

MALIGNANT HYPERTHERMIA PREPARATION IN THE UNITED STATES AIR  
FORCE

Kenneth A. Williams

APPROVED:

---

1. Jane McCarthy, Ph.D., CRNA, FAAN  
Date

---

John P. McDonough, Ed.D., CRNA Date

---

Kenneth P. Miller, Ph.D., RN, FAAN Date

APPROVED:

---

F.G. Abdellah, Ed.D., ScD., RN, FAAN Date  
Dean

## **DISCLAIMER STATEMENT**

### **Department of Defense**

This work was supported by the Uniformed Services University of the Health Sciences Protocol No. T01689. The opinions or assertions contained herein are the private opinions of the author and are not to be construed as official or reflecting the views of the Department of Defense or the Uniformed Services University of the Health Sciences.

## **COPYRIGHT STATEMENT**

The author hereby certifies that the use of any copyrighted material in the thesis entitled:

Malignant Hyperthermia Preparation in the United States Air Force

beyond brief excerpts is with the permission of copyright owner, and will save and hold

harmless the Uniformed Services University of the Health Sciences from any damage which

may arise from such copyright violations.

## **ABSTRACT**

Are United States Air Force hospitals prepared to treat a patient undergoing a malignant hyperthermia crisis? Malignant Hyperthermia (MH) is a life threatening syndrome that affects genetically susceptible individuals when exposed to volatile agents or succinylcholine. Patient survival is based on rapidly diagnosing MH, having a treatment plan in place, and having the necessary drugs and equipment available to treat the patient. The Malignant Hyperthermia Association of the United States (MHAUS) has advocated a five step readiness plan for hospitals to be prepared to treat an MH crisis. The results of two previous studies show a large number of hospitals are not fully prepared to handle an MH episode. A survey questionnaire was developed based on MHAUS guidelines to perform a quantitative study of USAF hospitals. A telephone interview was conducted with all 39 USAF hospitals in the continental United States and Alaska that provide general surgery and anesthesia. The results showed 100% of the hospitals had a treatment plan in place and the emergency Hotline number to MHAUS was accessible. Also, 100% of the hospitals had an MH treatment cart. The results showed 38 out of 39 hospitals stocked the recommended supply of dantrolene. All of the hospitals fully stocked the ancillary drugs needed when treating MH. All of the hospitals had an ice source and equipment needed to cool the patient during an MH episode. An annual inservice on MH recognition and treatment was performed at 33 out of 39 hospitals. Overall, based on MHAUS standards, USAF hospitals are well prepared with the supplies, equipment and training to treat a patient experiencing an MH crisis.

**Key Words: Malignant Hyperthermia, preparedness, USAF hospitals, dantrolene, Malignant Hyperthermia Association of the United States**

MALIGNANT HYPERTHERMIA PREPAREDNESS IN THE  
UNITED STATES AIR FORCE

by

Kenneth Alan Williams, BSN

THESIS

Presented to the Graduate School of Nursing Faculty of  
the Uniformed Services University of the Health

Sciences in Partial Fulfillment of the

Requirements for the

Degree of

MASTER OF SCIENCE

UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES

October 1999

## **DEDICATION**

To my wife and children, the credit for this thesis is just as much yours as mine.

Thank you for letting me have the free time I needed and for giving me all of your support with the deadlines and re-writes.

## TABLE OF CONTENTS

<b>DEDICATION</b> .....	vii
<b>LIST OF TABLES</b> .....	x
<b>CHAPTER I : INTRODUCTION</b> .....	1
Background of the Problem .....	1
Research Questions .....	3
Conceptual Framework .....	3
Variables of Interest.....	7
Definitions of Terms .....	8
Assumptions .....	9
Limitations.....	9
Summary.....	9
<b>CHAPTER II: LITERATURE REVIEW</b> .....	10
Literature Review .....	10
Summary.....	14
<b>CHAPTER III: METHODOLOGY</b> .....	15
Research Design.....	15
Protection of Human Rights.....	16
<b>CHAPTER IV: ANALYSIS OF DATA</b> .....	17
Demographics.....	17
Malignant Hyperthermia Cart.....	18
Malignant Hyperthermia Drugs .....	18

Cooling Equipment.....	20
MH Protocol .....	22
MH Hotline.....	22
MH Education.....	23
Summary.....	24
<b>CHAPTER V: CONCLUSIONS.....</b>	<b>25</b>
Survey Response.....	25
Recommendations for Future Studies.....	28
<b>REFERENCES .....</b>	<b>29</b>
<b>APPENDICES.....</b>	<b>32</b>
<b>APPENDIX A:</b> Survey Questionnaire	
<b>APPENDIX B:</b> IRB Approval: Uniformed Services University of the Health Sciences	
<b>APPENDIX C:</b> Survey Control Number, United States Air Force	
<b>APPENDIX D:</b> IRB Approval: Wright Patterson Air Force Base	



## LIST OF TABLES

Table 1. The Number of Surgeries per Month at USAF Hospitals.....	17
Table 2. Location of Stocking Dantrolene in 39 USAF Hospitals.....	19
Table 3. Responsibility for Content Checks of Malignant Hyperthermia Cart.....	20
Table 4. Frequency of Malignant Hyperthermia Drugs Checked on MH Cart.....	20
Table 5. Chilled Fluids and Cooling Blanket Available in 39 USAF Hospitals .	21
Table 6. Location of Posting Protocol in 39 USAF Hospitals	21
Table 7. Location of Posting the Hotline Telephone Number in 39 USAF Hospitals	...22
Table 8. Yearly Malignant Hyperthermia Education for Operating Room Personnel in 39 USAF Hospitals	. .22
Table 9. Hospitals Saving Dantrolene for Inservice Demonstrations	.. .23

## CHAPTER I : INTRODUCTION

### Background of the Problem

Malignant Hyperthermia (MH) is a life threatening syndrome that occurs in genetically susceptible individuals when exposed to volatile anesthetic agents and the muscle relaxant succinylcholine. The incidence of MH is approximately 1:15,000 anesthetics for children and 1:50,000 anesthetics for adults. The number of people dying from MH and its complications has dramatically decreased since it was first noted as a potential anesthetic complication. The improved survival rate can be attributed to a better understanding of MH, new drugs to treat it, and new equipment to monitor its earliest symptoms. However, even with all of these improvements, patients still die from MH (Byers & Krishna, 1992).

In 1960, Denborough and Lovell published the first clinical presentation that led to the identification of MH as a pharmacogenetic disorder. However, unpublished accounts from 1919 record familial predisposition and symptoms similar to MH (Harrison & Isaac, 1992). Even with the awareness of MH as an anesthetic risk, there was no treatment beyond cooling the patient and the mortality rate was eighty percent. In 1979, Dantrolene Sodium, which interferes with calcium release in muscle cells, was approved by the Food and Drug Administration for treating MH and drastically decreased the mortality rate to ten percent (Miranda, Donovan, Schuster, & Gerber, 1997).

