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**A replication study: Saline vs heparin in maintaining patency of
intermittent infusion devices**

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San Jose State University, 1992

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A REPLICATION STUDY: SALINE VS HEPARIN
IN MAINTAINING PATENCY OF INTERMITTENT INFUSION DEVICES

A Thesis

Presented to

The Faculty of the Department of Nursing
San Jose State University

In Partial Fulfillment

of the Requirements for the Degree
Master of Science

By

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November, 1992

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ABSTRACT

A REPLICATION STUDY: SALINE VS HEPARIN IN MAINTAINING PATENCY OF INTERMITTENT INFUSION DEVICES

by Helen Ritchey

The purpose of this study was to examine the efficacy of 0.9% sodium chloride injection alone versus 0.9% sodium chloride with 10 units of heparin to maintain patency of peripheral intermittent intravenous infusion locks (IVL). The IVL is more commonly known as a heparin lock. Protocols for maintaining IVLs have not been firmly established, even though these devices have been in use since the early 1960's.

The study used a quasi-experimental double-blind design with a sample of (N=30) hospitalized adult patients on two units. The results were analyzed using frequencies. It was concluded that the heparin group had more incidence of phlebitis and loss of patency than the normal saline group. This study supports the literature that normal saline is sufficient to maintain IVLs.

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TABLE OF CONTENTS

	Page
LIST OF TABLES	vii
Chapter	
1. INTRODUCTION	1
The Problem and Research Question	4
Hypothesis	6
Purpose and Need	6
Definition of Terms	15
Research Design	16
Scope and Limitations	17
2. CONCEPTUAL FRAMEWORK AND REVIEW OF RELATED LITERATURE	18
Conceptual Framework	18
Related Literature	19
Summary	24
3. THE METHOD	26
Research Design	26
Data Collection	30
Analysis of the Data	32
4. ANALYSIS AND INTERPRETATION OF DATA	33
Description of the Sample	33
Analysis	33

	Page
5. CONCLUSIONS AND RECOMMENDATIONS	38
Conclusions	38
Recommendations	38
REFERENCES	40
APPENDIXES	
A. Data Collection Form	47
B. Hospital Approval Letter	49
C. San Jose State University Approval Letter	51
D. Patient Consent Form	53
E. Letter to Physicians	56
F. Letter to Staff Nurses	58
G. Guidelines for Study Nurses	60
H. Second Letter to Staff Nurses	62

LIST OF TABLES

Table	Page
1. Sample Ages for Each Solution	34
2. Diagnosis or Medical History	35
3. Intravenous Catheter Used	36
4. Reason for Discontinuance of IVL	37

Chapter 1

INTRODUCTION

Since the passage of the diagnosis-related group (DRG) system of reimbursement, providing cost-effective quality health care has become increasingly necessary. Health care today is about eleven percent of the gross national product and continues to rise significantly (Stein, 1988, p. 46; Thurow, 1985). Keeping the quality of health care high while reducing costs is a challenge to all health care professionals. To determine the most efficient and least costly methods, routinely performed procedures need to be reassessed and studied. While changes are important, it is essential to maintain standards of care, patient comfort, and patient safety as priorities. An area of concern is intravenous therapy.

The use of intravenous therapy has become commonplace in today's hospital setting. The 1600's saw the first attempts to intravenously inject medications and blood into humans and animals (Schmidt, 1959, pp. 59-62). This early experimentation, as would be expected, often had disastrous outcomes. Since that time the safety of intravenous injection has greatly improved and, as a result, the administration of parenteral solutions through veins has also increased greatly. And yet, according to Plumer (1987), "in spite of all the advances in scientific and

medical technology, complications have increased to alarming proportions" (p. 5). Thus, even with advancements in technology, it is apparent that standards of care and techniques need to be improved through the exchange of ideas, experience, knowledge, and research.

Standards of care guide procedural changes and are essential in maintaining quality of care in nursing and medicine. Each profession is responsible for monitoring its practitioners and for setting standards. The Intravenous Nurses Society (formerly the National Intravenous Therapy Association) has developed standards of practice for intravenous care (Intravenous Nurses Society, 1981). In 1976, Deeb and DiMattia stated there was a lack of standardization in the procedures and protocols concerning intravenous preparation and delivery.

A particular area of concern is the intermittent intravenous lock (IVL), more commonly known as a "heparin lock." An IVL is placed in a patient's vein to administer medications intermittently when continuous fluid or medication therapy is not needed or is contraindicated. The IVL is a specially designed IV catheter with a resealing rubber diaphragm on the end to allow intermittent infusion of medications (Donham & Denning, 1987). A dilute solution of heparin in normal saline over various periods of time has traditionally been injected through the diaphragm and into

the catheter to maintain patency in the vein.

Even though these devices have been in use since the early 1960's, protocols for maintaining IVLs have not been firmly established (Donham & Denning, 1987; Dunn & Lenihan, 1987). To maintain the IVL, heparin solution has been injected at intervals of 6, 8, 12, or even 24 hours and after each infusion of medication (Deeb & DiMattia, 1976). The amount of heparin has also varied from 10 units, 100 units, and 1000 units. At present, studies generally agree, if heparin is used, 10 units every eight hours is sufficient to maintain patency (Dunn & Lenihan, 1987; Garrelts, LaRocca, Ast, Smith, & Sweet, 1989; Hanson, Grant, & Majors, 1976). Due to this low dilution of heparin, studies suggest that normal saline alone is sufficient to maintain patency of IVLs and it may be the flushing action that keeps the device patent (Barrett & Lester, 1990; Dunn & Lenihan, 1987; Epperson, 1984; Garrelts et al., 1989; Hamilton, Plis, Clay, & Sylvan, 1988; Harrigan, 1985; Jowett, Stephens, Thompson, & Sutton, 1986; Lombardi, Gundersen, Zammett, Walters, & Morris, 1988; Miracle, Fangman, Kayrouz, Kederis, & Pursell, 1989; Schustek, 1984; Shearer, 1987). As far back as 1976, Deeb and DiMattia raised the question, "Could heparin be replaced by normal saline solution" (p. 26)? Others maintain that heparin is still needed (Cole, 1989; Cyganski, Donahue & Heaton, 1987; Morris, 1989). Thus, the

controversy of using saline instead of heparin evolved from studies conducted to determine the lowest effective concentration of heparin solution to effectively keep an IVL patent.

