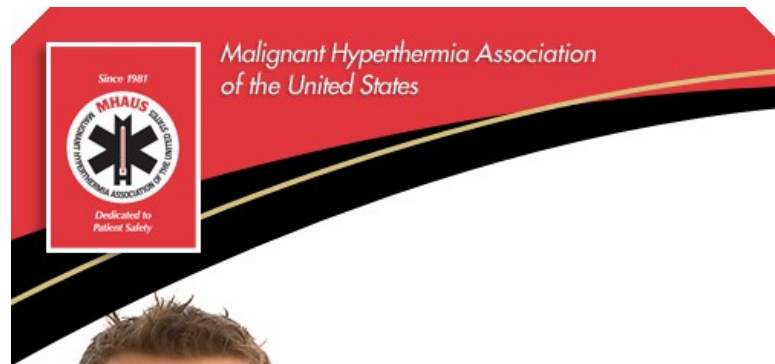


Malignant Hyperthermia Association of the United States (MHAUS)



Annual Report
for
2006-2007 Fiscal Year

MISSION STATEMENT

The Malignant Hyperthermia Association
of the United States (MHAUS)
is dedicated to reducing morbidity and mortality of MH by

- 1) improving medical care related to MH,
- 2) providing support information for patients and
- 3) improving the scientific understanding and research related to MH and other kinds of heat-related syndromes.

EXECUTIVE SUMMARY

In the last two decades, significant progress has been made in building MH awareness and improving treatment of MH episodes. The life-threatening reaction to anesthetics has been declining from a high of 80% in the 1970s to less than 5% in recent years. Much of this was due to the introduction in 1979 of an antidote, dantrolene sodium for injection, as well as the continued education/awareness efforts of MHAUS.

There are many new and exciting developments in the MH world including DNA testing for MH, a better understanding of where and how often MH occurs and, through a variety of new and innovative programs including webinars, podcasts, posting new materials on the website, development of MH procedure manuals, and keeping the public and medical community up-to-date on the latest advancements in the field, we have helped to contribute to the reduction of deaths from MH.

There still remains the challenge of sharing info with Ambulatory Surgery Centers and Office-based Surgicenters, where preparedness and staffing numbers may not be at the same level as in a hospital.

It is obvious that MHAUS' work is not yet done and we will strive to educate both medical professionals and patients about the recognition, treatment and prevention of malignant hyperthermia. We at MHAUS are still concerned that MH deaths still occur, not all places where triggers are administered have a supply of dantrolene on hand, and not everyone is prepared to handle MH. Thus we continue to be dedicated to managing the problem and assuring that no one will ever die from MH.

WHAT IS MALIGNANT HYPERTHERMIA (MH)?

Malignant hyperthermia (MH) is an uncommon and potentially lethal syndrome that is triggered in susceptible individuals by the commonly used potent inhalation gas anesthetics such as isoflurane, enflurane, sevoflurane and succinylcholine, a muscle relaxant. Scientists have not determined the cause of MH, but continue to investigate evidence that it involves a derangement of the processes that regulate muscle contraction. MH is an inherited disorder and is due to an aberration in the biochemistry of muscle when exposed to commonly used anesthetic agents.

An MH crisis appears in susceptible individuals during, or shortly after, application of one of the anesthetic drugs that are known to cause the syndrome. Patients can experience greatly increased body metabolism, muscle rigidity and fever of up to 106°F or more. If not diagnosed quickly and properly treated, an MH crisis may lead to death or organ damage. However, thanks to the availability of the antidote, dantrolene sodium for injection, a negative MH outcome may be avoided if the syndrome is recognized in a timely fashion and dantrolene administered in proper doses.

Laboratory Diagnosis for MH

The most accurate diagnostic test for MH involves a specialized biopsy from a leg muscle that is only available from a limited number of centers across the US. Because MH is inherited. Several genetic abnormalities have been found in some MH patients. The muscle biopsy test remains the "gold standard" to determine MH susceptibility in patients; however, only a small number of medical centers across the U.S. offer the test. In 2005 molecular genetic testing for MH was introduced but only two MHAUS-approved laboratories are available that perform the test. A virtue of this test is that DNA can be extracted from cells found in the blood and the known genetic mutations that predispose to MH searched for. The test is limited at the moment to specific individuals already known to be MH-susceptible and their family members, it is felt there are more mutations that are as yet unknown, but it can be helpful in identifying those mutations (or variants) we are aware of and is certainly a step in the right direction.