MH preparedness is important to the practice of nurse anesthesia because every time a general anesthetic is administered there is a risk of the patient developing MH. The American Association of Nurse Anesthetists (AANA) recognizes the Malignant

Hyperthermia Association of the United States (MHAUS) as the leading authority on the diagnosis, treatment, and prevention of MH. The AANA advocates all anesthesia providers and health care facilities follow the recommendations of MHAUS (<http://www.aana.com/docs/hyperthermia.htm>, 1998). According to the guidelines of MHAUS and the AANA, five essential practices need to be implemented to be MH prepared. First, all operating and recovery room personnel need to be trained in the recognition and treatment of MH. Second, a designated MH cart with 36 vials of dantrolene and other drugs used to treat the MH side effects must be readily available. Third, a written treatment plan must be posted with the MH cart. Fourth, the 24-hour emergency hotline number of MHAUS must be posted on the cart. Fifth, there must be ready access to an ice machine (MHAUS, 1996).

Even with the MHAUS and AANA approved recommendations several studies (Haag, 1990; Hein, 1987; Hein, 1988;) showed that clinical facilities often lack these life-saving measures. When hospitals are unprepared, the nurse anesthetist is unprepared and the patient is at risk. This study will identify, on the basis of MHAUS criteria, whether United States Air Force (USAF) hospitals meet the minimum requirements to handle an MH crisis.

#### Problem Statement and Purpose

For a successful outcome, MH must be identified and treated early on the progression of the pathophysiology. Once identified, the anesthesia provider must act quickly to prevent organ damage and death. If the hospital, surgical center and anesthesia provider are unprepared because of missing drugs or equipment, the outcome could be

fatal. Although MH is not a common occurrence, every surgical center and hospital which provides general anesthesia to surgical patients should be prepared for an MH crisis. It is currently unknown if USAF hospitals are following MHAUS standards for preparedness in dealing with an MH crisis. The purpose of this study was to determine whether MHAUS guidelines and standards are followed in USAF hospitals.

### Research Questions

This study answered the following research questions:

1. How many USAF hospitals have an MH Cart in their anesthesia department?
2. How many USAF hospitals have the drugs necessary to treat an MH crisis in their anesthesia department as outlined by MHAUS?
3. How many USAF hospitals have cooling equipment available in the operating area to treat an MH crisis?
4. How many USAF hospitals have a treatment protocol to manage an MH crisis on the MH cart or in the anesthesia department?
5. How often do USAF hospitals provide operating room personnel MH educational programs?
6. How many USAF hospitals have the 24 hour emergency Hotline telephone number for MHAUS posted on the MH cart?

### Conceptual Framework

The pathophysiologic model of MH serves as a guide for the preparation for an MH episode. Preparing for MH can not be accomplished without understanding how MH is triggered and the damage caused to the body. Knowing what metabolic insults will occur

allows pre-set plans, medications, and training to control the situation and prevent further injury. When MHAUS standards, developed from the MH pathophysiologic model, are followed the anesthesia provider has the annual training, plans, medications, and guidance required to effectively treat a patient during an MH crisis.

MH is a genetic disease in which the increased release of intracellular calcium from the sarcoplasmic reticulum of the skeletal muscle causes a hypermetabolic state which rapidly consumes available oxygen and energy stores leading to cell death (Kaplan, 1997). Once MH is diagnosed, the goal is to stop the hypermetabolic state and simultaneously treat the metabolic complications. Normal skeletal muscle contraction occurs when depolarization of a motor nerve releases acetylcholine from the presynaptic membrane, crosses the neuromuscular junction and binds to the postsynaptic membrane of the skeletal muscle. Depolarization continues along the muscle cell membrane to the T tubules down the sarcolemma to the sarcoplasmic reticulum. Depolarization activates a voltage sensor which triggers the release of calcium from the terminal cisterna of the sarcoplasmic reticulum. The interaction of calcium on the troponin-tropomyosin complex releases the inhibition of actin and myosin and contraction occurs. Calcium pumps decrease the intracellular calcium levels and calcium is taken up into the terminal cisterna. With no calcium available troponin moves tropomyosin to block actin and myosin and muscle relaxation occurs (Rhoades & Tanner, 1995).

The current focus of MH research is on the improper functioning of the voltage sensor, the ryanodine receptor, in the presence of volatile anesthetics and succinylcholine. It is theorized that the calcium pumps can not deplete the elevated calcium levels. The

calcium gradient concentration is changed and starts a self-sustaining calcium-induced release of calcium. The continued elevated levels of calcium allow actin and myosin to contract for a prolonged period. This quickly depletes the available adenosine triphosphate (ATP) leading to the loss of the integrity of the skeletal muscle membrane resulting in a cascade of metabolic insults that can lead to death (Ording, 1993).

The continued muscle contracture leads to a state of hypermetabolism and increased ATP utilization. When aerobic metabolism uses the available oxygen anaerobic metabolism takes over and releases hydrogen, potassium, magnesium, phosphate ions, and lactate into the extracellular fluid. In addition, an elevated level of carbonic acid is produced and the lungs may not be able to eliminate the excess carbon dioxide (CO<sub>2</sub>). Because skeletal muscle mass is equal to as much as 40% of body mass this quickly develops into metabolic acidosis. As ATP is exhausted the loss of the integrity of the mitochondrial and cellular membranes occur. With cell membrane disintegration increased amounts of electrolytes and myoglobin are released from the cell to the extracellular fluid (Heffron, 1988).

The metabolic acidosis, abnormally high extracellular electrolyte levels, and cellular debris lead to further problems. The kidneys may stop filtering because of the occlusion of the glomerulus caused by myoglobin. Disseminated intravascular coagulation may develop due to the release of cellular contents upon cell membrane destruction (Kaus & Rockoff, 1994). Because the myocardium is composed of cardiac smooth muscle its calcium regulation is not affected. However, metabolic acidosis and increased levels of potassium can lead to dysrhythmias, declining cardiac contractility, and eventual cardiac

arrest (Heffron, 1988).

An MH episode may have different presentations based on severity and when it occurs perioperatively. Sometimes the first symptom will be masseter muscle spasm during induction following succinylcholine administration. However, this is not a definite indication that MH will develop. The best early indicator is a rapid rise in end-tidal CO<sub>2</sub> as monitored by capnography associated with an increase in ventilation, hypoxemia, and heart rate. Other signs may include skeletal muscle rigidity, cyanosis, cardiac dysrhythmias, and the soda lime canister turning warm and violet secondary to the increased exothermic reactions and the rapid exhaustion of the absorbent. A late sign is an elevated core temperature (Byers & Krishna, 1992). Patient survival is related to early diagnosis and rapid intervention. If treatment is initiated early organ damage is more likely to be prevented. However, if treatment is delayed the injury from metabolic acidosis and hyperthermia becomes irreversible leading to death (Beck, 1994). Rapid intervention for this metabolic emergency requires the needed equipment, drugs, and treatment plan be readily available.