Problem and Research Question

The use of IVLs has greatly increased since the Center for Disease Control, in the early 1970's, recommended the use of "keep open" intravenous fluids be discontinued (Donham & Denning, 1987). "Keep open" is a slow intravenous rate, usually twenty milliliters each hour. The purpose of the slow infusion is to have an accessible vein if medications or fluid therapy is needed again. The IVL was designed to eliminate this need for a constant fluid flow in keeping the vein open. As stated, studies have found that 10 units of heparin will maintain patency and normal saline alone may be sufficient. In an informal telephone survey of hospitals in a large metropolitan area in which the investigator works, it was found that several hospitals successfully use normal saline alone to flush IVLs. Nevertheless, the controversy concerning whether normal saline is as effective as heparin has not been resolved (Cole, 1989; Donham & Denning, 1987; Morris, 1988).

Cyganski et al. (1987) found in a survey that no one procedure for flushing IVLs was common. In addition, none of the hospitals surveyed were able to cite studies to guide

their standards for IVL procedures. Dunn and Lenihan (1987) surveyed hospitals in 1980 and again in 1985 to discover "little consistency" prevailed in maintaining IVLs (p. 798). One hospital surveyed found policies did not exist at their institution: Many nurses injected the medicine and flushed with heparin to clear the line and prevent clotting; others flushed with normal saline before injection of the medicine and then flushed with heparin; and newer nurses used the S-A-S-H method of flushing with normal saline, injecting the medicine, injecting normal saline to flush the medicine through, then following with heparin (Barrett & Lester, 1990). All three methods have been observed at an acute care hospital where the investigator works even though standards of care using the S-A-S-H method have been established and are documented in the procedural manual.

Hypotheses

The routine use of a heparin flush solution to maintain patency of intermittent intravenous infusion devices (IVL) has been questioned in the literature. Some studies found normal saline as effective as heparin in maintaining patency (Barrett & Lester, 1990; Epperson, 1984; Harrigan, 1985, Jowett et al., 1986; Schustek, 1984). The objectives of this research study were to determine the effectiveness of normal saline as a flush solution to maintain patency of IVLs and to determine if there is a difference in the

incidence of phlebitis when flushing with normal saline. The first research hypothesis was the following: There will be no significant difference in loss of patency rates between a flushing solution containing 0.9% sodium chloride injection alone or a flushing solution of 0.9% sodium chloride containing ten units per milliliter of heparin for intermittent infusion devices. A second research hypothesis was: There will be no significant difference in the incidence of phlebitis between 0.9% sodium chloride injection and 0.9% sodium chloride containing ten units per milliliter of heparin in flushing solutions for intermittent intravenous infusion devices.

Purpose and Need

The purpose of this proposed research study was to examine the efficacy of 0.9% sodium chloride (NS) injection alone versus 0.9% sodium chloride with 10 units of heparin to maintain patency of peripheral intermittent intravenous infusion locks (IVL) in hospitalized adult patients. Since protocols for maintaining these devices have not been firmly established, even though they have been in use since the early sixties, it is necessary to further research their use.

Advantages of Using Saline Only

There are several potential advantages to using normal saline instead of heparin to flush IVLs. Of major concern

is the avoidance of drug incompatibilities. Heparin is a naturally occurring mucopolysaccharide prepared from porcine intestinal mucosa or bovine lung tissue in a commercially available sodium salt (Cole, 1989; Turco, 1976). In an article by Turco (1976), heparin was found to be incompatible with thirty-nine drugs. Obviously, other drugs which have not been tested with heparin are also potentially incompatible. For incompatible drugs, drug combinations, or new drugs with no information regarding compatibility, it is necessary to flush the IVL with normal saline before and after administration of each drug (Gordon, 1986). In reality, as already stated, this flushing does not always occur.

Possible systemic effects on coagulation have been cited as a potentially serious complication of heparin flushes (Dunn & Lenihan, 1987; Epperson, 1984; Garrelts et al., 1989; Laster, Cirkirt, Walker, & Silver, 1987). Eika, Godal, & Kierulf (1972) detected thrombin time changes with only 0.003 to 0.01 unit of heparin in one milliliter of plasma. O'Neill, Tierney, & Proulx (1974) in a study of heparin-lock induced alterations in activated partial thromboplastin time (APTT) found significantly elevated APTT levels developed in seven out of ten patients with heparin locks using up to 1000 units heparin in flushes. These APTT changes could result in a decreased ability of blood to

clot. However, Deeb and DiMattia (1976) stated the changes in APTT were insignificant. Even with current practice of using only 10 units of heparin in flushes, Garrelts et al. (1989) state patients with underlying coagulation disorders may be at increased risk for coagulation problems. They further warn that the interpretation of laboratory tests may also be affected by the heparin.

Thrombocytopenia, occurring in approximately 10% of medical patients, is a potentially serious complication in patients receiving heparin in any amount, including low doses in heparin locks (Doty, Alving, McDonnell, & Ondra, 1986). Thrombocytopenia is a decrease in the number of platelets in the circulating bloodstream. Since platelets are important for blood coagulation, too few platelets will decrease the body's ability to form blood clots and stop bleeding. Doty et al. (1986) cite two case studies in which heparin associated thrombocytopenia occurred in patients receiving as little as 250 to 500 units of heparin per day in intravenous flushes. Peripheral IVs seldom are flushed with this amount, but repeated flushing, even of low doses of heparin, increases the risk of clotting disorders. Also, according to the American Hospital Formulary Service (McEvoy, 1988, p. 737), thrombocytopenia does not appear to be dose related and has been reported to occur with both low-dose and high-dose heparin therapy. Laster et al.,

(1987) compared 62 heparin-induced thrombocytopenia patients in 1983 with 169 similar patients between 1983 to 1986. They reported one patient with thrombocytopenia who continued to receive heparin flushes and died of a massive lower intestinal hemorrhage. Heeger and Backstrom (1986) reported that a patient's platelet count dropped from 540,000 to 50,000/cu mm (normal values are 150,000-450,000/cu mm) while on heparin flushes of less than 500 units a day. Normal saline flushes without heparin have been used in these patients with thrombocytopenia to alleviate this problem.

Another possible complication of heparin therapy is sensitivity to beef and pork. Heparin is made from porcine intestinal mucosa or bovine lung tissue (Turco, 1976). Sensitivity may result in a severe reaction to the foreign substance resulting in chills, fever, hives with itching, or difficulty breathing (Cole, 1989).

Some studies cite that the properties of heparin are associated with pain at the injection site during flushing (Barrett & Lester, 1990; Dunn & Lenihan, 1987). Others state that normal saline causes pain during flushing (Advice PRN, 1986; Cyganski et al., 1987). However, pain during flushing may be due to a preservative hypersensitivity that some patient's experience (Gilman, Goodman, & Gilman, 1985). Advice PRN (1986) states "a cannula in the vein and

administration of medications always cause some irritation" (p. 10). Thus, it is difficult to determine the source of the pain.

