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## Comparison of the Efficacy of Heparinized and Non-Heparinized Normal Saline Solutions in Maintaining Patency of Arterial Catheters

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Comparison of the Efficacy of Heparinized and  
Non-heparinized Normal Saline Solutions  
in Maintaining Patency of Arterial Catheters

By

Juanita K. Bogart

A THESIS

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Grand Valley State University  
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## ABSTRACT

### Comparison of the Efficacy of Heparinized and Non-heparinized Normal Saline Solutions in Maintaining Patency of Arterial Catheters

By

Juanita K. Bogart

Although the need for heparin in flush solutions has not been established, the currently accepted standard of practice is to use heparinized solutions in arterial catheter flush devices. Exposure to heparin may place patients at risk for developing heparin-induced thrombocytopenia (HITP) and subsequent embolic events. The purpose of the study was to test the null hypothesis that there is no significant difference in patency of arterial catheters maintained with heparinized or non-heparinized normal saline solutions. An experimental design using a convenience sample (N=31) and random assignment into experimental and control groups was used. There was no statistically significant difference in catheter patency between the two groups. The null hypothesis was supported.

This thesis is dedicated to my parents, Bob and Polly Manning, for their faith in my ability to accomplish this goal. It is also dedicated to my husband, Jerry Bogart, for keeping the household running smoothly while I was in graduate school, and to my children, Jeremy, Josh, Ben, and Matt, for being so patient while I spent hours studying.

## ACKNOWLEDGMENTS

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## CHAPTER ONE

### INTRODUCTION

Invasive arterial cannulation for the purpose of monitoring arterial waveform and providing access for frequent blood sampling has become a routine part of modern intensive care. The patency of arterial catheters is generally maintained with a continuous flow of a solution containing heparin. A recent survey conducted by the American Association of Critical Care Nurses (AACN) reported that 96% of 1,072 randomly selected critical care nurses indicated that their institutions routinely heparinized arterial catheter flush solutions (AACN, 1990). Among the 96% who used heparinized solutions, varying amounts of heparin were used in the flush solution.

There are currently no standard guidelines for the maintenance of arterial catheters in critically ill patients. While heparinized flush solutions have been used to maintain the patency of arterial catheters since their inception (Johnson & Ito, 1969), concern about the risk of heparin-induced thrombocytopenia (HITP) has prompted discussion of heparin-free alternatives (Baldwin, 1989; Warkentin & Kelton, 1989; Becker & Miller, 1989).

The reason for the efficacy of the flush solution is unclear. It may be caused by the anticoagulant or by the

continuous flow of fluid. Recent studies have evaluated the use of heparinized and non-heparinized solutions in peripheral access devices and have suggested that non-heparinized solutions may be as effective as heparinized solutions in maintaining arterial line patency (Epperson, 1984; Garrelts, LaRocca, Ast, Smith, & Sweet, 1989; Ashton, Gibson, & Summers, 1990). There are to date, however, very few studies evaluating the contribution of heparin to line patency of arterial pressure monitoring systems, and the reported results are conflicting (Clifton, Branson, Kelly, Dotson, Record, Phillips, & Thompson, 1991; Hook, Reuling, Luetttgen, Norris, Elsesser, & Leonard, 1987).

It is important that an effective and safe flush solution be identified. Nurses are in a key position to evaluate effectiveness of flush solutions since they are at the bedside and monitor the arterial waveform 24 hours a day.

#### Problem Statement

The currently accepted standard of practice is to use heparinized solutions in arterial catheter flush devices. The need for heparin in flush solutions has not been established. The use of heparinized solutions in peripheral access devices may not be necessary and may unduly place patients at risk for developing HITP and subsequent embolic events. Therefore, it is necessary to

determine if non-heparinized solutions would maintain patency of arterial catheters with as much efficacy as heparinized solutions.

#### Purpose

The purpose of this study was to determine if there was a significant difference in patency between arterial catheters maintained with heparinized normal saline flush solutions and those maintained with non-heparinized normal saline flush solutions. Patency was measured by acceptable square waveform test and free backflow of blood. Measurements were done every four hours for seventy-two hours after insertion of the catheter, or until the catheter and line were removed, whichever came first.

The research was one site of a multiple site study being conducted by the American Association of Critical Care Nurses called Thunder Project (Ledbetter, Ahrens, Brown, Gawlinski, Quinn, & Walsh, 1991). The data used for this study was collected from a 300 bed acute care hospital in the Midwest. The author was the AACN site coordinator for the hospital where data were collected (see Appendix A).

## CHAPTER TWO

### LITERATURE AND CONCEPTUAL FRAMEWORK

#### Literature Review

Current and Past Nursing Practice. Arterial cannulation, the placement of an intra-arterial catheter, is indicated for continuous arterial pressure monitoring and to avoid the discomfort and injury from frequent arterial punctures. Arterial pressure is monitored by periodic assessment of the arterial waveform. The arterial waveform is a monitor tracing with visible fluctuations caused by stretching and increased tension within the arterial wall after each left ventricular ejection (Vitello-Cicciu, 1988). Patency of the arterial catheter is determined by a square wave test. This test is performed by activating a fast flush device on the arterial catheter solution tubing and assessing the resulting change in arterial waveform (Ledbetter et al., 1991). Since 1969 heparinized flush solutions have been recommended to maintain arterial catheters (Johnson & Ito, 1969; Gardner, Warner, Toronto, & Gaisford, 1970; Kaye, 1983; Hudson-Civetta & Caruthers-Banner, 1983).

Johnson and Ito (1969) described a new pressurized tubing and flush system developed for monitoring arterial waveform and maintaining arterial catheter patency. They recommended the use of heparinized solution in a

continuous low volume flush system. They did not, however, specify the concentration of heparin needed or the preferred base solution.

Gardner et al. (1970) also described a similar continuous flow system for arterial catheter and line maintenance. They introduced the fast flush into the flow system. This produced the square-wave test, an indication of patency of the arterial catheter. They recommended the use of heparin in the flush solution, but did not indicate the optimal concentration.

Opinions vary regarding the amount of heparin to be added to the flush solution. Kaye (1983) indicated that 2-4 units/ml. solution should be used. Hudson-Civetta and Caruthers-Banner (1983) recommended 10 units/ml.

A survey of randomly selected critical care nurses was conducted by AACN (AACN, 1990). Of the 1,072 who responded, 96% indicated that heparinized flush solutions were used for arterial lines in their institution. There was much variation in the concentration of heparin in the flush solutions used by the institutions. Thirty three and one-half percent of respondents ( $n = 349$ ) indicated that their institutions used a 1:1 concentration of heparin in arterial lines, 51.4% ( $n = 551$ ) used a 2:1 concentration, only 9% ( $n = 97$ ) used heparin concentrations stronger than 2:1, and 2% ( $n = 20$ ) used non-heparinized solutions. Clinical nurse specialists

from one critical care unit indicated that they had not used heparinized solutions to maintain arterial catheter patency for over five years and had no complications that could be linked to the use of non-heparinized solution (Jiricka, M., & Schweiger, J., personal communication, December 14, 1990). This seems to support continuous flow rather than an anticoagulant for maintaining patency of arterial catheters.

Pregnancy and Use of Heparin. There are conflicting reports in the literature about the safety of using heparin during pregnancy. Andrew et al. (1985) injected radioactive heparin into sheep at 108-119 days gestation (term: 147 days). After 4 hours, blood samples were drawn from each mother and fetus for measurements of activated partial thromboplastin times and radioactivity. There was no detectable radioactivity or anticoagulant effect in any fetus. They concluded that heparin did not cross the placental barrier.

Ginsberg, Hirsh, Turner, Levine, and Burrows (1989) reviewed the literature and also reported that heparin was not found to cross the placental barrier. However, they reported that the use of heparin during pregnancy is problematic because of the potential adverse effects to the mother. These conflicting reports supported the decision to use pregnancy as an exclusion criteria for recruiting subjects in the present study since the fetus



could potentially be placed at risk.

Heparin Induced Thrombocytopenia. According to Irvin (1990), heparin therapy is not without risk. The incidence of HITP may be much greater than reported. HITP, a phenomenon in which heparin paradoxically causes platelet aggregation, may be the most serious adverse reaction associated with heparin use. The resulting thrombi are usually arterial. If an embolic event occurs, the results may be a stroke, myocardial infarction, pulmonary embolus, loss of a limb, or death.

Chang (1987), in a retrospective study, reviewed the charts of 23 clients who had received low-dose heparin therapy and were suspected to have developed HITP. Death occurred in 40% ( $n = 9$ ) and 13% ( $n = 3$ ) needed amputation of a limb. Thrombocytopenia occurred 6-13 days after initiation of the heparin therapy.

Becker and Miller (1989) described the incidence of HITP in clients who had experienced strokes. A literature review identified 600 cases of stroke victims. Over 50% of the reported cases were a result of HITP and a subsequent embolic event. Prospectively, they estimated that 10% of clients receiving heparin would develop HITP, and of those, 10% would have a thrombo-embolic event, resulting from even very small doses of heparin. There were no significant relationships between the amount of heparin received and the incidence of HITP. Severe cases

developed with doses as low as 240-500 units/day, an amount commonly received in arterial catheter flush solutions. In contrast to Chang (1987), who reported that thrombocytopenia occurred 6-13 days after heparin therapy was started, Becker and Miller (1989) reported that an immune mediated response with catastrophic results could occur within 30 minutes after a repeat exposure to heparin. Persistent sensitivity to heparin was found to last up to 28 months after initial exposure. The study was limited by the selection of only clients who had experienced strokes.