Upon diagnosis of MH several tasks need to be performed simultaneously. The surgery must be stopped as soon as possible. The triggering agent or the anesthetic must be immediately discontinued and the patient hyperventilated on 100% oxygen with a new non-rebreathing anesthesia circuit to correct the hypoxia, hypercarbia, and prevent any additional volatile anesthetic leaching out of the rubber. An immediate call for assistance to aid with needed procedures such as cooling the patient and mixing dantrolene is important (Rosenberg, 1993).

The hypermetabolic state can elevate body temperature as high as 44 degrees Celcius (Heffron, 1988). To prevent this disastrous event, body cooling needs to be initiated early and aggressively. Body cooling can be achieved by various methods such as a cooling blanket, chilled intravenous fluids, ice packs, and irrigation with chilled fluids (Miranda et al. 1997).

Dantrolene sodium is initially given 2.5 mg/kg intravenously and repeated every five minutes until symptoms start to resolve. The recommended maximum dose is 10 mg/kg. Dantrolene is a skeletal muscle relaxant that inhibits the sustained release of calcium from the sarcoplasmic reticulum leading to cell relaxation. Dantrolene is packaged in 20 mg vials that require 60 ml of sterile water and vigorous shaking for several minutes to reconstitute. Based on the time needed to reconstitute it and the numerous vials required to reach an effective dose, several personnel mixing the dantrolene may be necessary (Beck, 1994). Several other drugs are often required to treat the secondary metabolic effects related to a hypermetabolic state. Sodium bicarbonate may be needed to correct the metabolic acidosis. Lasix and mannitol are used for assisting diuresis to prevent glomerular filtration damage due to myoglobinemia. Antidysrhythmics such as lidocaine need to be available. Glucose solutions and insulin and calcium chloride may be used to lower extracellular potassium levels (MHAUS, 1996).

#### Variables of Interest

The variables of this study are those items necessary to be prepared for an MH episode:

3. Equipment: designated MH cart, ice machine, chilled intravenous fluids, cooling



blanket

2. Drugs: dantrolene (36 vials), sodium bicarbonate, lasix, mannitol, glucose, insulin, calcium chloride, and antidysrhythmic drugs
3. Protocol: written preparation and treatment plan posted on MH cart or in operating room and the emergency Hotline telephone number to MHAUS
4. Training: training the anesthesia and perioperative personnel in the management of an MH episode

#### Definitions of Terms

For the purpose of this research, the following terms have been conceptually and operationally identified:

1. Equipment: devices used in an operation or activity. **Operational definition-** emergency cart and cooling source required for the treatment of MH as outlined by MHAUS (1996).
2. Drugs: A substance used as a treatment of a disease process. **Operational definition-** drugs required for the treatment of an MH crisis and its metabolic crisis as outlined by MHAUS (1996).
3. Protocol: The plan of a specific treatment. **Operational definition-** a plan of prevention and care required for the treatment of an MH episode as outlined by MHAUS (1996).
4. Training: The knowledge or experience required to complete a job or task. **Operational definition-** an annual hospital inservice or class on recognition of the signs of and treatment protocols for MH as outlined by MHAUS (1996).

### Assumptions

The following assumptions were pertinent to this study:

1. All USAF anesthesia providers will respond to this survey truthfully.
2. All of the USAF anesthesia providers are familiar with MHAUS standards.
3. The interviewee is knowledgeable with MH policies at his facility.
4. The survey sample chosen is representative of the hospitals of the USAF.

### Limitations

The following limitations were pertinent to this study:

1. The sample only included USAF hospitals.
2. The phone interviewee may not have been familiar with MHAUS standards and procedures.
3. The phone interviewee may not have been knowledgeable with MH policy at his facility.

### Summary

Because of the rapid and variable onset of MH, USAF anesthesia providers must be prepared to treat an MH episode whenever general anesthesia is administered with an anesthetic MH triggering agent. It is unknown at this time how well anesthesia providers at USAF hospitals are prepared for an MH episode. The background, pathophysiologic model, treatment of MH, the research questions, definition of terms, and the assumptions and limitations pertaining to this study were presented. The next chapter will focus on the review of literature regarding preparedness of hospitals for an MH episode.

## CHAPTER II: LITERATURE REVIEW

### Introduction

MH is a medical emergency requiring early recognition and immediate treatment for a successful outcome. Treating an MH crisis focuses on stopping the triggering agent, giving dantrolene immediately, and treating the life-threatening metabolic insults that develop during MH. Time is a critical element when combating an MH crisis. The longer the hypermetabolic process continues, the more difficult it is to control, and it can become irreversible leading to death (Beck, 1994). Rapid treatment requires operating rooms be prepared in advance to deal with an MH crisis. MHAUS (1996) advocates a cart containing dantrolene and other essential drugs, cooling equipment, and a treatment plan all easily accessible to the operating room. This chapter will review the studies regarding operating room preparedness for MH.

### Literature Review

Only a few studies have been undertaken to determine if hospitals and surgical centers are prepared for handling an MH crisis. These studies have mainly focused on the facilities dantrolene supply and if a treatment protocol is available in the facility. No study has investigated all five of the MHAUS criteria either in one study or separately. Specifically, no study examines the MH annual training of operating room personnel or ready access to an ice source. In addition, no study or review article discusses the outcomes if all of the MHAUS criteria are not met.

In 1985, a discussion of the inadequate stocking of dantrolene was presented in an editorial in the Canadian Anaesthetists Society Journal (Duncan, 1985). Because of the

high cost of dantrolene and its infrequent use cost conscious hospitals did not want to purchase dantrolene but instead shared a supply with another hospital. Another problem was the pharmaceutical company set the minimum purchase amounts. According to the standards of MHAUS (and the Malignant Hyperthermia Association of Canada) no anesthetic should be given without 36 vials of dantrolene available. Regionalization or sharing of dantrolene stocks is not appropriate to guarantee a quick administration.

Hein et al.(1987) presented the results of an informal telephone MH preparedness survey of hospitals and surgical centers around Dallas, Texas. Twenty-three institutions were polled regarding where their supply of dantrolene was stored. Four of the facilities had no dantrolene available. The other nineteen stored the dantrolene in the operating room. This study was limited in sample size, did not ask about the dantrolene quantity stocked or other items related to preparedness.