Standards of Practice

Standards of care are the guidelines that direct safe nursing practice. Standards of practice are derived from Standards of care and "determine the acceptable level of job performance and the scope of nursing care in which practitioners can measure their practice" (Kerfoot & Watson, 1985, p. 540). The American Nurses Association in Standards of Practice (1973, pp. 4-5) provides a broad foundation for practice and describes a "therapeutic alliance" between the nurse and client. The nurse must make decisions and perform nursing duties based on prudent, accepted nursing judgment and care with a strong theoretical knowledge base that does no harm. This theoretical knowledge comes from scientific research upon which nursing theory, practice, and education are based (Polit & Hungler, 1983, p. 3).

Current standards of practice "suggest" that IVLs be flushed every eight hours or after each medication with a low solution of heparin (Intravenous Nurses Society, 1981; McEvoy, 1988). Intravenous standards of practice are formed by the Intravenous Nurses Society (1981) which states the following:

16. 3. If heparin is used, a dose of heparin that does

not alter the patient's clotting factors shall be used for maintaining patency of I.V. intermittent cannula devices. These devices should be flushed with heparinized saline solution to maintain patency. (p.5)

Cole (1989) gives the strongest argument for continuing to flush IVLs with heparin solutions. She states studies suggesting saline is as effective as heparin are not "scientifically" adequate for changing accepted practice. She further states policy changes should be initiated only when there are "definitive therapeutic advantages" and when "good scientific data demonstrate no disadvantage to the patient" (p. 24). As stated previously, there is no one accepted standard for maintaining IVLs. Even the Intravenous Nurses Society is ambiguous using the word "if" heparin is used. The way to effect change or determine procedures is through research. It is the link between theory, education, and practice that provides a knowledge base to institute standards of care (LoBiondo-Wood & Haber, 1986, p. 5).

Economic Realities

As stated before, since the passage of the diagnosis-related group (DRG) system of reimbursement and since health care is about eleven percent of the gross national product (Stein, 1988, p. 46), it has become increasingly imperative to provide cost-effective health care. However, the quality

of health care must still be maintained.

Keeping this quality of health care high while reducing costs is a challenge faced by all health care professionals. Procedures routinely performed need to be reassessed and studied to ascertain if there are more efficient and better methods available. Patient safety and comfort must still remain top priority, however. To work more efficiently, it is also imperative to reduce nursing time on unnecessary tasks. Taylor, Hutchinson, Milliken, and Larson (1989) stated nursing time to flush a heparin lock with the low dose heparin procedure took 120-160 seconds. The normal saline procedure took 45-60 seconds, a savings of 75-100 seconds. It was further estimated the annual savings for the hospital in the study would be \$30-40,000. Others estimated total cost in using heparin flushes ranges from \$10,000 to \$30,000 per year (Dean & Ridley, 1985; Lombardi et al., 1988; E. Muramoto, personal communication, September 10, 1991; Schustek, 1984; Swerling, 1982). Thus, elimination of the routine use of heparin flushes for IVLs could significantly reduce patient and hospital costs.

Nursing time would be reduced with the elimination of the necessity for triplicate flushing of IVLs resulting in more efficient use of time (Taylor et al., 1989). Heparin is available in pre-filled syringes which is time and cost effective compared to using multiple dose vials (Cyganski et

al., 1987). It also can reduce medication errors and the risk of contamination. Pre-filled saline syringes would also reduce medication errors, decrease nursing time, and decrease risk of contamination. Pre-filled saline and heparin syringes cost approximately the same (Donham & Denning, 1987; E. Muramoto, personal communication, September 10, 1991). Another important finding in Taylor et al. (1989) was that the nurse epidemiologist found an excessive number of nurse needle sticks occurring with the flushing of heparin locks. This could be reduced with fewer needle entries into the IVL.

Significance of the Study

Standards of care need to be updated and changed appropriately as advancing technology and new knowledge dictates. Previous ways of doing things may need to be changed. The use of heparin to maintain intermittent intravenous infusion devices (IVL) may be one of those areas. Several studies suggest normal saline may be sufficient to keep these devices patent. Others contradict this claim. The literature clearly indicates that the maintenance of IVLs has a haphazard history. Many hospitals have adopted policy procedures concerning IVLs that are not founded on current research. Many other hospitals have not developed policy or do not follow existing policy concerning IVL maintenance. This research study will contribute to

nursing practice by increasing awareness and knowledge concerning intravenous practice and the use of IVLs.

Eliminating drug incompatibilities, increasing patient comfort, decreasing possible systemic effects on coagulation including thrombocytopenia, decreasing nursing time, and decreasing costs at a time of rapidly escalating health care costs are all important reasons for this study.

Definition of Terms

For the purpose of this study, the following definitions apply:

1. Heparin is a naturally occurring mucopoly saccharide. It is derived from porcine (pork) intestinal mucosa or from bovine (beef) lung tissue (Turco, 1976). It is commercially available in a sodium salt mixture of various dilutions in pre-filled syringes or multiple dose vials. In this study pre-filled syringes of 10 units per milliliter in normal saline were used to flush the intermittent intravenous infusion devices (IVL) every eight hours routinely or after each drug infusion.

2. Sodium Chloride is a fluid and electrolyte solution that is available in different percentages (Malseed, 1982, p. 709). The percentage of 0.9% is physiologically normal to the human body and is often referred to as saline, normal saline, or sodium chloride. In this study pre-filled syringes of 0.9% sodium chloride were used to flush the IVL

at intervals of every eight hours routinely or after each drug infusion.

3. Intermittent Intravenous Infusion Devices or Locks is a device more commonly referred to as a heparin lock, I.V. lock, or PRN device (Cyganski et al., 1987; Donham & Denning, 1987; Epperson, 1984). It is a specially designed intravenous catheter with a resealing diaphragm on the end which allows easy access to the patient's vein with a needle for the purpose of infusing drugs. In this study, 22, 20, and 18 gauge angiocaths (Becton Dickinson, Deseret Medical) or cathlons (Critikon) were used for vein access. The needleless system (Safsite, Burrion Medical, Inc.) was also used. In this system a valve is placed on the end of the angiocath tubing, extension tubing, or needleless tubing. The flush or medication is given by connecting directly to the valve; thus, a needle is not used in flushing the device.