Warkentin and Kelton (1989) reviewed the literature and estimated the incidence of HITP to be 5% of those receiving heparin. They reported adverse reactions to include limb loss; myocardial infarction; pulmonary embolism; thrombotic strokes; thrombosis of the mesenteric, splenic, renal, and spinal arteries; adrenal thrombosis; and hemorrhage.

Flush Solutions. Most of the studies comparing the effects of heparinized and non-heparinized solutions on maintaining patency of catheters have been conducted in populations requiring intravenous peripheral access devices, more commonly called heparin locks. Epperson (1984) conducted a double-blind quasi-experimental study with a convenience sample ( $N = 412$ ). The hypothesis that Flush solutions containing 0.9% sodium chloride injection

alone were as effective as 0.9% sodium chloride injection containing either 10 or 100 units/ml. of heparin for preventing loss of patency in heparin-lock sites was supported. There were no statistically significant differences in length of patency of the device between the groups. A limitation of the study was the lack of random assignment into experimental and control groups. All subjects admitted to the study unit for two months received the first of the three flush solutions. After the initial two months a different solution was used for two months on all subjects admitted to the unit. The procedure was repeated for the third solution.

Garrelts et al. (1989) conducted a prospective randomized double-blind study on 147 subjects with a heparin lock. One group received heparin flushes, the other received normal saline flushes. Although there were no significant differences in phlebitis or loss of patency in the normal saline group, significantly more non-occlusive fibrin clots ( $p < .001$ ) were found at the tip of the catheter upon removal. There were no new onset stroke or embolic events in any of the subjects. Some subjects from both groups refused to have the device changed every 72 hours as the study protocol required. The data were adjusted to a set length of 72 hours for these clients, even though the catheter was not removed until much later. The investigators in the study

speculated that the additional time beyond 72 hours may have allowed more time for fibrin clots to form before the catheter was inspected, thus affecting the results of the study.

A study by Ashton et al. (1990) used a convenience sample ( $N = 32$ ) in a double-blind experimental design comparing the use of normal saline with 10 units of heparin/ml. and non-heparinized normal saline flush in heparin lock devices. The null hypothesis, that there was no difference in the effectiveness of non-heparinized and heparinized solutions in maintaining patency of heparin lock devices, was supported. The study was limited by the small sample size and non-random sampling.

There were only two studies found that compared the efficacy of heparinized and non-heparinized solutions in arterial catheters. Hook et al. (1987) used a convenience sample ( $N = 50$ ) with non-random assignment into groups for a quasi-experimental study. The subjects selected were hospitalized for cardiovascular surgery. The solutions used in the study were plain lactated ringers in the experimental group and lactated ringers with 2.5 units heparin/ml in the control group. There was no significant difference in patency variables, i.e. line irrigated easily, line drew easily, cuff pressure equaled monitor pressure  $\pm 10$  mm Hg, and the line functioned properly. A good waveform was reported more frequently in

the heparinized group than in the non-heparinized group ( $p=.03$ ). There were three incidents of clot formation in the non-heparin group and none in the heparin group, however the difference in clot formation was not significant ( $p=.13$ ). Most of the catheters had radial artery placement ( $n = 48$ ) and were in place less than 72 hours. The study was limited by the use of a convenience sample and non-random assignment into groups.

Clifton et al. (1991) used a double-blind experimental design with a small convenience sample ( $N = 30$ ). The research question was: Does heparin prolong the functional lifespan of peripheral arterial catheters and is there a difference in systemic adverse effects? The study design was for 40 subjects. Patency results were tested for significant differences after data collection was complete on 10, 20, and 30 subjects respectively. The study was stopped with 30 subjects because of significant differences found in arterial catheter patency ( $p<.01$ ). The arterial catheters flushed with 0.9% sodium chloride solution had a significantly greater loss of patency rate than catheters flushed with a 4 units/ml heparin solution. The study was limited by all subjects having only 20 gauge radial catheters. The authors stated that they used only subjects with normal platelet counts and coagulation indices, yet they used a platelet count of less than 50,000/microliter as inclusion

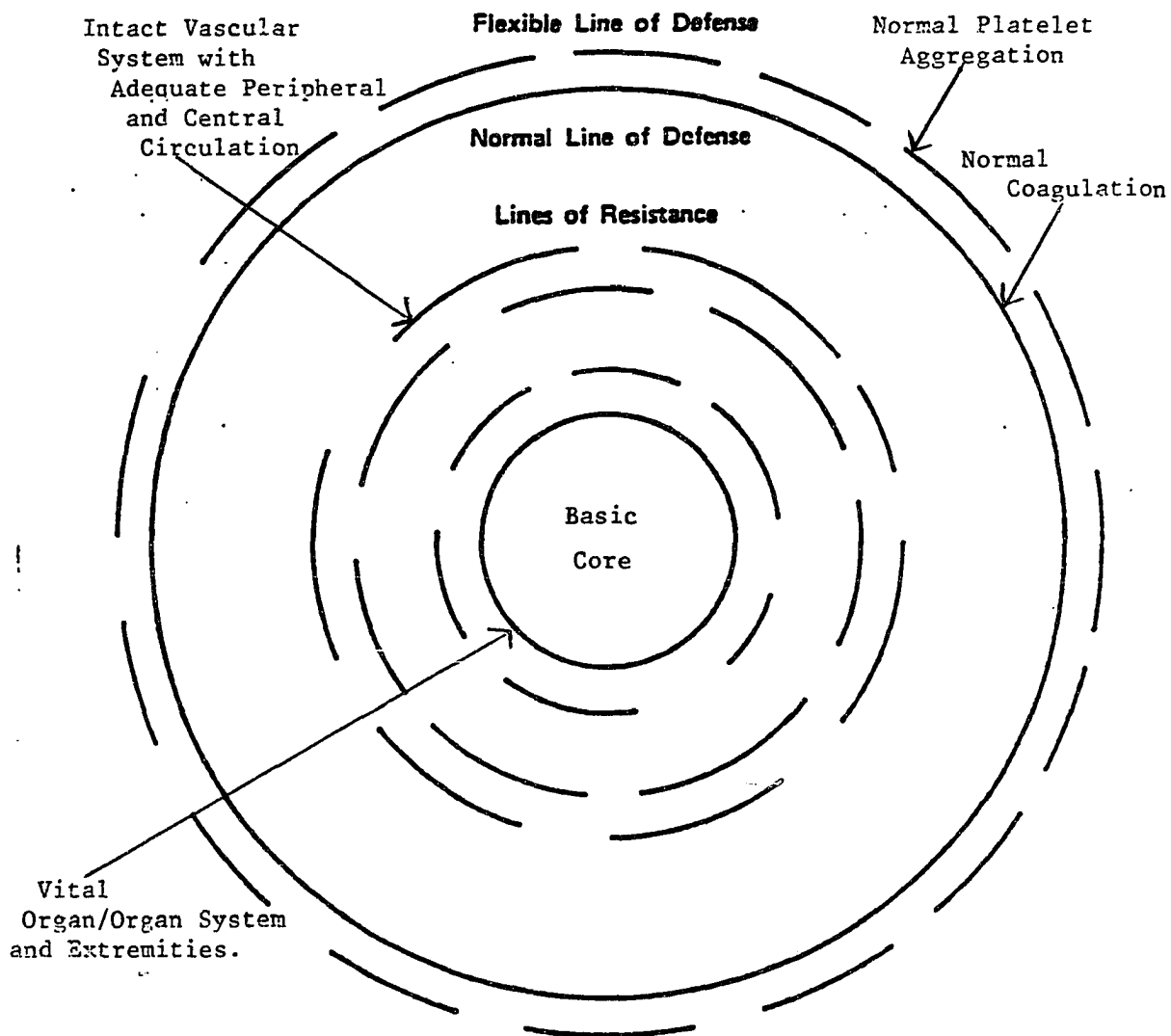
criteria. A level of less than 100,000/microliter is considered by many to be thrombocytopenic (Irvin, 1990; Chang, 1987; Warkenton & Kelton, 1989).

All arterial catheters place clients at risk for clot formation and subsequent thrombo-embolic events (Ledbetter et al., 1991). Although some studies reported fibrin clots in the catheters of subjects receiving non-heparinized flush solution, there were no reports of thrombo-embolic events (Hook et al., 1987; Garrelts et al., 1989). The literature does not support an increased risk associated with the use of non-heparinized flush solutions (Ashton et al., 1990; Hook et al., 1987; Epperson, 1984; Garrelts et al., 1989).

#### Conceptual Framework

Client/Client System. Neuman (1989) conceptualized the client/client system with concentric rings called flexible and normal lines of defense and lines of resistance which encircle a basic core (see Figure 1). The client system includes five variables: physiological, referring to bodily structure and function; psychological, referring to mental processes and relationships; sociocultural, referring to combined social and cultural functions; developmental, referring to life developmental processes; and spiritual, referring to spiritual belief influence. In this study the client is defined as anyone who requires the placement of an arterial catheter for

Figure 1



Neuman's Conceptual Model Applied to Heparinized Flush Solutions.