Building on his earlier study, Hein (1988) reviewed MH readiness on a national scale with more in-depth questions. A mail survey of 208 hospitals with 184 surveys returned and a telephone survey of 73 ambulatory surgical centers (ASC), with 50 participating. Seven hospitals and 11 ASCs stated they did not stock dantrolene in their facility but relied on another facility if needed. Ten hospitals and 16 ASCs stocked less than 12 vials of dantrolene. Fifty-three percent of hospitals and twenty percent of ASCs stocked 36 or more vials of dantrolene. It was stated that 28% of hospital pharmacies stock dantrolene for another facility. The author concluded that 17 of 184 hospitals and 25 of 50 ASCs were incapable of effectively treating a fulminant rapid MH episode in a timely manner to avert serious complications. This study found that 90% of the ASCs and

44% of hospitals had an MH protocol. The author noted that the smaller the facility the less often it was fully stocked with dantrolene. Based on this, he speculated that estimates of stocking dantrolene would be even lower than this study if every facility was polled. In addition, the author tried to extrapolate the results to estimate patient deaths using statistics from national hospital statistics. Based on the facilities judged not to be prepared for an MH crisis and number of general anesthetics delivered, he estimated that between 8 to 48 lives would be placed in jeopardy if these patients developed MH.

Another study on MH readiness was undertaken by the AANA Council for Public Interest in Anesthesia (CPIA). The findings of this research are based on the random sampling of 501 responses from 15,980 AANA members. This study found that 36% of CRNAs stated that dantrolene was stored in the pharmacy, 69% in the anesthesia department, and 29% in the operating room. Seventy-five CRNAs stated they did not stock any dantrolene, but of those 91% stated it could be obtained in an emergency. Only 56% stated their facility had 36 or more vials of dantrolene. Fifty-nine percent stated anesthesia services were responsible for checking the dantrolene supply and 58% stated pharmacy was responsible. Seventy-eight percent stated the MHAUS Hotline emergency phone number was listed in various places. Ninety-seven percent had a written MH protocol (Haag, 1990).

Currently there are still institutions that do not stock the recommended supply of dantrolene. A survey of questions from the MHAUS Hotline (Rosenberg, 1995) discussed a case where three hospitals in a thirty mile radius shared 36 vials of dantrolene. The anesthesia providers at these three facilities thought they had enough for an initial dose and

then could receive additional dantrolene from another facility if needed. According to Gronert (1990) this is not adequate preparation for an MH episode. He stated that information on MH is widespread and ignorance is not a valid defense. Liability would not be incurred if the anesthesia provider could show that the patient was continuously monitored, had the necessary resuscitation drugs and equipment immediately available, and provided quick and diligent care during an MH crisis.

Many authors (Gronert, 1980; Katz, 1992; Merz, 1986; Nelson & Flewellen, 1983) agree with the MHAUS standard of stocking 36 vials of dantrolene in the operating room area. Gronert (1980) states that dantrolene is only effective while there is still adequate muscle perfusion. Relying on dantrolene from a shared source is dangerous because of the time required to obtain and prepare the drug and because the body temperature can rise one degree Celcius every five minutes during an MH crisis. Dantrolene must be stored in the operating area so it can be administered as quickly as possible.

The concept of staff training appears to be the least discussed topic in MH planning. Katz (1992) states the health care team needs to work together planning for an MH episode which may not be seen for years. Newberry (1990) states that 8-10 people may be necessary to manage an MH episode. He lists the various tasks that need to be performed and the drugs to be given. He stated that all personnel need to know the location of the drugs and equipment needed during an MH episode and recommends a priority list be made as a poster and placed on the wall. Beck (1994) in addressing staff training states that her institution has MH treatment instructions during the perioperative nursing orientation, inservices, and also posts MH information on a bulletin board. Barta

(1995) discussed how a mock MH crisis increased their awareness and appreciation for preparedness. The operating room team was surprised at how long it took to mix dantrolene and to retrieve things not located on the MH Cart. Rosenberg (1995) states that using outdated dantrolene for inservice purposes allows personnel to experience how dantrolene is mixed before an actual MH episode occurs.

### Summary

Previous studies show a definite lack of achieving minimum standards for treating an MH crisis. No study has looked at facilities keeping a separate MH cart ready with all of the MH treatment drugs and equipment. Presently, the extent of annual training about MH for anesthesia providers and operating staff is unclear.

This study examines the same issues identified in previous studies. However, gaps in the knowledge base are addressed by reviewing the five MH preparation criteria developed by MHAUS. Specifically, this study addresses how prepared United States Air Force hospitals are to handle an MH crisis based on MHAUS standards. This information will benefit nursing by identifying if further improvements need to be made to improve patient safety.

## CHAPTER III: METHODOLOGY

### Introduction

The purpose of this study was to answer questions related to MH readiness. This study identifies how many USAF hospitals have an MH cart, the drugs necessary to treat an MH episode, cooling equipment, and a written treatment protocol to manage an MH episode. In addition, this survey identifies how often operating room personnel are given MH educational programs.

### Research Design

The descriptive research design for this study explored the MH readiness of USAF hospitals. The initial step was identifying the criteria for MH readiness (MHAUS, 1996) and reviewing previous studies (Haag, 1990; Hein, 1988) on MH readiness. The sample was all USAF hospitals in the continental United States and Alaska providing general anesthesia. Using this information a telephone questionnaire was developed and is shown in Appendix A. Content validity was established by having two anesthesia experts review and critique the questionnaire. The experts are a master's and doctoral prepared nurse anesthetist and an anesthesiologist not involved in the initial development of the questionnaire. Both are active members on the MHAUS Professional Advisory Council.

The next step involved obtaining approval to perform the study. First, a copy of the study was sent to the USAF research department at Randolph Air Force Base, Lou Datko (DatkoL@hq.afpc.af.mil), for review and a survey control number was issued, USAF SCN 98-58. Second, IRB approval was obtained from Wright-Patterson Air Force



Base Clinical Investigations. Third, IRB approval was obtained from the Uniformed Services University of the Health Sciences.

Once approval for the study was obtained a telephone interview was conducted. An anesthesia provider at the facility was contacted by telephone using the Defense Security Network (DSN) and asked the questionnaire.

#### Protection of Human Rights

This study did not involve patient contact of any nature. Participants and facility names were known to the researcher only for contact purposes. All data collection were coded for anonymity. No specific institution will be identified. All of the data were analyzed and reported in the aggregate.

The data collection was coded and entered into a computer for analysis via the Statistical Package for the Social Sciences (SPSS)(1998) software program. Data was summarized in terms of frequency distributions, mean, and standard deviations.