4. Patency is the "condition of being wide open" (Dorland, 1982, p. 503). Patent means open, unobstructed, or not closed. Patency in this study was measured by the ability to flush the IVL catheter with one milliliter of flushing solution, either normal saline or heparin.

5. Flush is to wash out with a flow of water or a rush of water, as for cleansing (Morehead & Morehead, 1981, p. 214). The purpose of injecting the heparin or normal saline

into the IVL catheter is to flush retained medicine into the patient's blood stream and blood out of the catheter, thus avoiding clotting.

6. Phlebitis is "inflammation of a vein" (Dorland, 1982, p. 536). For the purposes of this study, phlebitis is defined and operationalized as in Appendix A.

7. S-A-S-H is a method for injecting medication through IVLs (Barrett & Lester, 1990). Normal saline is flushed through the catheter first to insure patency and to avoid possible drug incompatibilities, the medication is infused, normal saline is again flushed through the catheter to avoid incompatibilities, and, finally, heparin is injected.

Research Design

This research study proposed the following hypotheses:

1. There will be no significant difference in loss of patency rates between a flushing solution containing 0.9% sodium chloride injection alone or a flushing solution containing 0.9% sodium chloride and ten units per milliliter of heparin.

2. There will be no significant difference in the incidence of phlebitis between 0.9% sodium chloride injection and 0.9% sodium chloride containing 10 units per milliliter of heparin in flushing solutions for intermittent intravenous infusion devices.

The design was a quasi-experimental double-blind examination of catheter failures using two different flushing solutions on two hospital units. It was a replication study drawing from several previous studies by Barrett & Lester (1990), Epperson (1984), Garrelts et al. (1989), and Hamilton et al. (1988). The data were analyzed using descriptive statistics to determine if there was a difference between normal saline or heparin in flushing IVLs. The sample was viewed as IVL sites of adult hospital patients. A data collection sheet was kept daily on each IVL site with information and changes documented by research assistants.

Scope and Limitations

The scope of this study impacts the maintenance of IVLs in the hospital setting. The safest, most efficient, and most effective methods of maintaining these devices is critical to intravenous standards of care and patient care.

Limitations of this study include: (a) the sample was not randomly selected as the participants were those from two units in one particular hospital in Northern California, (b) the number of IVL sites used was not large enough to allow generalizations, (c) the technique for starting IVLs was not strictly controlled, (d) and the S-A-S-H method of flushing may not have been adhered to by each nurse.

Chapter 2

CONCEPTUAL FRAMEWORK AND REVIEW OF RELATED LITERATURE

Conceptual Framework

The Roy Adaptation Model was developed by Sister Callista Roy with adaptation as the central theme (Tiedeman, 1983). The model's theoretical framework was derived from systems theory, Helson's Adaptation Theory, and humanism (Blue, Brubaker, Papazian, & Riester, 1986). Roy (1980) views the person as an adaptive system in constant interaction with a changing environment. Manipulation of the environment is the method for nursing intervention (Blue et al., 1986; Roy, 1980).

Roy describes the person as an adaptive system with six subsystems (Tiedeman, 1983). The first two are called the cognator and the regulator and are the main functional mechanisms for adaptation. The cognator subsystem encompasses the pathway for information processing, learning, judgment, and emotion in the psychosocial realm. The regulator subsystem is concerned with neural, endocrine, and perception-psychomotor areas. The two are linked through the process of perception. The other four subsystems are secondary adaptive modes that affect how the cognator and regulator mechanisms work. They are physiologic needs, self-concept, role function, and interdependence (Tiedeman, 1983; Fawcett, 1984). In short,

the four adaptive modes affect how the regulator and cognator mechanisms work with the person using the mechanisms to adapt to the changing environment. If unable to adapt, then there is an ineffective response.

This study looks at the physiological response, a subsystem of the adaptive modes outlined by Sister Roy, to a stimulus or manipulation of the environment. The stimuli are the flushing solutions used in IVs, heparin in normal saline solution or normal saline alone. Thus, this research study was undertaken to help determine the physiological needs of hospitalized patients requiring vein access for medication therapy.

Related Literature

Fourteen studies were found indicating that normal saline was as effective as heparin in maintaining patency of IVs. Only two were found with opposite results. Two articles take an opposite view stating that it is not appropriate to switch to normal saline flushes for legal, ethical, and safety reasons. They emphasized the need for further studies.

Epperson's (1984) study was the first major research comparing normal saline and heparin. He used a double-blind quasi-experimental design involving 412 people. The conclusion was that saline was as effective as heparin and there was no increase in phlebitis with either solution. He

did not look at fibrin clot formation at the catheter tip. In answer to criticism regarding this, Epperson responded that "unless fibrin particles can be demonstrated to affect rates of phlebitis, the question is merely academic and offers little to improving patient care" (Epperson, 1984, p. 489). Jowett et al. (1986) also found no difference in patency and stated that "heparin did not seem to prevent inflammation between the two groups" (p. 18). It was noted inflammation was related to the length of insertion time of the cannula.

A study by Dunn & Lenihan (1987) looked at heparin versus saline flushes every 8 or 24 hours and found a higher incidence of phlebitis in the heparin group that was flushed every eight hours. They stated the difference was statistically insignificant. Schustek (1984) reported significant cost savings using saline over heparin for flushes and stated "there were no callbacks for problems with catheters that could be related to heparin" (p. 527). Changes in policy and procedures were made and examination of all procedures was instigated to update policies.

Harrigan (1985), in a study of 35 patients over three months, supported Epperson's findings. If the device was not used more frequently, it was flushed every twelve hours with saline. The new protocol was instituted using saline and had been in use successfully for three years when the

article was written.

A different technique of using positive pressure while withdrawing the needle was used by Shearer (1987) who found no difference in patency rates. She suggests another study using this technique with saline and heparin both as the technique was used with the saline solution only.

Two different studies by Hamilton et al. (1988) and by Lombardi et al. (1988) again found no difference in patency rates or incidence in phlebitis rates. Looking at a total of 304 IVL sites, Garrelts et al. (1989), support the use of normal saline since it produced similar rates of phlebitis and patency loss as heparin. The study extended Epperson's (1984) as it examined the IVL tip for the presence of a clot. They concluded that the presence of clots was not clinically significant as no new episodes of pulmonary embolism or strokes occurred in the saline group. They suggested a longer follow-up period to verify their conclusion, however.

Taylor et al. (1989) modeled their study after Epperson's (1984). They concluded that there were no significant differences in rates of clotting, phlebitis, or infiltration. Locks flushed with normal saline also had significantly less site leakage than those flushed with heparin. There was a savings in costs, nursing time, and decreased risk of nursing needle sticks.