(Adapted from Neuman, B., and Young, R.J., 1972. A model for teaching total person approach to patient problems. Nursing Research, 21, 265.)

arterial waveform analysis or frequent blood sampling and is admitted to either one of the two Intensive Care Units (ICUs) of a hospital in the Midwest.

The basic core is composed of basic survival factors common to the species such as normal temperature range, genetic structure, response pattern, strength of organs and organ systems, and ego structure. These survival factors are necessary to maintain system integrity and life. For the purpose of this study the basic core is defined as any organ/organ system which sustains the life of the client. It also includes extremities which could require amputation secondary to a thromboembolic event.

The lines of resistance are a series of broken circles surrounding the basic core. They are activated following invasion by stressors of the normal line of defense. They contain certain factors which support the individual's basic core, thus protecting system integrity. Ineffectiveness of the lines of resistance in preventing or reversing the reaction to stressors leads to energy depletion and probable death. The line of resistance of interest to this study is an intact vascular system with adequate peripheral and central blood flow to extremities and organs/organ systems.

The normal line of defense is defined as the usual wellness state of the client. This is a state to which the client has evolved. It is changed and adapted to over



time. When the normal line of defense is penetrated by a stressor, symptomatology may begin to appear (Neuman, 1989, p. 29). Normal coagulation is considered to be the normal line of defense in this study. Normal coagulation includes a platelet count of greater than 100,000/microliter with the rest of the coagulation process intact (Ledbetter et al., 1991).

The outermost ring, the flexible line of defense, is a buffer to protect the normal line of defense from insult by stressors. It is dynamic rather than stable and can be altered over a very short period of time, such as in emergent situations. Stressor impact, whether multiple or single, has the potential for reducing the effectiveness of the flexible line of defense. In this study the flexible line of defense is defined as normal platelet aggregation.

Environment. "The environment is broadly defined as all internal and external factors or influences surrounding the identified client or client system" (Neuman, 1989, p. 31). Stressors arise from the environment and can be internal (intrapersonal) in nature, external (interpersonal or extrapersonal) in nature, or a created environment (intra-, inter-, or extrapersonal) in nature. A stressor is anything which produces disharmony among the variables. More than one stressor may occur simultaneously. Stressors may vary in impact and reaction

produced. Heparin, arising from a created extrapersonal environment, is the stressor in this study.

Health. Wellness, or health, is defined as the condition in which all five variables are in harmony with the whole of the client. Health for the client is viewed "as being on a continuum and dichotomous with illness" (Neuman, 1989, p. 33). Disharmony among the variables reduces the wellness state and is considered illness. HITP is an illness state that can result from insult by heparin to the normal line of defense, the coagulation process. In clients who are sensitive to it, heparin can alter the cell wall of platelets causing them to aggregate abnormally. This decreases the number of platelets for normal coagulation resulting in HITP. The aggregated platelets can lead to thrombus formation and subsequent embolic events (Irvin, 1990).

Nursing. Neuman's model has three levels of prevention. The first is primary prevention, such as reducing the possibility of encounter with stressors and strengthening the flexible line of defense. Secondary prevention consists of early case-finding and the treatment of symptoms. Tertiary prevention is the maintenance of stability, rehabilitation, and reeducation to prevent future occurrences.

The goal of nursing is to assist the individual to attain/maintain an optimal wellness level. Any means by

which stressors can be reduced will decrease insults to the basic core and the potential for death. Eliminating exposure to the stressor heparin in arterial catheter flushes is a means of primary prevention. This is accomplished by reducing encounters with a stressor which has the potential for penetrating the flexible line of defense via alteration of platelet aggregation (Irvin, 1990) and disruption of the coagulation process, the normal line of defense, which results in HITP and the potential for a thromboembolic event. A thromboembolic event could lead to obstructions in the vasculature system, one line of resistance, causing loss of extremities or death of the client, which results from overwhelming insult to the basic core. Determining the efficacy of non-heparinized flush solution in arterial catheters will result in knowledge which when applied, will result in reducing insult to all lines of defense and resistance and to the basic core of clients.

#### Hypothesis

The following null hypothesis was tested: There will be no significant difference in patency of arterial catheters maintained with heparinized or non-heparinized normal saline solutions.

## CHAPTER THREE

### METHODOLOGY

#### Design

The study, which was conducted at one site of a multi-site study by AACN, used an experimental design and compared subjects randomly assigned into two groups, those with heparinized arterial flush solution as the control group, and those with non-heparinized arterial flush solution as the experimental group. The heparinized flush solution was the standard solution used by the hospital and consisted of 2,000 units of heparin in one liter of 0.9% sodium chloride (normal saline) solution. The non-heparinized solution was normal saline.

Written approval for human subjects use was obtained from human research review committee of Grand Valley State University (see Appendix B). Verbal approval to conduct the study was obtained from an institutional review panel in the hospital where data were collected.

#### Sample

A convenience sample ( $N=31$ ) was recruited from two ICUs of a hospital in the Midwest. Fifteen subjects were in the control (heparin) group and sixteen were in the experimental (no heparin) group. Age ranged from 34-84 years with a mean of 68.94 years and a standard deviation of 10.81 years. Characteristics of the sample are listed

in Table 1. Both units were similar in size and patient acuity and had a patient population that consisted of medical, surgical, and neuro-trauma patients.

Inclusion and exclusion criteria were consistent with those used by the AACN in Thunder Project (Ledbetter et al., 1991). Inclusion criteria consisted of the following:

- measurement of arterial pressure and/or drawing blood via arterial catheter required because of medical condition
- 18 years of age or older
- arterial catheter connected to monitoring equipment which could display waveform and fast flush
- enrolled in the study and placed in the appropriate randomly assigned group at the time the arterial catheter was inserted.

Exclusion criteria consisted of:

- known platelet count of less than 100,000/microliter at the time of insertion of the arterial catheter
- enrolled in the study at a previous time
- enrolled in an experimental drug protocol
- known sensitivity to heparin or a physician's order excluding heparin from the treatment plan
- pregnancy.

The use of drugs with anticoagulant effects were made note of on the data collection instrument, but were not cause

Table 1

Characteristics of the Sample (N=31)

	<u>n</u>	<u>%</u>
Gender		
Male	16	51.61
Female	15	48.39
Ethnicity		
Caucasian	28	90.32
Afro-American	3	9.68
Diagnosis		
Medical	23	74.19
Surgical	8	25.81

for exclusion from the study. This was consistent with the AACN study (Ledbetter et al., 1991).

#### Operational Definitions

Patency was defined as the maintenance of an unobstructed arterial catheter as measured by two criteria, acceptable square wave test and free backflow of blood from the catheter.

Acceptable square wave test was achieved when upon activation of the fast flush device, there was a rapid upstroke which terminated in a flat line at the maximal indicator on the tracing paper and, upon release of the fast flush device, there was a rapid and unimpeded downstroke approximating a 90 degree angle with a negative deflection below baseline and a return to the arterial waveform within 12/100ths of a second (see Appendix C).

Free backflow of blood was defined as a flashback of blood in the tubing at the interface of the catheter and pressure tubing within one second when the stopcock was turned off to the transducer and opened to air.

Heparinized flush solution was 0.9% sodium chloride intravenous fluid containing the drug heparin in a 2:1 concentration. The solution was infused continuously under 300 mm Hg. pressure.

Non-heparinized flush solution was 0.9% sodium chloride intravenous fluid without the addition of the

drug heparin. This solution was also infused continuously under 300 mm Hg. pressure.

#### Instrument

Data collection instruments (see Appendix D) were provided by AACN. The instruments included tracings of acceptable and dampened (non-acceptable) square waves to assist the raters in accurate identification. Also included on the instrument were checklists for arterial bag pressure, acceptable square wave, arterial backflow, and use of anticoagulants since the previous data collection time. Demographic and clinical data were collected on gender, age, ethnicity, primary diagnosis, pressure monitoring system used, type of unit subject was in at the time of the study, descriptives of the arterial catheter used, type of arterial flush solution used, and the use of any other arterial or central lines during the study.

Content validity for the instrument was established by a panel of experts from AACN with consideration of clinical practice and the literature (Ledbetter et al., 1991). The clinical indicators of arterial line patency that were used were suggested through research conducted by Clifton et al. (1991), Hook et al. (1987), and Kaye (1983).

Interrater reliability for assessing patency and treatment of arterial lines in the two groups was



established and the protocol refined during Phase I and Phase II of a pilot study by AACN (Ledbetter et al., 1991). During Phase I, preliminary instruments and protocols were tested at one site with 11 subjects. The data collection instrument was revised based on input from the site. The level of interrater reliability for the instruments, as established by AACN in the pilot studies, was not specified.

Two sites and 34 subjects were used for Phase II of the AACN pilot study. The purpose of this phase was to enlarge the number of subjects to identify data collection problems, continue evaluation of safety, and to test the revised instrument. During this phase it was identified that heparin and non-heparin lines were sometimes treated differently. The protocol was clarified and changes were made in the inservice material presented to the data collectors.

Phase III of the AACN pilot study consisted of 3 additional sites and 21 subjects. The purpose of this phase was to validate the instrument and the inservice process and to continue monitoring the safety of the protocol. No changes were made in the instrument, inservice process, or protocol during this phase.