## CHAPTER IV: ANALYSIS OF DATA

### Introduction

In this study the MH preparedness of USAF hospitals was identified using MHAUS guidelines. A survey was developed to examine USAF hospitals stocking of dantrolene, having a MH protocol, maintaining the 24 hour emergency Hotline number to MHAUS, annual MH training, and a supply to an ice source. The point of contact for the survey at each hospital was a CRNA or anesthesiologist, who was knowledgeable regarding MH preparation at their facility. Demographic data about MH preparation patterns was identified at each of the hospitals.

### Demographics

The 39 USAF hospitals in the continental United States and Alaska that provide general anesthesia were interviewed by telephone. Hospitals that do not provide general anesthesia were not included in the study. Assessing the hospitals by size and number of surgeries, demonstrated if MH preparation was consistent in all USAF facilities or if there are patterns evident based on hospital size. The hospitals were grouped by 0 to 100, 101 to 200, 201 to 300, and greater than 300 surgeries per month. The results showed that 50% (19/39) of the hospitals performed less than 100 surgeries per month and only five hospitals performed greater than 300 surgeries per month, (see Table 1).

**Table 1.**

**The Number of Surgeries per Month at 39 USAF Hospitals (1999)**

Surgeries per Month	Number of Hospitals	Mean number of Surgeries per Month
0 - 100	19	49
a. 200	9	114
201 - 300	6	220
>301	5	452

### Malignant Hyperthermia Cart

The results showed that each anesthesia department had a dedicated MH cart readily available. However, in one of the small hospitals (0-100 surgeries) the MH cart was not specifically designated for MH. This cart was used as a combination MH and difficult airway cart. The point of contact stated a designated MH cart was on order and would soon be in operation.

### Malignant Hyperthermia Drugs

In this survey the availability of the drugs needed to treat an MH crisis was identified. In addition, information on where drugs were stored, who checks the drugs, and how often the cart was checked was obtained. Dantrolene, was the first drug on the questionnaire. Of the 39 hospitals questioned 97% (38/39), had at least the recommended 36 vials of dantrolene. One small hospital (0 - 100 surgeries/month) stocked only 12 vials and stated it had a plan to get more from a local civilian facility if needed. This is the same hospital that did not have a dedicated MH cart. According to this data, the frequency of surgeries in a USAF hospital does not appear to influence the availability of dantrolene because 96% of the smaller hospitals met the recommended supply. The reason given by the hospital that only stocked 12 vials of dantrolene was low number of surgical cases

The next several questions on the survey looked at the other drugs stocked on the MH cart. All 39 hospitals stated they stocked sterile water, sodium bicarbonate, calcium chloride, mannitol, furosemide, dextrose, and regular humulin insulin. However, four hospitals stated they kept their mannitol in a warmer in the operating room area to prevent crystals forming in the bottle. In addition, three hospitals stored the insulin in a

refrigerator in the operating room area. These hospitals stated the insulin or mannitol would be immediately available if needed.

The next question was where is the dantrolene stocked. No hospital stocked the dantrolene solely in the pharmacy. Among all hospitals, 67% stored the dantrolene in the MH cart only and 33% stored it both in the MH cart and the pharmacy (see Table 2). The hospitals stated dantrolene was stored in the pharmacy usually because of lack of storage space in the MH cart or pharmacy personnel could mix the dantrolene when notified of an MH crisis. MHAUS (1996) recommends that 36 vials of dantrolene are stocked in the MH cart for ready access for mixing in an emergency. This study did not question how many vials of dantrolene were stocked in the MH cart and how many were stocked in the pharmacy. Seven facilities stated they stocked a larger supply than the recommended 36 vials. It was not questioned if these facilities stocked 36 vials of dantrolene in the MH cart and the rest in the pharmacy.

**Table 2.**

Location of Stocking Dantrolene in 39 USAF Hospitals

Surgeries per Month	Number of Hospitals	Location of Stocking Dantrolene		
		MH Cart	Cart and pharmacy	Total
0 - 100	19	74	26	100
7. 200	9	56	44	100
201 - 300	6	67	33	100
>301	5	60	40	100
All Hospitals	39	67	33	100

The survey identified who checked the contents of the MH cart at the hospitals and how often. The CRNA was most frequently responsible for this checking, either alone in

41% of the hospitals or with the pharmacy in 18% of the hospitals (see Table 3).

**Table 3.**

**Responsibility for Content Checks of Malignant Hyperthermia Cart**

Surgeries per Month	Number of Hospitals	Pharmacy	Operating Room	Anesthesia Technician	CRNA	CRNA plus Pharmacy	Total
0 - 100	19	11	11	11	47	20	100
a. 200	9	11	33	0	45	11	100
201 - 300	6	17	17	17	32	17	100
>301	5	0	0	60	20	20	100
All Hospitals	39	11	15	15	41	18	100

Drugs on the MH cart were also checked for expiration outdates and quantity.

Among all hospitals 85% check contents monthly whereas 13% check them every week

(see Table 4).

**Table 4.**

**Frequency of MH Drugs Checked on Malignant Hyperthermia Cart**

Surgeries per Month	Number of Hospitals	Weekly	Monthly	Quarterly	Total
0 - 100	19	5	95	0	100
8. 200	9	11	78	11	100
201 - 300	6	17	83	0	100
>301	5	40	60	0	100
All Hospitals	39	13	85	2	100

**Cooling Equipment**

The next question focused on the MHAUS (1996) guideline for ready access to an ice machine to help cool the body during an MH crisis. While no previous study has been performed on this topic it is an important first line measure in treating an MH crisis. Ice

was readily available in the operating area at 38 of the 39 hospitals (97%). The hospital, 100-200 surgeries/month, stated ice could be quickly obtained from the adjacent ward but was not in the immediate operating area. Based on the MHAUS (1996) wording that ice be readily available, and not just in the operating area, 100% compliance was judged for all the hospitals.

This study also reviewed other methods to cool the body such as chilled intravenous fluids and a cooling blanket. These measures are not fully within the MHAUS(1996) recommended preparation criteria but they are known as important adjuncts for cooling a patient. The results showed that 90% of all hospitals had chilled intravenous fluids ready for immediate use and 43% had a cooling blanket for emergency use (see Table 5). Lack of a cooling blanket is one of the few areas where smaller facilities were more lacking in preparation than larger facilities. When questioned about not having a cooling blanket in the operating area the facilities stated it was not a required item and that it would be seldom used.

**Table 5.**

**Chilled Fluids and Cooling Blanket Available in 39 USAF Hospitals**

Surgeries per Month	Number of Hospitals	Prepared with Chilled Fluids	Prepared with Cooling Blanket
0 - 100	19	95	32
a. 200	9	78	33
201 - 300	6	83	67
>301	5	100	80
All Hospitals	39	90	43

## MH Protocol

The survey identified which hospitals had a written MH treatment protocol and asked where it was posted. All of the 39 hospitals had a written protocol. There was some variation in where the written plan was posted, (see Table 6).