A quasi-experimental design study conducted by nurses at Baptist Hospital East in Kentucky on 167 IVL sites also found no difference between saline and heparin in loss of patency rates (Miracle et al., 1989). They did not look at phlebitis rates.

The most recent published study by Barrett and Lester (1990) found that there was no statistically significant difference in patency loss between heparin and saline groups. They stated the "flushing action was responsible for prevention of clotting at the catheter tip" (p. 118). While not controlling for the phlebitic potential of other medications, they found there was a statistically greater incidence of phlebitis in the heparin group. Since heparin is a foreign protein and surfactant, they suggest heparin is a direct irritant to the vein. The study did not check for fibrin clots at the catheter tip. They did state recent advances in catheter materials and technology have reduced clotting complications.

Several articles take an opposite view in that it is not appropriate to switch to saline flushes legally, ethically, and safely. Cole (1989) admonishes the current studies for being "scientifically inadequate to justify elimination of heparinized saline as the flushing solution of choice for routine maintenance of intermittent I.V. devices" (p. S23). She further affirms that legally and ethically, changes in

policies should only be instigated when there is no harm to the patient and there is a benefit. Her strongest statement concerns the hospital's liability for medical claims that may result from the use of saline flushes that deviate from accepted standards of practice. Citing the average cost to investigate and defend a claim was \$10,985 in 1984, Cole demonstrates the savings in using saline over heparin would be quickly used up.

Morris (1989) states using a normal saline flush in place of heparin to maintain patency of intermittent intravenous devices is "one highly controversial strategy for cost containment" (p. S21). He, too, agrees with Cole that standards of practice cannot be ignored and patient safety is of utmost importance.

In a non-control group study, Cyganski et al. (1987) estimated a 35 percent increase in incidence of phlebitis in using normal saline for IVL flushes. She found twice as many restarts necessary for saline flushed locks and patients complained of burning at the site during flushing. The conclusion was that 100 units of heparin flushes were more cost-effective as there were fewer restarts needed. This study lacks credibility as it did not use control subjects or a double-blind design.

Certainly it is agreed standards of care guide and direct the health care delivery system. Nevertheless, it is

also important to question and research old methods of doing procedures as technology and advances in knowledge lead to possibly better and more beneficial ways to deliver health care. Cost-containment is a very real concern of society today and warrants scrutiny in order to provide the very best health care for all people. Everyone benefits from scientific study and the resultant improved methods of health care delivery. Thus, the question of whether or not saline is as effective as heparin in maintaining patency of IVLs is an important research study to pursue.

Summary

Peripheral intermittent intravenous infusion locks (IVL), commonly known as heparin locks, have been in use since the early 1960's. A dilute solution of heparin and saline have traditionally been used to flush these locks. The question of whether normal saline is as effective as heparin in maintaining patency of the IVL was raised by Deeb and DiMattia (1976) when it was found that only 10 units of heparin was effective.

The purpose of this research was to examine the efficacy of using normal saline alone versus normal saline with 10 units of heparin to maintain patency of the IVL. The study was a quasi-experimental double-blind design on adult hospitalized patients on a telemetry unit and a step-down unit of an acute care hospital.

There are several potential advantages to using saline alone. Eliminating drug incompatibilities, eliminating possible systemic effects on coagulation including thrombocytopenia, avoiding allergic reactions to heparin, lower costs in supplies, and decreased nursing time are all important reasons for this study.

This study used the Roy Adaptation Model of Nursing for a conceptual framework. The study looked at the physiological response of the human body to a stimulus. The stimulus was the flushing solution used in maintaining the IVL.

In reviewing the literature, it was found that many studies found normal saline as effective as heparin in maintaining IVLs. Few authors contradicted these findings. However, many researchers recommended more studies to verify the results. Thus, this study has the potential to add to the literature. Standards of care need to be backed by scientific study before changes can be made.

Chapter 3

THE METHOD

This chapter outlines the research design, procedures for data collection, and analysis of the data. The study was conducted in December 1991 through March 1992 in a hospital setting.

Research Design

The study was a quasi-experimental double-blind design. It was a replication study drawing from several previous studies by Barrett & Lester (1990), Epperson (1984), Garrelts et al. (1989), and Hamilton et al. (1988). It was a descriptive study using two groups of patients in two different hospital units. The independent variables were the 0.9% sodium chloride solution and the 0.9% sodium chloride solution with ten units per milliliter of heparin. The dependent variables were absence of phlebitis and patency of the IVL as defined on the data collection sheet (See Appendix A).

The setting was a general, district acute care hospital with 200-250 beds. The two units were a telemetry unit (4West) for patients who needed cardiac monitoring and a critical care step-down unit (TCU) where nursing care is one nurse to two patients. Patients on both units can have a variety of medical needs that usually includes cardiac monitoring. A convenience sample of adult patients,

eighteen years of age or older, were eligible to be in the study. The participants were viewed as the veins or IVL sites of the patient. Patients receiving chemotherapy, heparin therapy, investigational drugs, streptokinase, or urokinase were excluded from the study.

Permission to conduct this study was granted by the Human Subjects Institutional Review Boards of the participating hospital (See Appendix B) and San Jose State University (See Appendix C). Patient consent (See Appendix D) and a physician order were obtained when a patient had a continuous intravenous infusion (IV) changed to an IVL or when an IVL was started. Each physician at the hospital received a letter (See Appendix E) describing and explaining the study. Several informal meetings were held with the chief pharmacist to outline the study and determine the role of the pharmacy department. The pharmacist informed his staff of the study. When filling medication orders, they were not to send heparin pre-filled syringes to those patients participating in the study. This was documented on the medication print-out for the patient.

Meetings were held with the Directors of each unit to obtain verbal consent to conduct the study on their units and to explain the study design and purpose. Letters explaining the study were given to each nurse on each unit prior to starting the study (See Appendix F). Specific

study nurses/research assistants were trained to assist in the study. They consisted of three registered nurses per shift on 4West and five on each of two twelve hour shifts on TCU. Four training sessions were held to accommodate the various shifts before starting the study. The purpose of the study and the design were explained. Each study nurse was given detailed instructions (See Appendix G) on how to obtain consent from the physician and patient, documentation in the computer system, filling out the data collection form (See Appendix A), and daily inspection of each IVL site. The study nurses were specially trained to assess the IVL sites daily and before removal of the IVL by using standardized definitions of phlebitis and patency (See Appendix A). During the training sessions each group of study nurses looked at existing IVL sites on the units to assess for phlebitis. During these sessions, there was 100% agreement as to site condition assessing for phlebitis. This resulted in 100% interrater reliability. Loss of patency was determined by each patient's daily assigned registered nurse.