#### Procedure

Staff registered nurses were inserviced by the investigator. The inservice consisted of viewing a video

tape prepared by AACN that described the data collection protocol and data collection forms. The staff nurses were each given written guidelines for data collection (see Appendix E). The procedure for obtaining informed consent was presented by the investigator. The staff nurses were given a square wave form self assessment (see Appendix F) to complete and return anonymously to the investigator. Fifty percent of the self assessments were completed and returned. Interrater reliability for waveform identification was established at .94, based on the self assessment. This may have been spuriously high because of the low return rate on the self assessments.

A master log with random assignment into groups was provided by AACN. As subjects were recruited into the study, the subject's hospital identification number was placed on the next available space on the master log. This made assignment into experimental or control group.

Subjects were recruited at the time consent for arterial catheter insertion was obtained. Informed consent to participate in the study (see Appendix G) was obtained from each subject, or the appropriate representative if the subject was too ill to give consent. Selection of the appropriate representative was determined by the standard practice of the hospital: a. spouse, b. adult child, c. parent, d. adult sibling, e. guardian.

Data were collected by unit staff registered

nurses who had been inserviced on the data collection protocol. The time of the insertion of the catheter and demographic and clinical data were placed on the data collection instrument as soon as possible and less than four hours after the insertion. Four hour time intervals were calculated and the appropriate data collection points identified. Data collection was performed at the specified four hour intervals with an acceptable range of plus or minus one hour. Data collection continued for seventy-two hours or until the catheter was removed, whichever came first. The data collected at the four hour intervals were assessment of the arterial site, arterial waveform, fast flushform, and whether or not the pressure on the solution was at 300 mm Hg.

Risks were minimal. In rare circumstances thromboembolic events have occurred subsequent to the placement of any invasive catheter. There was no increased risk to the client because of the study (Ashton et al., 1990; Hook et al, 1987; Epperson, 1984; Garrelts et al., 1989).

## CHAPTER FOUR

### RESULTS

The results are reported according to demographic characteristics and patency assessment. Data were analyzed with the use of the chi-square statistic and student t-test to detect differences between groups and to determine statistical significance. The significance level was set at  $p < .05$ . The sample size was sufficient for two by two and two by three tables. A total of one loss of patency in the no heparin group and no loss of patency in the heparin group resulted in empty cells and cells with an expected frequency of  $< 5$ . Since the low loss of patency violated an assumption of sample size for the chi-square statistic, a Yate's correction was used.

#### Sample Characteristics

The groups were equivalent in demographic and arterial catheter characteristics. Fifteen subjects were in the control group and sixteen were in the experimental group. Arterial catheter characteristics are listed in Table 2. Hours of data collection during catheter placement ranged from 20 to 72 hours with a mean time of 59.74 hours ( $SD = 15.39$ ). Some catheters were removed for reasons other than loss of patency before the 72 hour cut off for data collection. According to the AACN Thunder Project protocol, data collection stopped at 72 hours even

Table 2

Arterial Catheter Characteristics (N=31)

	<u>n</u>	<u>%</u>
Site		
Radial	21	67.74
Femoral	8	25.81
Brachial	2	6.45
Length		
<2 cm.	21	67.74
>4 cm.	10	32.26
Gauge		
22	2	6.45
20	19	61.29
18	7	22.58
16	3	9.68

though some catheters remained in place longer.

Characteristics of the sample according to group membership are shown in Table 3. Arterial catheter characteristics according to group membership are shown in Table 4. When the groups were compared for equivalence in age the student t-test was used. Mean age of the no heparin group was 71.60 years (SD=5.33). The mean age of the heparin group was 66.44 years (SD=13.91). The difference in mean age between the groups was not significant ( $T=1.38$ ,  $df=19.55$ ,  $p=.18$ ). All other variables were nominal level data for which the chi-square test was used. Although chi-square value varied among the variables, there were no significant differences between groups in gender, ethnicity, diagnosis, catheter site, catheter length, or catheter gauge.

#### Patency Assessment

The hypothesis that there would be no significant difference in the patency of arterial catheters maintained with heparinized or non-heparinized normal saline solutions was supported. As shown in Table 5, only one subject lost patency of the arterial catheter. This subject was in the no heparin group. The registered nurse who determined that the catheter needed to be removed reported that there was bruising at the catheter site. She removed the catheter and documented it as loss of patency. The charge nurse in the unit at the time

Table 3

Sample Characteristics According to Group Membership

	No Heparin	Heparin	$\chi^2$
	( $n=16$ )	( $n=15$ )	
Gender			
Male	7	9	$\chi^2 = .03$
Female	8	7	$df = 1$
			$p = .86$
Ethnicity			
Caucasian	14	14	$\chi^2 = .00$
Afro-American	1	2	$df = 1$
			$p = 1.00$
Diagnosis			
Medical	12	11	$\chi^2 = .09$
Surgical	3	5	$df = 1$
			$p = .76$

Table 4

Arterial Catheter Characteristics  
According to Group Membership

	No Heparin	Heparin	$\chi^2$
	( $n=16$ )	( $n=15$ )	
Catheter Site			
Radial	10	11	$\chi^2 = .02$
Femoral	4	4	$df = 2$
Brachial	1	1	$p = .99$
Catheter Length			
<2cm.	10	11	$\chi^2 = .00$
>4cm.	5	5	$df = 1$
			$p = 1.00$
Catheter Gauge			
22	1	1	$\chi^2 = .49$
20	9	10	$df = 3$
18	3	4	$p = .92$
16	2	1	



Table 5

Patency Assessment

	No Heparin ( <u>n</u> =16)	Heparin ( <u>n</u> =15)	Total (N=31)
Patency*			
Maintained	14	16	30
Loss of	1	0	1

\*  $\chi^2=.001$ ,  $df=1$ ,  $p=.97$

reported that the bruising had been present prior to the placement of the catheter. A follow-up check of the medical record indicated that there were no untoward embolic events following the removal of the catheter.

The dependent variable in the hypothesis was patency. The independent variable was type of flush solution. Both variables were at the nominal level of measurement. The chi-square statistic with Yate's correction was used to determine if there was a statistically significant difference in catheter patency when heparinized and non-heparinized normal saline flush solutions were used. There was no significant difference in maintenance of patency between the groups ( $X^2 = .001$ ,  $df=1$ ,  $p=.97$ ).

## CHAPTER FIVE

### DISCUSSION

Exposure to the stressor heparin has been associated with life-threatening thromboembolic events (Irwin, 1990; Chang, 1987; Warkenton & Kelton, 1989; Becker & Miller, 1989). Historically, heparin has been used to maintain arterial line patency despite the lack of empirical evidence supporting the need for it. Studies to provide empirical evidence to support the efficacy of non-heparinized solutions in maintaining patency of arterial catheters have had conflicting results. Clifton et al. (1991) found that arterial catheters flushed with 0.9% sodium chloride solution had a significantly greater loss of patency than catheters flushed with heparinized solution. Hook et al. (1987) found no significant differences in patency when arterial catheters were flushed with heparinized and non-heparinized solutions. Consistent with Hook et al. (1987), this study demonstrated no significant difference in arterial catheter patency between the catheters maintained with heparinized solutions and those maintained with non-heparinized solutions in equivalent groups.

The most frequent recipients of arterial catheters are clients who have multiple insults to all lines of resistance and to the basic core in many or all of the

variables. Much of the nursing care provided to these clients is secondary or tertiary prevention as opposed to primary prevention. The Neuman Systems Model (Neuman, 1989) provides a useful conceptual framework for studying primary prevention in these clients by eliminating the stressor of heparin in maintaining patency of arterial catheters. The placement of the arterial catheter is a created extrapersonal stressor which reduces the effectiveness of the lines of resistance by disrupting the vasculature system. Heparin in the flush solution is an additional stressor which may penetrate the flexible line of defense by altering platelet aggregation. Eliminating the additional external stressor, heparin, is a means of primary prevention.

This study built on the study of Hook et al. (1987). Both studies found no significant difference in the maintenance of patency of arterial catheters maintained with heparinized and non-heparinized solutions. This suggests that patency can be maintained in arterial catheters without stressing the client with heparin. The risk of HITP which results in insult to the basic core of the client should be considered before routinely using heparinized flush solutions to maintain catheter patency.

#### Limitations

The study was limited by the small sample size (N=31). A larger sample size would reduce the possibility

that a Type II error was made. By using power analysis, AACN determined that a sample size of  $N=11,000$  was needed (Ledbetter et al., 1991) for an alpha of .05 and power equal to .80.

All of the subjects in this study had medical or surgical diagnoses. Trauma, burns, and neurological insult are common diagnoses in critical care, but were not represented in the sample of this study. Because response to stressors may vary with diagnosis, it cannot be assumed that the results of this study would apply to any other than a medical or surgical population.

This study used only 0.9% sodium chloride as the flush solution for arterial catheters. The 0.9% sodium chloride solution was chosen because it was the customary solution for the hospital in which data were collected. According to the protocol for the AACN study (Ledbetter et al., 1991) other solutions such as dextrose in water and lactated ringers solution could be used in the flush solution. These other solutions, in the absence of the heparin, may be as effective in maintaining patency of arterial catheters as 0.9% sodium chloride, but this cannot be assumed from the results of this study.