**Table 6.****Location of Posting Protocol in 39 USAF Hospitals**

Surgeries per Month	Number of Hospitals	Operating			Total
		MH Cart	Room	Both	
0 - 100	19	63	11	26	100
101 - 200	9	67	0	33	100
201 - 300	6	67	17	16	100
>301	5	100	0	0	100
All Hospitals	39	69	23	8	100

## MH Hotline

The survey identified how many hospitals posted the MHAUS 24-hour emergency Hotline telephone number. The results showed all 39 hospitals had at least one Hotline phone number posted on the MH cart, in each operating room or both (see Table 7).

**Table 7.****Location of Posting the Hotline Telephone Number in 39 USAF Hospitals**

Surgeries per Month	Number of Hospitals	Operating			Total
		MH Cart	Room	Both	
0 - 100	19	58	32	10	100
a. 200	9	67	11	22	100
201 - 300	6	33	50	17	100
>301	5	100	0	0	100
All Hospitals	39	69	23	8	100

### MH Education

The frequency of MH education presented to operating room personnel was identified in the survey. The results showed that 84% of the hospitals had a yearly MH inservice for the operating room personnel (see Table 8). The smaller hospitals had more frequent MH inservices than the larger hospitals. Four hospitals stated MH preparation information was provided during orientation.

**Table 8.**

#### **Yearly MH Education for Operating Room Personnel in 39 USAF Hospitals**

Surgeries per Month	Number of Hospitals	Yes	No	Total
0 - 100	19	90	10	100
11 - 200	9	78	22	100
201 - 300	6	67	33	100
>301	5	80	20	100
All Hospitals	39	84	16	100

The survey asked what was done with the dantrolene when it becomes outdated. The hospitals were asked do they use outdated dantrolene for inservice demonstrations. Thirteen out of 39 hospitals saved some of the outdated dantrolene for inservice and training purposes. The other 26 hospitals returned the dantrolene to the pharmacy or discarded it (see Table 9).



**Table 9.****Hospitals Saving Dantrolene for Inservice Demonstrations**

Surgeries per Month	Number of Hospitals	Yes	No	Total
0 - 100	19	27	73	100
a. 200	9	33	67	100
201 - 300	6	33	67	100
>301	5	60	40	100
All Hospitals	39	33	67	100

## Summary

The results of this survey identified if USAF hospitals follow the MHAUS (1996) recommended guidelines for being prepared to treat an MH crisis. While there is not 100% compliance with the hospitals the results show USAF hospitals appear to be well prepared for a malignant hyperthermia event. In addition, the results showed the larger hospitals better prepared in some areas of MH preparation but there was no clear or consistent pattern of deficiency related smaller hospitals.

## CHAPTER V: CONCLUSIONS

### Introduction

Malignant Hyperthermia is a pharmacogenetic disorder triggered by halogenated agents or succinylcholine during anesthesia. MH causes an excessive release of calcium from skeletal muscle causing a hypermetabolic state. When this occurs the available oxygen for the cells is rapidly consumed, massive cell death begins and body temperature elevates to a fatal level. With prompt recognition and treatment of MH the patient has a 90% likelihood of survival. However, rapid treatment depends on the immediate availability of drugs and equipment.

The purpose of this study was to determine how well USAF facilities were prepared for an MH crisis based on MHAUS (1996) guidelines. A telephone survey was performed on the 39 USAF hospitals in the continental United States and Alaska that provided general anesthesia during surgery. Survey questions were derived from the MHAUS (1996) standards and from questions on prior studies. Previous studies focused on dantrolene storage and supply and if a treatment plan was in place. This study looked at drugs pre-stocked in an MH cart, a treatment plan prepared, posting of the 24-hour emergency Hotline phone number, ready access to an ice source, and MH education for operating room personnel in USAF hospitals.

### Survey Response

A dedicated MH cart and stocking 36 vials of dantrolene are advocated by Beck (1994) and Gronert (1980) in addition to MHAUS (1996). All 39 USAF hospitals surveyed had a MH cart. The only facility where the cart was not solely dedicated for

MH was in the process of changing to a dedicated MH cart. As surveyed, 38 out of 39 hospitals stocked at least the minimum recommended supply of 36 vials of dantrolene in the facility. Hein's study (1988) found that only 53% of hospitals and 20% of ASCs stocked 36 or more vials of dantrolene. Another study evaluating the dantrolene supply was the AANA Council for Public Interest in Anesthesia (Haag 1990). The CRNAs responded that only 56% of their facilities, unknown size or if civilian or military, stocked 36 vials of dantrolene. In addition, Hein (1988) stated smaller facilities were less likely to stock the recommended 36 vials of dantrolene. This study did not question how many vials of dantrolene were specifically stored in the MH carts versus in conjunction with pharmacy. The USAF hospitals had some similar stocking patterns compared to civilian facilities. The AANA CPIA (Haag 1990) showed pharmacy solely stocked dantrolene 36%, anesthesia area 69%, and in the operating room 29%. It is apparent that, like the USAF hospitals, there are multiple supply areas for the dantrolene.

Because Haag (1990) looked at who checks the MH cart contents it was included in this survey. The USAF hospitals had a wide range of personnel responsible for checking the MH carts. Pharmacy was solely or partially responsible for MH cart checks in 28% of hospitals, CRNA solely or partially responsible in 59% of hospitals, other anesthesia or operating room personnel in 30% of hospitals. It appears the civilian facilities rely on pharmacy to check the MH cart to a greater degree than the USAF. The USAF hospitals combined pharmacy numbers, 28%, are significantly lower compared to 58% for the civilian facilities.

The survey showed that all of the USAF hospitals had a written MH treatment protocol to use during an MH crisis. In addition, most hospitals had the protocol posted in multiple areas. These numbers are comparable to Haag(1990) reporting that 97% of facilities had a written MH protocol but far exceeds Hein (1988) reporting 44% of hospitals and 90% ASCs had a written MH protocol.

The 24-hour emergency MH Hotline telephone number was posted in all of the USAF hospitals and, like the protocol, many facilities posted the MH Hotline number in multiple areas. The USAF hospitals 100% posting exceeded Haag (1990) reporting only 78% of facilities had the Hotline number posted.

As recommended by MHAUS and advocated by Newberry (1994) and Katz (1992), 38 of the 39 hospitals had an ice source immediately in the operating area. The solitary facility not meeting this criteria could easily obtain ice from an adjacent ward. All together, 35 out of 39 hospitals had chilled intravenous fluids on hand for an emergency, but only 17 out of 39 hospitals had a cooling blanket readily available. This is one of the few areas where it was evident smaller facilities were lacking in MH preparation compared to larger facilities.

