Abbott Laboratories, North Chicago, IL 60064.
- g. Prepared Media Laboratory, Tualatin, OR 97062.
- h. Abbott Laboratories, North Chicago, IL 60064.
- i. Abbott Laboratories, North Chicago, IL 60064.
- j. Abbott Laboratories, North Chicago, IL 60064.
- k. Abbott Laboratories, North Chicago, IL 60064.
- l. Abbott Laboratories, North Chicago, IL 60064.
- m. Invenex Laboratories, Chagrin Falls, OH 44022.
- n. Invenex Laboratories, Chagrin Falls, OH 44022.
- o. Abbott Laboratories, North Chicago, IL 60064.
- p. Abbott Laboratories, North Chicago, IL 60064.
- q. Abbott Laboratories, North Chicago, IL 60064.
- r. Abbott Laboratories, North Chicago, IL 60064.
- s. Lederle Parenterals, Carolina, Puerto Rico 00630.

BIBLIOGRAPHY

1. Anon. 1983 Annual Report. Home Health Care of America. Newport Beach, CA.
2. Robb, et al. Subjective Assessment of Patient Outcomes of Home Parenteral Nutrition. *AJHP* 1983; 40: 1646-1650.
3. Ladeford K. Quality of Life in Patients on Permanent Home Parenteral Nutrition. *J. Parenter. Entr. Nutr.* 1980; 5: 132-137.
4. Ryan JA, et al. Catheter Complications in Total Parenteral Nutrition. *N. Engl. J. Med.* 1974; 290: 394-396.
5. Broviac JW, Scribner BH. Prolonged Parenteral Nutrition in the Home. *Surg., Gyn., and Ob.* 1974; 139: 24-28.
6. Reilla MC, Scribner BH. Five Years Experience with a Right Atrial Catheter for Prolonged Parenteral Nutrition at Home. *Surg., Gyn., and Ob.* 1976; 143: 205-208.
7. Strobel CT, et al. Home Parenteral Nutrition: Results in 34 Pediatric Patients. *Ann. Surg.* 1978; 188 (3): 394-403.
8. Fleming RC, et al. Home Parenteral Nutrition as Primary Therapy in Patients with Extensive Crohn's Disease of the Small Bowel and Malnutrition. *Gastroenterology* 1977; 73: 1077-1081.
9. Dudrick SJ, et al. Long-Term Total Parenteral Nutrition with Growth, Development and Positive Nitrogen Balance. *Surgery* 1968; 68: 134-142.
10. Broviac JW, Scribner BH, et al. A Silicone Rubber Atrial Catheter for Prolonged Parenteral Alimentation. *Surg., Gyn., and Ob.* 1973; 136: 602-606.
11. Maini B, Blackburn GL, et al. Cyclic Hyperalimentation: An Optimal Technique for Preservation of Visceral Protein. *J. Surg. Research* 1976; 20: 515-525.
12. Lim JC. Technique for Microbial Testing of In-Use Intravenous Solutions and Administration Sets. *Am. J. Hosp. Pharm.* 1979; 36: 1202-1204.
13. Dixon WJ, Massey FJ. *Introduction to Statistical Analysis.* 3rd Ed. McGraw-Hill Book Company. 1969; 37-52.
14. Jackson RA. *Interpretation of Research Data: Selected Statistical Procedures.* *Am. J. Hosp. Pharm.* 1980; 37: 1673-1680.

15. Bryant EC. Statistical Analysis. McGraw-Hill Book Company. 1960; 67-99.
16. Copeland EM, Dudrick SJ, et al. Prevention of Microbial Catheter Contamination in Patients Receiving Parenteral Hyperalimentation. Southern Medical J. 1974; 67: 303-306.
17. Scheckelhoff DJ, et al. Growth of Bacteria and Fungi in Total Nutrient Admixtures. Am. J. Hosp. Pharm. 1986; 43: 73-77.

APPENDICES

APPENDIX A: ASEPTIC TECHNIQUE IN THE PREPARATION
OF INTRAVENOUS ADMIXTURES

1. Wash hands frequently with a broad spectrum antiseptic--
Betadine Surgical Scrub.
2. Wipe dust off bottle, vials and ampuls with a cloth dampened
with alcohol.
3. Remove cardboard and paper wrappers before placing objects
on the table.
4. Do not place extraneous material on the table.
5. Watch your hands.
6. Check all solutions before and after mixing against a well
lighted dark and light background for cracks and particulate
matter.
7. Double check all manipulations and calculations.
8. If there is any doubt at all--discard the solution.

USE OF SYRINGES AND NEEDLES

Removal of Sterile Syringe from Package and Placement of
Needle.

1. Select proper syringe and needle.
2. Examine outercovering of syringe and needle; pinholes or
breaks in the wrap render the contents non-sterile.
3. In the case of paper-wrapped syringes, peel sides apart
and expose syringe. Avoid touching the plunger.
4. Peel back needle wrapping and expose hub.

5. Aseptically remove plastic protective cap from syringe and needle.
6. Attach needle to syringe with a twist, keeping needle sheath intact and avoid touching needle hub.
7. When ready to use, pull needle sheath straight off.
8. Perform transfer and replace needle sheath.