Nurses at the hospital where data were collected reported that it was unusual to have 31 catheters and only 1 loss of patency. Prior to the study it was common in that hospital to lose patency in as many as 10% of

arterial catheters with the use of heparinized flush solution. The nurses speculated that the loss of patency prior to the study may have been due in part to lack of attentiveness in assessing and maintaining the catheters by frequent flushing and waveform analysis. During the inservice for data collection the nurses were instructed to treat all arterial catheters the same; to do nothing different to the catheters in the heparin and non-heparin groups (Appendix E, item 2). All arterial catheters may have been treated differently during this study than they were prior to this study. It is possible that they were flushed more frequently, the pressure bags delivering 300 mm Hg pressure were checked and pressure maintained more consistently, and the waveforms were analyzed on a more regular basis. If this did occur, there may be a reasonable possible alternative hypothesis for the findings of this study. It may be that there would be a decrease in the loss of patency in arterial catheters when the frequency of patency checks is increased.

Although the use of waveform and flush analysis and backflow of blood in the pressure line are valid measurements of arterial catheter patency (Kaye, 1983; Johnson & Ito, 1969; Hudson-Civetta & Banner, 1983; Gardener et al., 1970), they may not have been measured reliably in this study. A self assessment (Appendix F)

was given to each nurse participating in data collection and was to be returned anonymously to the author. The nurses may have collaborated in responding on the self assessment, which may have altered the responses to the measure used to determine interrater reliability of waveform and flush analysis. Because only 50% of the self assessments were returned, the calculation of interrater reliability may have been spuriously high.

#### Recommendations for Practice

Several studies reported in the literature suggest that venous access devices can be maintained without heparin (Ashton et al., 1990; Epperson, 1984; Garrelts et al., 1989). This study and Hook et al. (1987) suggest that arterial catheters can be maintained with non-heparinized normal saline solutions.

#### Recommendations for Future Research

Similar studies on multi-lumen central venous access devices and pulmonary artery catheters would be beneficial in evaluating the need for heparin in maintaining the patency of these devices. It may be possible that clients could be spared the insult of the stressor heparin in all types of invasive catheters.

Comparing different intervals of arterial catheter patency checks could help answer the question that arose from this study: why was there less loss of patency during the study than prior to the study? More meticulous care

of arterial catheters and the flush system may significantly decrease the incidence of loss of patency.

Solutions other than normal saline may not be as effective in maintaining patency of arterial catheters in the absence of heparin. The AACN Thunder Project study protocol did not limit the study sites to normal saline. It was the only base solution used in this study because it was the standard solution used by the hospital in flush systems. Future research using a variety of solutions is needed.

#### Implications

The findings of this study and Hook et al. (1987), provide implications for nursing practice. The studies suggest that a change of policies which specify the routine use of heparin in flush solutions of arterial catheters might be appropriate. This would benefit clients by reducing exposure to a created stressor, heparin. Comparing changes in platelet counts between groups receiving heparinized and non-heparinized flush solutions could provide valuable information on the effect of low dose heparin in the development of thrombocytopenia. More studies are needed before any policy changes should be made. These studies should include larger samples, examine the frequency of patency checks, and use subjects with diverse medical diagnoses.



## Appendix A



## Appendix A

### Site Coordinator Acceptance

July 23, 1991

Juanita Bogart, RN, BSN, CCRN  
ICU Charge Nurse  
Battle Creek Health System - Leila  
300 North Avenue  
Battle Creek, MI 49016

Dear Juanita:


Welcome to the educational and data collection phases of *Thunder Project*<sup>TM</sup>. Your educational package and 60 data collection packages will be arriving within 5 working days by UPS. You may want to alert your institutional mail service to be expecting this delivery. The boxes are prominently labeled, *Thunder Project*<sup>TM</sup>.

Enclosed are the *Thunder Project*<sup>TM</sup> pre-randomized Master Data Lists for your institution. As patients enter the study, they are consecutively placed on the data list and receive their assignment to the heparin or non-heparin treatment groups based on their position on the list. As discussed in your materials, you will need to keep the lists in a central location for use by Site Research Associates.

You have been assigned the institutional number of 094. This number needs to appear on all data collection forms and on the institutional description form which will come with your educational materials.

If you do not receive your materials promptly or if you have questions when they arrive, call the Research Department at the National Office for assistance. The office now has extended hours from 7:30 AM to 5:30 PM Monday through Friday, West Coast time. Also, you may call and leave a message with the answering service at any time.

Sincerely,

  
Karen R. Sechrist, PhD, RN, FAAN  
Director of Research  
*Thunder Project*<sup>TM</sup> Task Force  
Staff Liaison

**AACN**

AMERICAN ASSOCIATION  
OF CRITICAL-CARE NURSES  
P.O. Box 50006  
Laguna Niguel, CA 92607  
714-644-9310  
FAX 714-640-4903  
TLX 296937 AACN UR

## Appendix B

Appendix B



1 CAMPUS DRIVE • ALLENDALE MICHIGAN 49401-9403 • 616/895-6611

Approval by Human Subjects Review

December 12, 1991

Juanita Bogart  
22109 Waubascon Rd.  
Battle Creek, MI 49017

Dear Juanita:

The Human Research Review Committee of Grand Valley State University is charged to examine proposals with respect to protection of human subjects. The Committee has considered your proposal, "Comparison of the Efficacy of Heparinized and Non-heparinized Solutions in Maintaining Patency of Arterial Catheters", and is satisfied that you have complied with the intent of the regulations published in the Federal Register 46 (16): 8386-8392, January 26, 1981.

Please note that approval is contingent upon the following modifications.

1. When using the Informed Consent form with patients use a shortened and easier version for them to understand.
2. In the Informed Consent document - change the last sentence of the fourth paragraph to read - Risks are present whether you choose to participate or not participate in this study.
3. In the Patient Acknowledgement section, the quotation marks should be omitted and you should include a contact person at the Battle Creek Health Center who the subject can contact in the event of questions.

Sincerely,

A black rectangular box redacting the signature of Paul Huizenga.

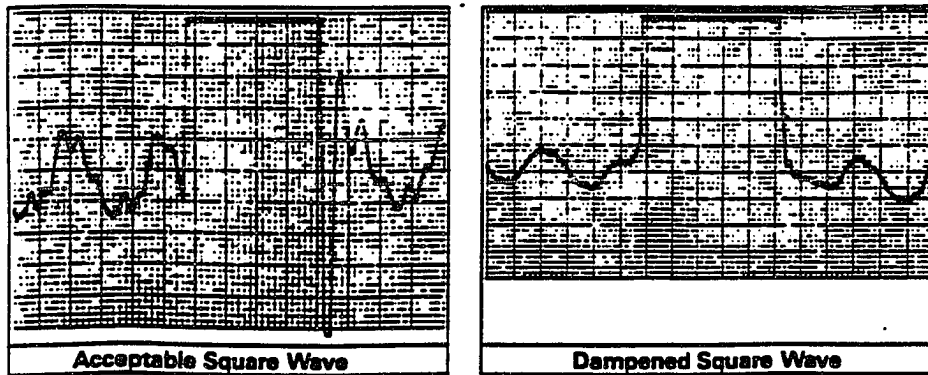
Paul Huizenga, Chair  
Human Research Review Comm

## Appendix C

## Appendix C

### Acceptable Square Wave Test

Figure 2



## **Appendix D**

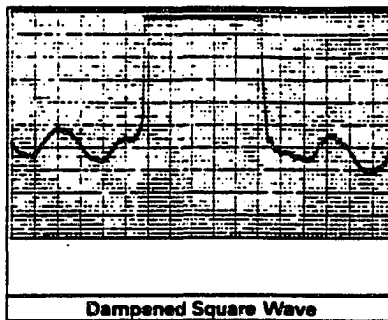
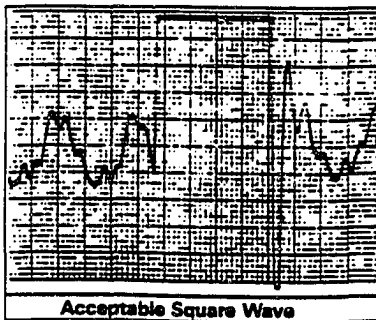
# Appendix D

## Data Collection Instruments



## AACN THUNDER PROJECT DATA COLLECTION SHEET

### HEPARIN



#### INSTITUTIONAL CODE

0	0	0
1	1	1
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6
7	7	7
8	8	8
9	9	9

Heparinized  
Flush Solution?