Each IV or IVL was inserted on the units or in the emergency department by qualified, hospital certified and trained registered nurses, or by a paramedic in the field when a patient was brought to the hospital by ambulance. The choice of needle size and type was decided by the person

inserting the IVL according to patient and medication needs. The needleless system (Safsite) was used with each patient according to hospital policy for the flushing. This system consists of a self-closing valve that is attached to the end of the IVL catheter tubing. It replaces the self-sealing diaphragm that is usually on the end of an IVL to allow needle access. The purpose of this equipment is to avoid nursing needle sticks as a needle is necessary to inject fluids or medications.

The IVL site was flushed using the S-A-S-H method of (S) flushing and checking for patency using normal saline, (A) injecting the agent or medication, (S) flushing with normal saline again, and finally (H) flushing with the study solution. The IVLs were flushed a minimum of every eight hours. The study solutions were pre-filled syringes of 0.9% sodium chloride and 0.9% sodium chloride with 10 units per milliliter of heparin. When the syringe was used to flush the IVL, the needle was first removed and then a Safsite adapter was attached. This fit the Safsite valve that had been placed on the end of the IVL catheter. Prior to the study the normal saline was drawn up by each nurse as it was needed from multiple dose vials. In order to insure a double-blind study, the pharmacist was able to obtain pre-filled normal saline syringes for the study. Care was taken to have the needle covers and sizes the same as the heparin

syringes. The only difference was in the fill amounts. The heparin contained one milliliter and the normal saline contained two milliliters. At the end of the study, in casual conversation with some nurses on the unit, the investigator did not find any nurses who noted the difference.

Each solution was labeled Solution A or Solution B. Only the chief investigator and the pharmacist knew which solution contained heparin and which solution contained normal saline only. The investigator peeled the mylar identifying label off each pre-filled syringe and attached a pre-printed label, Solution A or B, around each needle cover and then supplied each unit with the appropriate solution.

Data Collection

Data for the study were collected over a four month period. Solution B was started on 4West and Solution A was started on TCU on December 20, 1991. At the beginning of each shift during patient reports, a study nurse answered questions about the study and reminded each nurse to report all new IVLs.

When the patient was to have an IVL, the study nurse obtained an order from the attending physician for the patient to participate in the study. Then written consent was obtained from the patient. Appropriate documentation was entered in the computer system and the data collection

sheet (See Appendix A) was started. The appropriate flush solutions were supplied on each unit in the medication area. The investigator was responsible for keeping the supply of forms and solutions on each unit.

A data collection sheet was kept daily on each IVL site and information and changes documented as needed by the study nurse. Patient demographics, medications given, and type of device inserted was documented. Each shift had at least one study nurse on duty at all times.

One month into the study some changes were made. To increase the number of participants and lessen the nursing staff workload, both units were switched to using the same study solution at the same time. Thus, participants who were started on the study in TCU were able to continue on the study when transferred to 4West. The second change was a list of physicians giving standing orders for any of their patients to be in the study was developed. The third change was that consent forms for the study would be a part of the admission packets, thus eliminating the need to obtain physician consent at inconvenient hours (See Appendix H). The purpose of these changes was to decrease nursing time needed in the study and, thus, increase participant numbers in the study.

Even with these changes, it was difficult to obtain numbers for the study. It was a particularly busy time at

the hospital. Thus, due to time constraints, the data collection was ended at a sample of thirty sites.

Analysis of the Data

Descriptive statistics were used to analyze the information. The data collected were subjected to the Statistical Package for Social Sciences (SPSS) program of descriptive statistics. The statistician involved in the study did multiple tests to analyze the data. He recommended the data be presented using frequencies. The findings were organized into tables showing percentages of reasons for changing the IVL or discontinuance of the IVL.

Chapter 4

ANALYSIS AND INTERPRETATION OF THE DATA

Description of the Sample

The sample consisted of 30 IVL sites, 19 received heparin flushes and 11 received normal saline flushes. Of the heparin group there were 14 patients, and of the saline group there were 9. The number of patients is smaller than the number of sites as a few patients had more than one IVL. This was because some were restarted due to infiltration, phlebitis, 72 hour restarts, or accidental removal. All of the patients were capable of making their own health care decisions. Of the 30 IVL sites, 26 had documented cardiovascular disease and 4 had other medical problems. None were receiving chemotherapy, heparin therapy, investigational drugs, streptokinase, or urokinase. Table 1 lists the ages of the sample. The age range of the heparin group ($n=14$) was 48-88 with a mean of 67. The age range of the normal saline group ($n=9$) was 48-89 with a mean of 72. The analysis and interpretation was based on the thirty IVL sites.

Analysis

Descriptive statistics were used to analyze the data. Most of the sample participants had cardiovascular disease as presented in Table 2. This is consistent with the usual patient population in both units, TCU and 4West. Often

patients in these units have multiple diseases and health problems. In this study, only the main diagnosis for hospitalization was documented.

Table 1

Sample Ages for Each Solution

Age	Normal Saline (n=11)	Heparin (n=19)
48	1	1
52		2
53		1
59	1	
61		1
65	1	
66	1	
67		1
68		3
69		2
70		3
71		2
74		1
75	2	
76	1	
78	1	
82	2	
83		1
88		1
89	1	

M=72 SD=11.8

M=67 SD=10.2

Based on number of IVL sites rather than the number of patients.

Table 2

Diagnosis or Medical History

Diagnosis	Normal Saline (<u>n</u> =11)	Heparin (<u>n</u> =19)
Cardiovascular	10	16
Disease	1	3

Based on number of IVL sites rather than the number of patients.

All IVL sites used the Safsite device that was attached to each catheter as seen in Table 3. This device enabled the registered nurse to access the vein without using a needle. The device has a valve that opens only when fluid is infused through the catheter.

The two groups were evenly matched with respect to the type of intravenous catheter used. Table 3 identifies the percentages of catheters used. Of the heparin group, 56% (n=9) had cathlons and 44% (n=7) had angiocaths. The data were missing for three of the devices. The normal saline group had 55% (n=6) with cathlons and 46% (n=5) with angiocaths. Table 4 presents the reasons for discontinuance of each IVL device. Most of the IVLs were removed for discharge of the patient from the hospital which is of no significance to the hypotheses of this study. An almost equal percentage of IVLs were changed due to the 72

hour policy and procedural change required of all intravenous catheter devices to reduce the incidence of phlebitis. Sometimes, a device is either pulled out by a patient or it inadvertently comes out. This occurred in the heparin group only.