WITHDRAWAL OF CONTENTS OF AMPULS

1. Tap ampul gently while in the upright position to release solution that may be trapped in the stem above the neck.
2. Wipe neck of ampul with an alcohol swab. Wrap swab around top of ampul to avoid cuts if ampul breaks.
3. Using swab, thumb, and index finger on neck of ampul, and the thumb and index finger of the other hand on the base, **snap off the neck.**
4. Inspect the opened ampul for glass particles.
5. Remove needle sheath on syringe. If air is present in syringe, remove it. Injection of air into ampul may cause it to overflow. Tilt ampul, submerge needle in solution and avoid touching the outside rim of the ampul with the needle.
6. Do not draw solution from the bottom of the ampul. This will prevent aspiration of glass particles.
7. Pull plunger back with thumb, using index finger for support, placing it on the wing of the syringe.

8. Hold the syringe with needle upward, tap syringe to allow air bubbles to surface, then remove excess air in syringe and needle.
9. Measure desired amount on syringe barrel.
10. Replace needle with a filter needle.
11. Replace needle sheath.

WITHDRAWAL OF CONTENTS FROM VIALS

1. Remove dustcover and aluminum tab over target area and discard. Cleanse the exposed rubber surface with Povidone-Iodine. Avoid excess Povidone-Iodine and lint as they may be carried with the needle into the vial.
2. Remove needle sheath from syringe and calibrate plunger rod to the volume of solution desired. A volume of air equal to the volume of solution needed must be injected into the vial in order to equalize the pressure differential.
3. Penetrate the rubber closure with the needle, beveled edge up, at an angle of 45° to 60° . As the closure is penetrated, but before complete penetration, elevate the needle to a vertical position. This will minimize coring and floaters.
4. Invert vial and inject air from syringe into vial. Avoid bubbling air through the solution.
5. Holding the vial with one hand and the needle and syringe with the other, draw the solution into syringe, keeping the needle submerged to avoid entrance of air into syringe.

A slightly larger volume of solution is withdrawn than is needed.

6. With the syringe and needle held upward, tap the syringe to allow air bubbles to surface. Remove air bubbles and eject solution slowly to remove air from the needle. Withdraw the needle from the vial.
7. Read volume of solution by aligning rubber end of plunger with calibration markings on the barrel of syringe.

APPENDIX B: PROCEDURE FOR TPN TUBING, FILTER
AND BOTTLE FOR ABBOTT PUMP

PURPOSE:

To change tubing and filter of hyperalimentation lines using aseptic technique.

EQUIPMENT:

1. Abbott Pump tubing set with or without 0.22 filter
2. 0.22 filter if pump set doesn't have in-line filter
3. Alcohol swabs
4. Idophor swabs
5. New hyperalimentation container
6. Silk tape

PROCEDURE:

1. Gather equipment.
2. Wash hands thoroughly and dry.
3. Remove protective seal from the hyperal container. Do not touch the surface under seal.
4. Wipe off top of container with idophor swab--allow to dry for two minutes.
5. While idophor solution is drying, remove pump set and filter from boxes and attach filter to pump set. (Some pump sets already have inline filter.)
6. Apply idophor solution to junction of pump set and filter--allow to dry for two minutes and then apply small piece of silk tape to secure filter and pump set.

7. Close main side clamp on newly prepared tubing one inch below drip chamber.
8. Insert piercing pin into container and suspend solution on pump pole.
9. Fill drip chamber $\frac{1}{2}$ full by squeezing between fingers, tap chamber to remove trapped air bubbles.
10. Open main slide clamp, close roller clamp, push in white plunger on top of set pump chamber until it snaps into the down position.
11. Begin a slow flow rate with the roller clamp. Invert the upper Y injection site and clear air by tapping on tubing.
12. Invert pump chamber to a 45 degree angle. Slowly rotate the chamber to eliminate air. Continue rotation to allow the balance of the pump chamber to fill. Stop flow with the roller clamp.
13. Hold the pump chamber horizontally . . . tap lightly and look through the top part of the chamber for any trapped air bubbles.
14. If air bubbles are present . . . invert the pump chamber to a vertical, open roller clamp, and tap lightly to remove.
15. Clear air from rest of pump set, when fluid reaches the filter, invert filter and allow to fill slowly from the bottom. Tap filter lightly to remove air.
16. Clear air from remainder of tubing.
17. Turn main control of pump to Reset.
18. Remove flow detector from present hyperal container and attach to newly primed container.

19. Turn main control switch to OFF, close roller clamp on old tubing, remove old tubing from pump.
20. Insert new tubing into pump.
21. Clamp Hickman catheter, remove tubing from Hickman and insert new tubing into Hickman, tape junction securely with silk tape.
22. Unclamp catheter, turn pump to operate at desired rate of flow.
23. Double check to be sure that all junctions are taped securely and slide clamp and roller clamp are open.
24. Time bottle by marking approximate infusion times on bottle.

PROCEDURE FOR ADDITION OF TPN BOTTLE WHEN INFUSION COMPLETE:

1. Wash hands.
2. Wash bottle top with povidone-iodine swab and let dry (2 minutes).
3. Turn pump to RESET.
4. Close Clair clamp on tubing.
5. Remove the drop sensor.
6. Remove old bottle from tubing.
7. Using aseptic technique, insert tubing into new bottle.
8. Hang new bottle.
9. Replace drop sensor.
10. Check rate setting.
11. Unclamp tubing.
12. Turn pump to operate.
13. Check drip chamber to insure flow established.

CHARTING:

1. Chart hyperal solution on parenteral fluid sheet.
2. Charge for all tubing used on parenteral fluid sheet.