☒ Yes  
☐ No

Arterial Catheter Insertion Time

Date

M / D / Y

First Data Collection Time to begin 4 hours after insertion time. Then q 4<sup>x</sup> X 72<sup>x</sup>

TIME*	ARTERIAL BAG PRESSURE		PATENCY CHECKS				ANTICOAGULANTS / THROMBOLYTICS**	
	300 MM/HG OR MANF SPEC	RE-INFLATED TO 300 MM/HG	Acceptable Square Wave		Arterial Backflow		Received Previous 4 hours.	
			YES	NO	YES	NO	YES	NO
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63	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
64	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
65	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
66	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
67	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
68	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
69	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
70	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
71	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
72	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

\* Comments regarding data collection points can be made according to

on this page

\* Data collected is +/- 1 hour of data collection



## Appendix D

### Data Collection Instruments



HEPARIN	
MARKING INSTRUCTIONS	
• Make dark marks that completely fill the bubble.	
CORRECT MARK <input type="radio"/>	INCORRECT MARKS <input type="radio"/> <input type="radio"/> <input type="radio"/>

Use blue or black ink or number 2 pencil

Eligibility Checklist																																			
<p>Patients may be entered into the study if they meet the following inclusion criteria and are not excluded by one or more of the exclusion criteria.</p> <p><b>Inclusion Criteria</b> - Identify responses by filling the appropriate bubble. All answers must be yes to INCLUDE the patient in the study</p> <table> <tr> <th>Yes</th> <th>No</th> <th></th> </tr> <tr> <td><input type="radio"/></td> <td><input type="radio"/></td> <td>1. Patient is 18 years of age or older.</td> </tr> <tr> <td><input type="radio"/></td> <td><input type="radio"/></td> <td>2. The arterial line is inserted into the patient for the purpose of monitoring arterial blood pressure and/or drawing blood.</td> </tr> <tr> <td><input type="radio"/></td> <td><input type="radio"/></td> <td>3. The arterial catheter is connected to monitoring equipment which can display arterial waveforms.</td> </tr> <tr> <td><input type="radio"/></td> <td><input type="radio"/></td> <td>4. Patient is enrolled into the study and placed in the appropriate randomly assigned protocol at the time the arterial line is inserted.</td> </tr> </table> <p><b>Exclusion Criteria</b> - If the answer to any of the following questions is yes, by history, the patient is excluded from the study. Indicate responses by filling in the appropriate bubble.</p> <table> <tr> <th>Yes</th> <th>No</th> <th></th> </tr> <tr> <td><input type="radio"/></td> <td><input type="radio"/></td> <td>1. Patient has a known platelet count below 100,000.</td> </tr> <tr> <td><input type="radio"/></td> <td><input type="radio"/></td> <td>2. Patient is currently enrolled in an experimental drug protocol.</td> </tr> <tr> <td><input type="radio"/></td> <td><input type="radio"/></td> <td>3. Patient was enrolled in this study at a previous time.</td> </tr> <tr> <td><input type="radio"/></td> <td><input type="radio"/></td> <td>4. Patient has a known sensitivity to heparin or existing physician order excluding heparin from the treatment plan.</td> </tr> <tr> <td><input type="radio"/></td> <td><input type="radio"/></td> <td>5. Patient is pregnant.</td> </tr> </table>			Yes	No		<input type="radio"/>	<input type="radio"/>	1. Patient is 18 years of age or older.	<input type="radio"/>	<input type="radio"/>	2. The arterial line is inserted into the patient for the purpose of monitoring arterial blood pressure and/or drawing blood.	<input type="radio"/>	<input type="radio"/>	3. The arterial catheter is connected to monitoring equipment which can display arterial waveforms.	<input type="radio"/>	<input type="radio"/>	4. Patient is enrolled into the study and placed in the appropriate randomly assigned protocol at the time the arterial line is inserted.	Yes	No		<input type="radio"/>	<input type="radio"/>	1. Patient has a known platelet count below 100,000.	<input type="radio"/>	<input type="radio"/>	2. Patient is currently enrolled in an experimental drug protocol.	<input type="radio"/>	<input type="radio"/>	3. Patient was enrolled in this study at a previous time.	<input type="radio"/>	<input type="radio"/>	4. Patient has a known sensitivity to heparin or existing physician order excluding heparin from the treatment plan.	<input type="radio"/>	<input type="radio"/>	5. Patient is pregnant.
Yes	No																																		
<input type="radio"/>	<input type="radio"/>	1. Patient is 18 years of age or older.																																	
<input type="radio"/>	<input type="radio"/>	2. The arterial line is inserted into the patient for the purpose of monitoring arterial blood pressure and/or drawing blood.																																	
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<input type="radio"/>	<input type="radio"/>	5. Patient is pregnant.																																	

## Appendix D

### Data Collection Instruments

#### AACN THUNDER PROJECT COMMENTS SHEET



\*\*If the patient has received any of the following from sources other than the arterial line in the study during the previous 4 hour of data collection, indicate yes in the thrombolytics/ anticoagulants data collection column:

##### Anticoagulants

Acetylsalicylic acid (Aspirin)  
Dipyridamole (Persantin)  
Sulfinpyrazone (Anturane)  
Heparin sodium (Hepalean, Heparin Lock Flush Solution, Hep Lock, Liqueamin Sodium)  
Heparin calcium (Calcilean, Calciparine)  
Warfarin sodium (Coumadin, Panwarfin, Warfilone Sodium, Carfin, Sofarin)  
Dicumarol (Dicoumarin)  
Anisindione (Miradon)

##### Thrombolytics

Tissue plasminogen activator (t-PA) or Alteplase (Activase)  
APSAC or Anistreplase (Eminase)  
Streptokinase (Kabikinase, Streptase)  
Urokinase (Abbokinase)

#### COMMENTS

##### LINE NUMBER

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# Appendix D

## Data Collection Instruments

INSTITUTIONAL CODE

0	0	0
1	1	1
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6
7	7	7
8	8	8
9	9	9

## PATIENT DEMOGRAPHICS

ARE

0	0
1	1
2	2
3	3
4	4
5	5
6	6
7	7
8	8
9	9

**Instructions:** Complete this form for each person enrolled in the study prior to returning data.

<b>Description of arterial catheter used in study</b>  <table> <tr> <th>gauge</th> <th>length</th> <th>material</th> </tr> <tr> <td><input type="radio"/> &lt;14</td> <td><input type="radio"/> ≤2</td> <td><input type="radio"/> Teflon</td> </tr> <tr> <td><input type="radio"/> 14</td> <td><input type="radio"/> 2½ - 4</td> <td><input type="radio"/> Polyurethane</td> </tr> <tr> <td><input type="radio"/> 16</td> <td><input type="radio"/> &gt;4</td> <td><input type="radio"/> Other →</td> </tr> <tr> <td><input type="radio"/> 18</td> <td></td> <td></td> </tr> <tr> <td><input type="radio"/> 20</td> <td></td> <td></td> </tr> <tr> <td><input type="radio"/> 22</td> <td></td> <td></td> </tr> </table>		gauge	length	material	<input type="radio"/> <14	<input type="radio"/> ≤2	<input type="radio"/> Teflon	<input type="radio"/> 14	<input type="radio"/> 2½ - 4	<input type="radio"/> Polyurethane	<input type="radio"/> 16	<input type="radio"/> >4	<input type="radio"/> Other →	<input type="radio"/> 18			<input type="radio"/> 20			<input type="radio"/> 22			<b>At any time during the study did the patient have any of the following arterial or central lines</b>  <table> <tr> <th></th> <th>Heparinized Flush</th> <th></th> </tr> <tr> <td></td> <td>Yes</td> <td>No</td> </tr> <tr> <td>Pulmonary artery</td> <td><input type="radio"/></td> <td><input type="radio"/></td> </tr> <tr> <td>Intra-aortic balloon pump</td> <td><input type="radio"/></td> <td><input type="radio"/></td> </tr> <tr> <td>Left atrial</td> <td><input type="radio"/></td> <td><input type="radio"/></td> </tr> <tr> <td>Other →</td> <td><input type="radio"/></td> <td><input type="radio"/></td> </tr> <tr> <td colspan="3"><input type="text"/></td> </tr> <tr> <td>No other lines</td> <td><input type="radio"/></td> <td></td> </tr> </table>		Heparinized Flush			Yes	No	Pulmonary artery	<input type="radio"/>	<input type="radio"/>	Intra-aortic balloon pump	<input type="radio"/>	<input type="radio"/>	Left atrial	<input type="radio"/>	<input type="radio"/>	Other →	<input type="radio"/>	<input type="radio"/>	<input type="text"/>			No other lines	<input type="radio"/>	
gauge	length	material																																													
<input type="radio"/> <14	<input type="radio"/> ≤2	<input type="radio"/> Teflon																																													
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Other →	<input type="radio"/>	<input type="radio"/>																																													
<input type="text"/>																																															
No other lines	<input type="radio"/>																																														
<b>Is catheter heparin bonded?</b> <input type="radio"/> Yes <input type="radio"/> No																																															
<b>Arterial line insertion site</b> <table> <tr> <th></th> <th>Left</th> <th>Right</th> </tr> <tr> <td>Brachial</td> <td><input type="radio"/></td> <td><input type="radio"/></td> </tr> <tr> <td>Radial</td> <td><input type="radio"/></td> <td><input type="radio"/></td> </tr> <tr> <td>Femoral</td> <td><input type="radio"/></td> <td><input type="radio"/></td> </tr> <tr> <td>Pedal</td> <td><input type="radio"/></td> <td><input type="radio"/></td> </tr> <tr> <td>Other →</td> <td><input type="radio"/></td> <td><input type="radio"/></td> </tr> <tr> <td colspan="3"><input type="text"/></td> </tr> </table>			Left	Right	Brachial	<input type="radio"/>	<input type="radio"/>	Radial	<input type="radio"/>	<input type="radio"/>	Femoral	<input type="radio"/>	<input type="radio"/>	Pedal	<input type="radio"/>	<input type="radio"/>	Other →	<input type="radio"/>	<input type="radio"/>	<input type="text"/>			<b>Pressure monitoring system used (brand)</b> <input type="radio"/> Abbott/Sorenson <input type="radio"/> Other → <input type="radio"/> Baxter/Edward <input type="radio"/> <input type="text"/> <input type="radio"/> Cobe <input type="radio"/> Spectra-Med																								
	Left	Right																																													
Brachial	<input type="radio"/>	<input type="radio"/>																																													
Radial	<input type="radio"/>	<input type="radio"/>																																													
Femoral	<input type="radio"/>	<input type="radio"/>																																													
Pedal	<input type="radio"/>	<input type="radio"/>																																													
Other →	<input type="radio"/>	<input type="radio"/>																																													
<input type="text"/>																																															
<b>Arterial flush solution used</b> <input type="radio"/> Saline <input type="radio"/> Other → <input type="radio"/> Glucose <input type="radio"/> <input type="text"/> <input type="radio"/> Lactated ringers		<b>Primary diagnosis when patient entered study</b> <input type="radio"/> Medical <input type="radio"/> Other → <input type="radio"/> Surgical <input type="radio"/> <input type="text"/> <input type="radio"/> Trauma/burn																																													
<b>Unit where patient is enrolled in the study</b> <input type="radio"/> SICU/Cardiothoracic <input type="radio"/> Neuro ICU <input type="radio"/> MICU <input type="radio"/> Intermediate Care <input type="radio"/> CCU <input type="radio"/> Other → <input type="radio"/> Combined SICU/MICU <input type="radio"/> <input type="text"/>		<b>Gender</b> <input type="radio"/> Male <input type="radio"/> Female																																													
<b>Unit where patient is enrolled in the study</b> <input type="radio"/> SICU/Cardiothoracic <input type="radio"/> Neuro ICU <input type="radio"/> MICU <input type="radio"/> Intermediate Care <input type="radio"/> CCU <input type="radio"/> Other → <input type="radio"/> Combined SICU/MICU <input type="radio"/> <input type="text"/>		<b>Ethnicity</b> <input type="radio"/> American Indian <input type="radio"/> Hispanic <input type="radio"/> Asian/Pacific Islander <input type="radio"/> Other → <input type="radio"/> Black <input type="radio"/> <input type="text"/> <input type="radio"/> White																																													