A greater percentage of devices were removed for phlebitis in the heparin group (17%) than the normal saline group (9%). There was also a greater percentage removed for loss of patency in the heparin group (17%) than the normal saline (9%). This supports the hypotheses of the study.

Table 3

Type of Intravenous Catheter Used: Expressed in Percentages

Type	Normal Saline (<u>n</u> =11)	Heparin (<u>n</u> =19)
Cathlon	55	56
Angiocath	45	44

Based on number of IVL sites rather than the number of patients. Three were missing for the heparin group.

Table 4

Reason for Discontinuance of IVL: Expressed in Percentages

Reason	Normal Saline (<u>n</u> =11)	Heparin (<u>n</u> =19)
Phlebitis	9	17
Patency Loss	9	17
Pulled by Patient	0	6
72 Hour Change	9	11
Discharged	73	50

Based on number of IVL sites rather than the number of patients.

Chapter 5

CONCLUSIONS AND RECOMMENDATIONS

Conclusions

This descriptive study was designed to examine the efficacy of using normal saline alone to maintain peripheral intermittent infusion locks. Using specific definitions of loss of patency and phlebitis, a sample of thirty IVL sites was assessed.

The study revealed that phlebitis and loss of patency occurred in 34% of the heparin group as opposed to 18% of normal saline group. This suggests that normal saline is as effective or more so as heparin in maintaining patency and preventing phlebitis. The results of this study validate previous studies that found normal saline was as effective as heparin in maintaining these devices.

The small sample size limits the interpretation of the results. Also, the study was conducted on units that have a patient population of predominantly cardiovascular diagnoses. Reliability of the data was enhanced, however, by the use of a double-blind study.

Recommendations

Recommendations are based on the results of this study and previous research. Since the veins and arteries of persons with cardiovascular disease are often compromised, more conclusive results may have been obtained from a

healthier population such as maternity patients. Further studies using a more diverse and larger population sample might be advantageous. However, there are numerous studies of larger populations that support using normal saline alone for maintaining IVLs and many hospitals are doing so presently with success. Due to this, it is recommended that the hospital where the study was conducted and other hospitals change their heparin lock procedure from using heparin in normal saline to using normal saline alone for flushing intermittent infusion locks.

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APPENDIX A
Data Collection Form

HEPARIN FLUSH VS SALINE FLUSH STUDY
DATA COLLECTION FORM

ROOM NO. _____ PT. INITIALS _____ AGE _____

DIAGNOSIS _____ MEDICAL HX _____

INTRAVENOUS DEVICE: SAFSITE ____ CATHLON ____ ANGIOCATH ____ GAUGE

DATE & TIME STARTED _____ DATE & TIME ENDED _____

DATE & TIME HL CONVERTED TO IV _____

DATE & TIME IV CONVERTED TO HL _____

REASON FOR DISCONTINUATION (CIRCLE):

PHLEBITIS

PATENCY LOST

PULLED BY PATIENT

CHANGED TO CONTINUOUS IV

72 HR CHANGE

DAILY EVALUATION

DATE							
NO.							

1. Phlebitis-inflammation of a vein, with redness and pain as symptoms.
2. Patency loss-inability to flush lock with 1cc of flushing solution.
3. No change in site.

MEDICATIONS INFUSED:

+ USE ONE SHEET FOR EACH INTRAVENOUS DEVICE +

APPENDIX B
Hospital Approval Letter

December 21, 1990

Helen Ritchey, B.S.N., R.N.
1220 Vienna Drive, # 484
Sunnyvale, Ca. 94089

RE: Replication Study: Saline vs. Heparin in Maintaining
Patency of Intermittent Infusion Locks.

Dear Ms. Ritchey:

The Institutional Review Board has reviewed your study and suggested several modifications. The protocol should include a physician's approval statement for patient participation. It should also contain a statement regarding compensation for injury sustained as a result of participating in the study.

As of December 24, 1990, your revised consent form was reviewed and approved. The Institutional Review Board has, therefore, granted approval for this study at _____ Hospital. Please provide a follow up report at the conclusion of the study or within 6 months.

Sincerely,

ir/

APPENDIX C

San Jose State University Approval Letter

A campus of The California State University

Office of the Academic Vice President • Associate Academic Vice President • Graduate Studies and Research
One Washington Square • San Jose, California 95192-0025 • 408/924-2480

To: Helen Ritchey, Nursing
1220 Vienna Drive #484
Sunnyvale, CA 94089

From: Charles R. Bolz
Office of Graduate Studies and Research

Date: March 12, 1991

A handwritten signature in cursive script that reads 'Charles R. Bolz'.

The Human Subjects Institutional Review Board has approved
your request to use human subjects in the study entitled:

"Saline vs. Heparin in Maintaining Patency of
Intermittent Infusion Locks"

This approval is contingent upon the subjects participating in your research project being appropriately protected from risk. This includes the protection of the anonymity of the subjects' identity when they participate in your research project, and with regard to any and all data that may be collected from the subjects. The Board's approval includes continued monitoring of your research by the Board to assure that the subjects are being adequately and properly protected from such risks. If at any time a subject becomes injured or complains of injury, you must notify Dr. Serena Stanford immediately. Injury includes but is not limited to bodily harm, psychological trauma and release of potentially damaging personal information.

Please also be advised that each subject needs to be fully informed and aware that their participation in your research project is voluntary, and that he or she may withdraw from the project at any time. Further, a subject's participation, refusal to participate or withdrawal will not affect any services the subject is receiving or will receive at the institution in which the research is being conducted.

If you have any questions, please contact Dr. Stanford or me at (408) 924-2480.

cc: Mary Reeve, Nursing

APPENDIX D
Patient Consent Form

Consent Form

AGREEMENT TO PARTICIPATE IN RESEARCH

RESPONSIBLE INVESTIGATOR: Helen Ritchey

TITLE OF PROTOCOL: Normal Saline vs Heparin Flushes in Intermittent Intravenous Infusion Locks (IVL)/ tube in vein.

I have been asked to participate in a research study that is investigating normal saline vs heparin solution flushes in maintaining patency of IVLs (tube in my vein).