MH Triggers

Scientists believe most of the agents that will stimulate an MH crisis have been identified. These agents include the volatile gaseous inhalation anesthetics (e.g., halothane, enflurane, isoflurane, sevoflurane, desflurane and methoxyflurane) and the muscle relaxant, succinylcholine. Many drugs have been determined NOT to trigger MH as well. Barbiturates, narcotics (opioids), tranquilizers, local anesthetics, intravenous anesthetic induction agents and the inhaled gas nitrous oxide will not trigger MH, as well as the muscle relaxants pancuronium, atracurium, vecuronium, mivacurium, rocuronium and cisatracurium. Furthermore, it is clear that the vast majority of prescription and non-prescription drugs will not trigger MH.

Despite the knowledge of which agents will and will not trigger MH, the reason why they trigger MH is still a mystery. Not everyone who has MH develops an episode each time a triggering agent is given to him or her. Deaths have occurred even after multiple prior uneventful surgeries. Thus, even patients who have had surgery without complications before cannot be certain they are not at risk.

MH Precautions

With proper preparedness by both the MH-susceptible and their OR team, bad outcomes from MH can be avoided in most cases. For medical professionals, this includes being familiar with MH testing protocols, trigger agents, symptoms and proper treatment procedures. MH-susceptible individuals must be aware of triggers and assure they share their complete medical history with their anesthesia care provider. It is highly recommended that MH patients always wear a medical ID tag and assure their hospital/ambulatory center stocks a full 36-vial supply of unexpired dantrolene sodium for injection. Should the “worst case scenario” occur, MH can be successfully managed in virtually all cases with the immediate use of the antidote, dantrolene sodium for injection, and implementing other lifesaving measures.

WHAT IS MHAUS?

The Malignant Hyperthermia Association of the United States, founded in 1981 by four individuals, Suellen Long Gallamore, Owen Davison, Robert Luckritz and George Massik, with the help of Dr. Henry Rosenberg, a researcher in malignant hyperthermia, is a patient-advocacy association dedicated to education and training on MH and to serve as a resource to families affected.

Today, almost 2,000 MHAUS members includes medical professionals from many disciplines as well as MH-susceptible individuals and their families, many have had firsthand experience with the devastating impact of an MH episode.

As a non-profit organization, the source of revenue includes memberships, additional contributions from patients and their families, medical professionals, hospitals, and ambulatory surgery centers, professional associations and corporations. In fiscal year 2006-2007 total revenues were \$738,425 with 17% supporting administrative and fundraising expenses.

GOVERNING BOARD

A volunteer Board of Directors governs, sets policy, and monitors performance against plans for MHAUS; term of office is one year. Most Board members have a personal connection with an individual who is susceptible to MH or have a strong interest in the problem.

The Board of Directors has two regularly scheduled board meetings and one two-day strategic planning meeting annually. During FY 06/07, the following meetings were held:

12/1/06, 10am – 4:15 pm	Winston and Strawn LLC	New York City
4/27/07, 11am – 3:15 pm	Webcast Board Meeting Chicago, IL, Greensboro, NC	Norwich, NY, NYC, NY Bethesda, MD, Savannah, GA
08/3-4/07, 11- 5:45 pm	Colgate University	Hamilton, NY

PROFESSIONAL ADVISORY COUNCIL

The Professional Advisory Council (PAC) of MHAUS advises the Board on the formulation of all MH medical policies and responds to inquiries from patients and physicians about malignant hyperthermia. PAC members are anesthesia care providers and other medical professionals, including a number of the world's leading malignant hyperthermia investigators and authorities.

MHAUS GOALS

- ❖ Educate the entire spectrum of medical professionals so that MH is automatically looked for, guarded against, recognized and properly treated by persons in all of the medical disciplines.
- ❖ Advise and prepare all medical facilities in the United States for prompt diagnosis and immediate treatment of MH episodes.
- ❖ Help MHS patients and their families learn to live with MH susceptibility and share with them the experience and knowledge which has been accumulated about MH.
- ❖ Encourage and support research into MH and MH-like syndromes.
- ❖ To stimulate the development of a noninvasive, accurate, diagnostic test.