## Appendix D

### Data Collection Instruments

**AACN**  
CRITICAL CARE



#### NO HEPARIN

##### MARKING INSTRUCTIONS

- Make dark marks that completely fill the bubble.

CORRECT MARK ●

INCORRECT MARKS ☉ ☒ ☉ ☒

Use blue or black ink or number 2 pencil

#### Eligibility Checklist

Patients may be entered into the study if they meet the following inclusion criteria and are not excluded by one or more of the exclusion criteria.

**Inclusion Criteria** - Identify responses by filling the appropriate bubble. All answers must be yes to INCLUDE the patient in the study

- | Yes                   | No                    |                                                                                                                                           |
|-----------------------|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------|
| <input type="radio"/> | <input type="radio"/> | 1. Patient is 18 years of age or older.                                                                                                   |
| <input type="radio"/> | <input type="radio"/> | 2. The arterial line is inserted into the patient for the purpose of monitoring arterial blood pressure and/or drawing blood.             |
| <input type="radio"/> | <input type="radio"/> | 3. The arterial catheter is connected to monitoring equipment which can display arterial waveforms.                                       |
| <input type="radio"/> | <input type="radio"/> | 4. Patient is enrolled into the study and placed in the appropriate randomly assigned protocol at the time the arterial line is inserted. |

**Exclusion Criteria** - If the answer to any of the following questions is yes, by history, the patient is excluded from the study. Indicate responses by filling in the appropriate bubble.

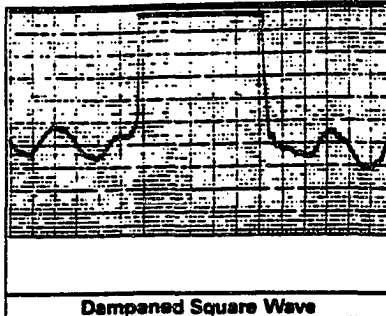
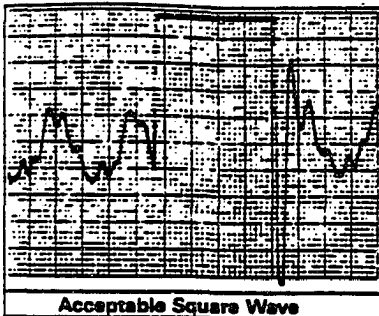
- | Yes                   | No                    |                                                                                                                      |
|-----------------------|-----------------------|----------------------------------------------------------------------------------------------------------------------|
| <input type="radio"/> | <input type="radio"/> | 1. Patient has a known platelet count below 100,000.                                                                 |
| <input type="radio"/> | <input type="radio"/> | 2. Patient is currently enrolled in an experimental drug protocol.                                                   |
| <input type="radio"/> | <input type="radio"/> | 3. Patient was enrolled in this study at a previous time.                                                            |
| <input type="radio"/> | <input type="radio"/> | 4. Patient has a known sensitivity to heparin or existing physician order excluding heparin from the treatment plan. |
| <input type="radio"/> | <input type="radio"/> | 5. Patient is pregnant.                                                                                              |

# Appendix D



## Data Collection Instruments AACN THUNDER PROJECT DATA COLLECTION SHEET

### NO HEPARIN



INSTITUTIONAL  
CODE

0	0	0
1	0	0
2	0	0
3	0	0
4	0	0
5	0	0
6	0	0
7	0	0
8	0	0
9	0	0

Heparinized  
Flush Solution?

☐ Yes  
☒ No

**ATTENTION:** Flush solution for patients in the NO HEPARIN group must be delivered through a single lumen to the study arterial line only.

Arterial Catheter Insertion Time

Date

M / D / Y

First Data Collection Time to begin 4 hours after insertion time. Then q4\* X 72\*

Data must be collected in the order listed.

TIME*	ARTERIAL BAG PRESSURE		PATENCY CHECKS				ANTICOAGULANTS/THROMBOLYTICS**		
	Data Collection Time	300 MM/HG OR MANF SPEC	RE-INFLATED TO 300 MM/HG	Acceptable Square Wave		Arterial Backflow		Received Previous 4 hours.	
				YES	NO	YES	NO	YES	NO
1		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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8		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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10		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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12		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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14		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
15		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
16		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
17		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
18		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Comments regarding data collection points can be made according to the number on next page it writes on this page.

\* Data collected is +/- 1 hour of d  
47  
tion time listed.

## Appendix D

### Data Collection Instruments

#### AACN THUNDER PROJECT COMMENTS SHEET



\*\*If the patient has received any of the following from sources other than the arterial line in the study during the previous 4 hour of data collection, indicate yes in the thrombolytics/ anticoagulants data collection column:

##### Anticoagulants

Acetylsalicylic acid (Aspirin)  
Dipyridamole (Persantin)  
Sulfipyrazone (Anturane)  
Heparin sodium (Hepalean, Heparin Lock Flush Solution, Hep Lock, Liqueamin Sodium)  
Heparin calcium (Calcilean, Calciparine)  
Warfarin sodium (Coumadin, Panwarfin, Warfilone Sodium, Carfin, Sofarin)  
Dicumarol (Dicoumarin)  
Anisindione (Miradon)

##### Thrombolytics

Tissue plasminogen activator (t-PA) or Alteplase (Activase)  
APSAC or Anistreplase (Eminase)  
Streptokinase (Kabikinase, Streptase)  
Urokinase (Abbokinase)

#### COMMENTS

##### LINE NUMBER

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# Appendix D

## Data Collection Instruments

### PATIENT DEMOGRAPHICS

INSTITUTIONAL CODE

0	0	0
1	1	1
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6
7	7	7
8	8	8
9	9	9