MHAUS (1996) recommends that yearly inservices be presented to all operating room personnel to be updated on the recognition and treatment plan for a MH crisis. As stated, no prior study has looked at continuing education for operating personnel. Overall, 33 out of 39 USAF hospitals stated they provided annual inservices. Four stated MH preparation was only reviewed during orientation of new personnel. The smaller

USAF hospitals appeared to do MH continuing education more frequently than the larger USAF hospitals.

#### Recommendations for Future Studies

Two studies for future research are readily apparent. First, a survey of civilian institutions may bring new information because the previous studies were done by Hein (1987) and by Haag (1990). Ambulatory surgical clinics and the physicians office need to be added in this survey because of the increase in the frequency of general anesthesia administration at these sites.

A replica of this study on Army and Navy hospitals may bring new information to the military to help discern if all military hospitals are properly prepared for an MH episode. In addition, a similar study of overseas military hospitals may be useful.

## REFERENCES

American Association of Nurse Anesthetists. (no date). Preparedness for treatment of MH (Online). Retrieved 18 March 1998 from the World Wide Web: HYPERLINK <http://www.aana.com/docs/hyperthermia.htm>

Barta, K. (1995). Mock MH demonstration to train O.R. staff. The Communicator, 13(3), 4.

Beck, C (1994). Malignant hyperthermia are you prepared? AORN Journal, 59(2), 367-390.

Byers, D. & Krishna, G. (1992). Malignant hyperthermia. Seminars in Pediatric Surgery, 1(1), 88-95.

Denborough, M., & Lovell, R. (1960). Anesthetic deaths in a family. The Lancet, 2(45), 78.

Duncan,P (1985). Availability of dantrolene in Canadian hospitals. Canadian Anaesthetists' Society Journal, 32, 205-209.

Gronert, G. (1980). Malignant hyperthermia. Anesthesiology, 53, 407-413.

Haag, G. (1990). Are you prepared for a malignant hyperthermia crisis? Journal of the American Association of Nurse Anesthetist, 58, 250-251.

Harrison, G., & Isaacs, H. (1992). Malignant hyperthermia an historical vignette. Anaesthesia, 47, 54-56.

Heffron, J. (1988). Malignant hyperthermia: biochemical aspects of the acute episode. British Journal of Anaesthesia, 60, 274-278.

Hein, H. (1988). Lack of availability of dantrolene in American surgical facilities. Anesthesiology, 69, 726.

Hein, H., Roewer, N., & Jantzen, J. (1987). Malignant hyperthermia: Are we really prepared? Anesthesiology, 66, 448.

Kaplan, R.F.(1997).Clinical presentations of malignant hyperthermia. American Society of Anesthesiologists Newsletter 5. (Online). Retrieved 2 March 1998 from the World Wide Web: [http://www.eur.nl/FGG/ANEST/gasnet/htdocs/mirror/asaNEWSLETTERS/1997/05\\_97/Clinical\\_MH.html](http://www.eur.nl/FGG/ANEST/gasnet/htdocs/mirror/asaNEWSLETTERS/1997/05_97/Clinical_MH.html)

Katz, D. (1992). Current understanding of malignant hyperthermia: Genesis, prevention, and treatment. CRNA: The clinical forum for nurse anesthetists, 3(2), 54-63.

Kraus, S. & Rockoff, M. (1994). Malignant hyperthermia. Pediatric Anesthesia, 41(1), 221-236.

Malignant Hyperthermia Association of the United States. (1996). Preventing malignant hyperthermia, an anesthetic protocol (Brochure)

Merz, B. (1986). Malignant hyperthermia: nightmare for anesthesiologists-and patients. Journal of the American Medical Association, 255, 709-715.

Miranda, A., Donovan, L., Schuster, L., & Gerber, D. (1997). Malignant hyperthermia. American Journal of Critical Care, 6(5), 368-375.

Nelson, T., & Flewellen, E. (1983). Current concepts the malignant hyperthermia syndrome. The New England Journal of Medicine, 309, 416-418.

Newberry, J. (1990). Malignant hyperthermia in the postanesthesia care unit: A review of current etiology, diagnosis, and treatment . Journal of Post Anesthesia Nursing, 5(1), 25-28.

Ording, H. (1993). Pathophysiology of malignant hyperthermia. In Aubert, A., Borsarelli, J., Kozak-Ribbens, G., & Khambatta, H. (Eds.), Malignant hyperthermias (2nd ed., Rev., pp. 21-26). Bad Homberg: Normed Verlag.

Rhoades, R. & Tanner, G. (Eds.). (1995). Medical Physiology (1st ed.). Boston: Little, Brown and Company.

Rosenberg, H. (1995). Ask the experts. The Communicator, 13(3), 5.

Rosenberg, H. (1993). Therapy of malignant hyperthermia. In Aubert, M., Borsarelli, J., Kozak-Ribbens, G., & Khambatta, H. (Eds.), Malignant hyperthermias (2nd ed., Rev., pp. 63-66). Bad Homberg: Normed Verlag.

SPSS (Statistical Program for the Social Sciences) 8.0 for Windows (computer program)(1988). Chicago IL: SPSS Inc



## **APPENDICES**

APPENDIX A: Survey Questionnaire

APPENDIX B: IRB Approval USUHS

APPENDIX C: Survey Control Number, United States Air Force

APPENDIX D: IRB Approval Wright Patterson Air Force Base

**APPENDIX A**

**SURVEY QUESTIONNAIRE**

## SURVEY QUESTIONNAIRE

1. How many surgical procedures are performed at your facility each month?
  - a. 0 - 100
  - b. 101 - 200
  - c. 201 - 300
  - d. >300
2. Do you have a Malignant Hyperthermia cart available in your operating room area?  
Yes \_\_\_\_\_ No \_\_\_\_\_
3. How many vials of dantrolene are available in your facility?
  - a. 0-10
  - b. 11-20
  - c. 21-35
  - d. 36-plus
4. Where is the dantrolene stored?
  - a. MH cart
  - b. Pharmacy
  - c. Both
5. Who is responsible for checking the MH cart drug expiration dates?
  - a. Pharmacy
  - b. Operating Room nurse
  - c. CRNA
  - d. Anesthesia technician
  - e. CRNA and pharmacy
6. How often is the MH cart checked?
  - b. Weekly
  - c. Monthly
  - d. Quarterly
  - e. Yearly
7. Which of the following drugs are on the MH cart?
  - b. Sodium Bicarbonate Yes \_\_\_\_\_ No \_\_\_\_\_
  - c. Mannitol Yes \_\_\_\_\_ No \_\_\_\_\_
  - d. Furosemide Yes \_\_\_\_\_ No \_\_\_\_\_
  - e. Glucose (D50) Yes \_\_\_\_\_ No \_\_\_\_\_
  - f. Regular Insulin Yes \_\_\_\_\_ No \_\_\_\_\_
  - g. Calcium Chloride Yes \_\_\_\_\_ No \_\_\_\_\_
  - h. Sterile Water Yes \_\_\_\_\_ No \_\_\_\_\_
8. Do you have the following cooling equipment available in the operating room area?
  - b. Ice Yes \_\_\_\_\_ No \_\_\_\_\_
  - c. Chilled IV s Yes \_\_\_\_\_ No \_\_\_\_\_
  - d. Cooling blanket Yes \_\_\_\_\_ No \_\_\_\_\_
9. Do you have a written treatment protocol for handling an MH crisis?  
Yes \_\_\_\_\_ No \_\_\_\_\_