I understand that

- 1). I will be asked to allow the nurse to use a syringe to flush/inject my IVL with a study solution every eight hours and/or after each medication is administered. The study solution will be either normal saline or heparin. At this hospital, IVLs are normally flushed/injected with a low dose solution of heparin. The nurse will follow _____ Hospital's written procedure for care of the IVL except that the study solution of normal saline may be used. The study will last for two months. My hospitalization is included within this study time, and I have been invited to participate in the study.
- 2). the possible risks of this study are that a clot may form at the end of the IVL catheter a)resulting in another tube being put into my vein (this sometimes occurs during the usual care of the IVL), and b) medications may be delayed temporarily.
- 3). the possible benefits of this study to me are a)that my IVL will be more closely monitored during the study, and b) there may be a decrease in the need for another tube to be put into my vein resulting in greater comfort.
- 4). alternative procedures include that the IVL will be cared for in the same manner as before this study. That includes flushing of the IVL, every eight hours and/or after each medication is infused, with a low heparin solution.

Consent Form
page 2

- 5). the results of this study may be published, but any information from this study that can be identified with me will remain confidential and will be disclosed only with my permission or as requested by law.
- 6). any questions about my participation in this study will be answered by Helen Ritchey BSN, R.N. at (408)734-0833. Complaints about the procedures may be presented to Mary Reeve Ed.D., R.N. at (408)924-3165 or _____ Hospital Medical Staff Office at _____. For questions or complaints about research subject's rights, or in the event of research-related injury, contact Serena Stanford, Ph.D. (Associate Vice-President for Graduate Studies & Research at San Jose State University) at (408)924-2480. I understand that there is no compensation available as a result of unforeseen injury due to my participation in the study.
- 7). my consent is given voluntarily without being coerced; I may refuse to participate in this study or in any part of this study, and I may withdraw at any time, without prejudice to my relations with San Jose State University and _____ Hospital.
- 8). my physician's approval has been obtained for my participation in this study.
- 9). I have received a copy of this consent form for my file.

I HAVE MADE A DECISION WHETHER OR NOT TO PARTICIPATE. MY SIGNATURE INDICATES THAT I HAVE READ THE INFORMATION PROVIDED ABOVE AND THAT I HAVE DECIDED TO PARTICIPATE.

DATE

PARTICIPANT'S SIGNATURE

WITNESS

APPENDIX E
Letter to Physicians

December 18, 1991

TO: Physicians
FROM: Helen Ritchey, RN, TCU X7135
SUBJECT: Heparin vs Saline Research Study

The Heparin Lock Research Study on 4West and TCU will begin Friday, December 20. The purpose of the study is to examine the efficacy of using normal saline vs heparin to maintain the patency of peripheral heparin locks. All patients with heparin locks have the potential to be in this study.

Each unit will have at least one nurse per shift who will be designated as a Research Assistant. This nurse will obtain consent from you for your patient to participate in the study, obtain patient consent, enter appropriate orders in the MIS, inspect the heparin lock for changes, and enter the appropriate documentation. You may also enter the order for patient participation yourself. A suggested wording is the following: "may participate in Heparin Lock Study" or "heparin lock flush per Heparin Lock Study protocol".

Thank you for your cooperation in this study.

APPENDIX F
Letter to Staff Nurses

November 4, 1991

TO: 4W/TCU Staff Nurses
FROM: Helen Ritchey, RN, TCU X7135
SUBJECT: Heparin vs Saline Research Study

I will be conducting a Research Study on 4West and TCU. The purpose of the study is to examine the efficacy of using normal saline vs heparin to maintain the patency of peripheral heparin locks. All patients with heparin locks have the potential to be in this study.

Each unit will have at least one nurse per shift who will be designated as a Research Assistant. This nurse will obtain consent for participation in the study, enter appropriate orders in the MIS, inspect the heparin lock for changes, and enter the appropriate documentation.

Your responsibility will be to inform the Research Assistant when your patient is to have a heparin lock, report any changes in an existing lock, and to use ONLY the designated Study Solution to flush the heparin lock. You will follow the usual method of caring for the heparin lock except that the pre-filled Study Solution will be used in place of the pre-filled heparin syringe.

YOU are the key to success! It is imperative that you use only the Study Solution and notify the Research Assistant of any changes in the site before removing the heparin lock.

The Research Assistant will be a resource for you and will explain the study in more detail during shift report prior to starting the study. I am also available either at home, 408-734-0833 or in TCU, x7135. I greatly appreciate your help and cooperation in this study.

Sincerely,

Helen L. Ritchey, RN

APPENDIX G
Guidelines for Study Nurses

HEPARIN LOCK STUDY
RESEARCH ASSISTANT GUIDELINES

1. Obtain order from MD for patient to participate in the study.
2. Obtain consent from patient to participate in the study. Copy to patient and original in chart with data collection sheet.
3. Documentation in MIS:
 - a) enter MD order "heparin lock flush per Heparin Lock Study protocol.
 - b) enter under additional diagnosis, "Heparin Lock Study"
 - c) enter pharmacy order through usual pathway, but type in "Heparin Lock Study Solution A (or B as appropriate).
4. Start Data Collection Sheet on patient.
5. Day Research Assistant (RA) inspect site of each heparin lock and document results.
6. Inspect and document any CHANGES in the heparin lock site PRN.
7. Be a resource to other nurses.
8. Advise me if Study Solution supply is getting low. I will be monitoring the supply.

APPENDIX H
Second Letter to Staff Nurses

January 21, 1992

TO: 4W/TCU Staff Nurses
FROM: Helen Ritchey, RN, TCU X7135
SUBJECT: Heparin vs Saline Research Study

This is to inform you of some changes I am making in the Heparin Lock Study. I am aware of the increased activity on the units and how difficult it is to get through the day and do one more thing. These changes should help make the Heparin Lock Study easier for you.

A list of physicians who have given standing orders for their patient's to be on the study will be posted in your medication area. Other physicians will still need to be asked before obtaining patient consent. Names will be added to this list, so check it frequently.

A Heparin Lock Study Consent Form will now be added to each patient admission packet. While admitting a patient, please obtain consent for the study in the event that the patient has or will have a heparin lock. After the consent is signed, you will need to enter in the computer "Heparin Lock Study Consent Signed" under additional diagnosis and put the consent form in the chart. Then when the patient is started on a heparin lock all the nurse will need to do is as before: put a sign over the bed, put sticker on opsite of heparin lock, and order through pharmacy the heparin flush in the usual way with the type in of "Heparin Lock Study Solution A or B" as appropriate.

The third change is that TCU and 4West will both use the same Study Solution. We will both start with Solution A. This way patients from TCU who transfer to 4West will be started on the study before the transfer and will continue on 4West. Then, at a designated time, both units will switch to solution A.

To summarize the changes:

1. A list of physicians names giving consent will be posted.
2. Consent forms will be in admission packets.
3. Both floors will use the same Study Solution at the same time.