AGE

0	0
1	1
2	2
3	3
4	4
5	5
6	6
7	7
8	8
9	9

**Instructions:** Complete this form for each person enrolled in the study prior to returning data.

<b>Description of arterial catheter used in study</b> <table> <tr> <th>gauge</th> <th>length</th> <th>material</th> </tr> <tr> <td><input type="radio"/> &lt;14</td> <td><input type="radio"/> ≤2</td> <td><input type="radio"/> Teflon</td> </tr> <tr> <td><input type="radio"/> 14</td> <td><input type="radio"/> 2¼ - 4</td> <td><input type="radio"/> Polyurethane</td> </tr> <tr> <td><input type="radio"/> 16</td> <td><input type="radio"/> &gt;4</td> <td><input type="radio"/> Other →</td> </tr> <tr> <td><input type="radio"/> 18</td> <td></td> <td></td> </tr> <tr> <td><input type="radio"/> 20</td> <td></td> <td></td> </tr> <tr> <td><input type="radio"/> 22</td> <td></td> <td></td> </tr> </table> <p><b>Is catheter heparin bonded?</b>  <input type="radio"/> Yes <input type="radio"/> No</p> <p><b>Arterial line insertion site</b></p> <table> <tr> <th></th> <th>Left</th> <th>Right</th> </tr> <tr> <td>Brachial</td> <td><input type="radio"/></td> <td><input type="radio"/></td> </tr> <tr> <td>Radial</td> <td><input type="radio"/></td> <td><input type="radio"/></td> </tr> <tr> <td>Femoral</td> <td><input type="radio"/></td> <td><input type="radio"/></td> </tr> <tr> <td>Pedal</td> <td><input type="radio"/></td> <td><input type="radio"/></td> </tr> <tr> <td>Other →</td> <td></td> <td></td> </tr> </table>		gauge	length	material	<input type="radio"/> <14	<input type="radio"/> ≤2	<input type="radio"/> Teflon	<input type="radio"/> 14	<input type="radio"/> 2¼ - 4	<input type="radio"/> Polyurethane	<input type="radio"/> 16	<input type="radio"/> >4	<input type="radio"/> Other →	<input type="radio"/> 18			<input type="radio"/> 20			<input type="radio"/> 22				Left	Right	Brachial	<input type="radio"/>	<input type="radio"/>	Radial	<input type="radio"/>	<input type="radio"/>	Femoral	<input type="radio"/>	<input type="radio"/>	Pedal	<input type="radio"/>	<input type="radio"/>	Other →			<b>At any time during the study did the patient have any of the following arterial or central lines</b> <table> <tr> <th></th> <th>Heparinized Flush</th> <th>Yes</th> <th>No</th> </tr> <tr> <td>Pulmonary artery</td> <td><input type="radio"/></td> <td><input type="radio"/></td> <td><input type="radio"/></td> </tr> <tr> <td>Intra-aortic balloon pump</td> <td><input type="radio"/></td> <td><input type="radio"/></td> <td><input type="radio"/></td> </tr> <tr> <td>Left atrial</td> <td><input type="radio"/></td> <td><input type="radio"/></td> <td><input type="radio"/></td> </tr> <tr> <td>Other →</td> <td></td> <td></td> <td></td> </tr> <tr> <td>No other lines</td> <td><input type="radio"/></td> <td></td> <td></td> </tr> </table>		Heparinized Flush	Yes	No	Pulmonary artery	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Intra-aortic balloon pump	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Left atrial	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Other →				No other lines	<input type="radio"/>		
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Other →																																																																	
No other lines	<input type="radio"/>																																																																
<b>Arterial flush solution used</b> <input type="radio"/> Saline <input type="radio"/> Other → <input type="radio"/> Glucose <input type="radio"/> Lactated ringers <p>If solution type is changed at any time during the data collection, note in the comments section</p>		<b>Pressure monitoring system used (brand)</b> <input type="radio"/> Abbott/Sorenson <input type="radio"/> Other → <input type="radio"/> Baxter/Edward <input type="radio"/> Cobe <input type="radio"/> Spectra-Med																																																															
<b>Unit where patient is enrolled in the study</b> <input type="radio"/> SICU/Cardiothoracic <input type="radio"/> Neuro ICU <input type="radio"/> MICU <input type="radio"/> Intermediate Care <input type="radio"/> CCU <input type="radio"/> Other → <input type="radio"/> Combined SICU/MICU		<b>Primary diagnosis when patient entered study</b> <input type="radio"/> Medical <input type="radio"/> Other → <input type="radio"/> Surgical <input type="radio"/> Trauma/burn																																																															
<b>Gender</b> <input type="radio"/> Male <input type="radio"/> Female		<b>Ethnicity</b> <input type="radio"/> American Indian <input type="radio"/> Hispanic <input type="radio"/> Asian/Pacific Islander <input type="radio"/> Other → <input type="radio"/> Black <input type="radio"/> White																																																															

## Appendix E



## Appendix E

### Guidelines for Data Collection

#### AACN THUNDER PROJECT™

#### SITE RESEARCH ASSOCIATE INFORMATION SHEET

Accuracy and consistency during data collection is of critical importance during the *Thunder Project™*. We would like to ask your cooperation in helping to maintain consistency and accuracy during data collection in the following areas.

1. Maintain your standard procedures for maintenance of arterial lines. Do not change your technique, flushing or positioning procedures during the study. It is important that your usual standard of care is maintained.
2. Treat all arterial lines the same. Do nothing different to patients in the heparin and non-heparin groups.
3. Do not flush arterial lines with a syringe prior to performing the square wave test.
4. Collect data in the order indicated on the data collection form, check arterial pressure bag, adjust pressure if indicated, perform square wave test, check for arterial backflow, determine if patient has received anticoagulants or thrombolytics in the last four hours.
5. Do not skip any data collection points. If a data collection point is missed by up to 60 minutes, perform the data collection and fill in the data. If the data collection is missed by greater than 60 minutes, omit the data collection point and make a written comment on the appropriate line in the comments section.
6. If the arterial flush solution is changed (lactated ringers to saline, for example) indicate the change on the comments lines.
7. At no time should the patient be changed from the heparin to non-heparin group or vice versa. Should the physician order such a change in the solution, the data collection should be terminated and the patient removed from the study.
8. Indicate any unusual situations or changes on the comments section. Fill in the circles where indicated. Please do not write on the data collection form except in the comments section.
9. If any untoward events occur while the patient is in the study, notify the site coordinator for instructions.
10. Enjoy your participation in *Thunder Project™*!

## Appendix F

## Appendix F

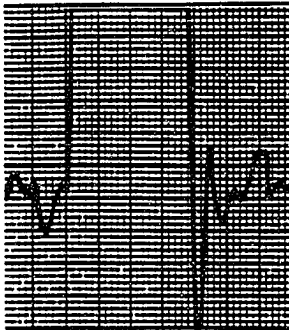
### Self Assessment

Darken the appropriate circle to indicate whether the sample square wave is acceptable or dampened.

Example

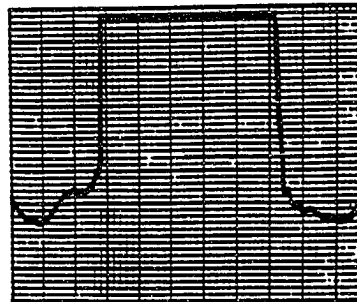
Example

1.



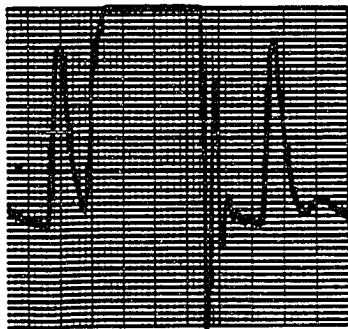
Acceptable square wave ☐ yes ☐ no

4.



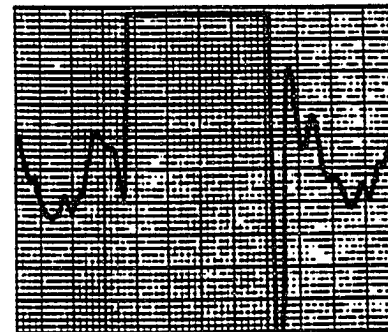
Acceptable square wave ☐ yes ☐ no

2.



Acceptable square wave ☐ yes ☐ no

5.



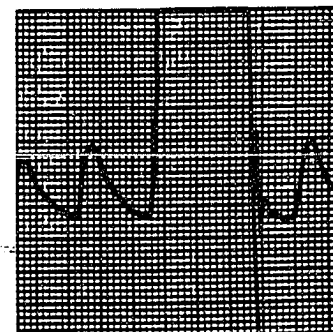
Acceptable square wave ☐ yes ☐ no

3.



Acceptable square wave ☐ 51 ☐ no

6.



Acceptable square wave ☐ yes ☐ no

## Appendix G

## Appendix G

### Informed Consent

#### Comparison of the Efficacy of Heparinized and Non-heparinized Solutions in Maintaining Patency of Arterial Catheters

You are being asked to participate in a national multisite research study developed by the American Association of Critical Care Nurses. The study will evaluate the effects of heparinized and non-heparinized flush solutions in maintaining an open and functioning arterial catheter. The results of the study will help determine which solution will best keep arterial catheters open and working. During this study you will be placed into one of two groups of patients. One group will have heparin in the flush solution and the other will not. The decision to participate in the study will not change the care you will receive and will not involve any additional costs beyond those incurred during normal care.

If clots form in the tubing, your doctor may have to remove the arterial line. In very rare cases, a clot may cause a decrease or loss of blood supply to the area beyond the catheter location. Risks are present whether you choose to participate or not participate in this study.

There are no immediate personal benefits to participation in the study. Withdrawal from the study once data collection has begun may or may not change the flush solution you receive.

#### Patient Acknowledgement

I have been given an opportunity to ask questions regarding this research study, and these questions have been answered to my satisfaction. I understand that if I have any additional questions I can contact Juanita Bogart, RN, at (616) 963-0436 or (616) 966-8555.

In giving my consent, I understand that my participation in this research project is voluntary, and that I may withdraw at any time without affecting my future medical care.

I understand that this study is part of a national study by the American Association of Critical Care Nurses and endorsed by the Society of Critical Care Medicine. I also understand that the investigator, Juanita Bogart, RN will use the information collected on all of the study participants at Battle Creek Health System to complete a thesis project for a Master of Science in Nursing degree from Grand Valley State University. I hereby authorize the investigator, Juanita Bogart, to release the information obtained in this study to the American Association of Critical Care Nurses for statistical analysis and to Grand Valley State University. I understand that results will be reported as group findings and not by individual names.

I understand that neither Battle Creek Health System, Grand Valley State University, nor Juanita Bogart agree to bear the expense of medical care for any new illness or complications which may develop during my participation in this study.

## Appendix G

### Informed Consent

"I acknowledge that I have read and understand the above information, and that I agree to participate in this study. I have received a copy of this document for my own records."

\_\_\_\_\_  
Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness

\_\_\_\_\_  
Date

The patient \_\_\_\_\_ is unable to provide informed consent due to his/her medical condition, consent is being obtained from a family member/guardian.

\_\_\_\_\_  
Family Member/Guardian

\_\_\_\_\_  
Date

\_\_\_\_\_  
Relationship

\_\_\_\_\_  
Witness/Date

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