10. Where is your MH treatment protocol located?
  - b. Posted in the OR
  - c. On the MH cart
  - d. By the phone in the OR
  - e. Other (specify) \_\_\_\_\_
11. Where do you post the 24 hour emergency MHAUS Hotline telephone number?
  - b. MH cart
  - c. Operating room
  - d. Both
  - e. Other (specify) \_\_\_\_\_
12. How often are MH educational programs given to your operating room personnel?
  - a. At least once a year
  - b. Less than once a year
  - c. Only during orientation
  - d. Other (specify) \_\_\_\_\_
13. What do you do with the outdated dantrolene?
  - a. Throw it out
  - b. Use it for inservice purposes
  - c. Return to pharmacy
  - d. Other (specify)

**APPENDIX B**

IRB APPROVAL, UNIFORMED SERVICES UNIVERSITY  
of the HEALTH SCIENCES



UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES

4301 JONES BRIDGE ROAD  
BETHESDA, MARYLAND 20814-4799



November 2, 1998

MEMORANDUM FOR KENNETH A. WILLIAMS, CAPT USAF, DEPARTMENT OF  
GRADUATE SCHOOL OF NURSING

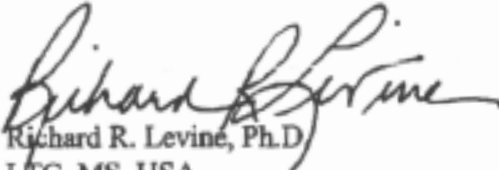
SUBJECT: IRB Approval of Protocol **T06189** for Human Subject Use

In accordance with USUHS Instruction 3201 and the Memorandum of Understanding for Clinical Affiliation between the Uniformed Services University of the Health Sciences and the U.S. Air Force Surgeon General designating the Wright-Patterson Air Force Base as a clinical affiliate, USUHS accepts their review and approval by their Institutional Review Board (IRB) for the research protocol entitled "*Malignant Hyperthermia Preparedness in the US Air Force*" under your direction. It is requested that the Wright-Patterson IRB provide this office with human subject use review updates at least annually.

The purpose of this study is to answer questions related to MH readiness at USAF clinical facilities. A telephone survey will be conducted to determine how many USAF clinical facilities have an MH chart, the drugs necessary to treat an MH episode, cooling equipment, and a written treatment protocol to manage MH episodes. Additionally, data will be gathered regarding how often OR personnel are given MH educational training programs.

You are required to submit amendments to this protocol, changes to the consent form, adverse event reports, and other pertinent information relative to human subject use for this project to this office for review. It is your responsibility to maintain an accurate and accessible file of all consent forms of participating human subjects.

If you have any questions regarding human subject use, please call me at 301-295-3303.

  
Richard R. Levine, Ph.D.  
LTC, MS, USA  
Director, Research Programs and  
Executive Secretary, IRB

cc: Director, Grants Administration



**APPENDIX C**

SURVEY CONTROL NUMBER, UNITED STATES AIR FORCE

From: Datko, L Civ DPSAS <DatkoL@hq.afpc.af.mil>  
To: 'Ken Williams' <kwsma@mci2000.com>  
Subject: Request for Survey Approval - Your e-mail, 27 July 1998  
Date: Wednesday, July 29, 1998 \*;56 AM

Capt Williams -

Your proposed "Are You Prepared for a MH Crisis?" survey has been reviewed and is assigned a Survey Control Number (SCN) of USAF SCN 98-58. This number and authorization will expire on 31 March 1999.

With regard to the survey and its associated results, it is important to draw your attention to the provisions of the Freedom of Information Act (FOIA). Under the FOIA, the results of your survey can be requested by the public. Finally, the SCN needs to appear either in the cover letter or on the face of the survey itself.

Questions or concerns can be directed to me or Mr. Hamilton at (210) 652-5680. Thank you and good luck with your data collection efforts.

Lou Datko  
Senior Personnel Survey Analyst  
HQ AFPC/DPSAS



**APPENDIX D**

IRB APPROVAL, WRIGHT PATTERSON AIR FORCE BASE



# DEPARTMENT OF THE AIR FORCE

HEADQUARTERS AIR FORCE MATERIEL COMMAND  
WRIGHT PATTERSON AIR FORCE BASE OHIO

6 August 1998

MEMORANDUM FOR 74 MDOS/SGOSA  
ATTN: CAPT KEN WILLIAMS

FROM: 74th MDOS/SGOA  
Clinical Investigations  
4881 Sugar Maple Drive  
Wright-Patterson AFB OH 45433-5300

SUBJECT: Proposed Protocol

1. The protocol you submitted, "Malignant Hyperthermia Preparedness in the United States Air Force," was reviewed via expedited review and approved by the Chair of the Institutional Review Board (IRB) of Wright-Patterson Medical Center on 16 July 1998. The Commander of Wright-Patterson Medical Center also reviewed the protocol on 22 July 1998. It was determined to be exempt and has been assigned file number FWPI9980028E. You may now begin your study.
2. Progress reports will be due annually. You will receive a reminder 30 days in advance when your report is due. If you complete your study prior to August 1999 a final report may be completed.
3. Any changes to the study must be submitted to the Clinical Investigations office for approval prior to initiation.
4. Any unanticipated major adverse reactions or other medical misadventures must be reported immediately to the department chairperson, the Chief of Medical Staff, the Clinical Investigations Coordinator and ultimately the commander IAW AFI 40-403. Such events will also need to be summarized in the subsequent progress report.
5. If you anticipate separating from the Air Force or changing assignments before the protocol is completed, you must notify the Clinical Investigations Office as soon as this is known. You will be required to either formally close the protocol, or to have another investigator take over the study. The latter process requires nomination by the flight commander, submission of a curriculum vitae, and approval by the Institutional Review Board.
6. Please indorse below and return to Clinical Investigations. I hope that your study will prove to be a worthwhile experience for you. Let us know if there is any way we can assist you.

DEBBIE BACHMAN

Clinical Investigations Coordinator

1st IND

TO: Investigations

Noted/Acknowledged

---

Principle Investigator

---

Date