ONGOING SERVICES

The MH Hotline A Patient Lifeline

The most notable and important of MHAUS' services is the MH Hotline. The Hotline provides healthcare professionals with access to anesthesiologists with special expertise in 24 hours per day, 365 days per year. These volunteer hotline consultants provided MH expertise and support to medical professionals in successfully managing an MH crisis over 750 times in this fiscal year. Additionally, the MHAUS staff handled over 300 calls.

MHAUS, along with a generous grant from the American Society of Anesthesiologists (ASA), funds the MH Hotline and administrates all activities necessary to keep it manned with MH experts and running smoothly. Additionally, MHAUS is responsible for informing medical professionals of the hotline's availability and quick access during an MH emergency.

MHAUS Hotline Consultants:

Michael G. Adragna, MD – SUNY School of Medicine, Buffalo NY
Gregory C. Allen, MD, FRCPC – Olympia Anesthesia Associates, Olympia WA
Kumar G. Belani – University of Minnesota Medical Center, Minneapolis MN
Barbara Bandom, MD – Children's Hospital, University of Pittsburgh, Pittsburgh PA
James W. Chapin, MD – University of Nebraska Medical Center, Omaha NE
Brian J. Gronert, MD – Anesthesia Associates of New Mexico, Albuquerque NM
Andrew Herlich, MD – Temple University Children's Medical Center, Philadelphia, PA
Richard F. Kaplan, MD – Children's National Medical Center, Washington, DC
Ronald S. Litman, DO – Children's Hospital of Philadelphia, Philadelphia PA
Agi Melton, MD – Sierra Anesthesia, Reno NV
Jordan D. Miller, MD – UCLA Medical Center, Los Angeles CA
Marshall S. Millman, MD, PhD – Anesthesia/Pain Management Services, Manchester, TN
Michele Moro, MD – University of New Mexico Health Science Center, Albuquerque, NM
Jerome Parness, MD – Children's Hospital of Pittsburgh, Pittsburgh, PA

MHAUS Hotline Consultants (continued)

Harvey K. Rosenbaum, MD – UCLA Medical Center, Los Angeles, CA
Henry Rosenberg, MD – St. Barnabas Medical Center, Livingston, NJ
Scott R. Schulman, MD – Duke University Medical Center, Durham NC
Mohanad Shukry, MD – Children’s Hospital of Oklahoma, Oklahoma City, OK
John Skoog, MD – Mercy Hospital Medical Center, Des Moines, IA
Lena S. Y. Sun, MD – Columbia University, New York NY
Timothy Tautz, MD – University of California, Davis CA
Mary C. Theroux, MD – The duPont Hospital for Children, Wilmington, DE
Joseph R. Tobin, MD – Wake Forest University, Winston-Salem, NC
Charles B. Watson, MD, FCCM – Bridgeport Hospital, Bridgeport CT
Denise J. Wedel, MD – Mayo Medical School, Rochester, MN
Margaret Weglinski, MD – Mayo Medical School, Rochester, MN
Cynthia A. Wong, MD – Northwestern University Medical School, Chicago IL

PROGRAMS AND INITIATIVES

Educational Programs

A critical component is knowledge of the necessary precautions to take, symptoms to look for, and steps to treat malignant hyperthermia. This will largely determine a positive or negative outcome from an MH crisis. Thus, a critical component of our effort to conquer MH are educational programs to medical professionals covering topics such as diagnosis and treatment, advice and counseling of MH patients, and informing the healthcare professionals of the latest research in the field. Nearly 7,000 packets of educational material were sent out throughout North America during this fiscal year and much of our educational materials have been translated into Spanish. The following educational programs are provided on an ongoing basis:

- MH crisis protocol posters and pocket cards
- Patient education brochures
- MH awareness public relations programs
- In-service training material in videotape and DVD formats
- MH Slide Shows
- Podcasts and Hotline Case of the Month on our website
- Training Procedure Manuals (hospital, ambulatory and office-based versions) - proven to reduce the response time by up to 50%
- Educational literature for healthcare professionals including OR Nurses, Anesthesia Care Providers, Surgeons, Post-anesthesia care nurses, etc.

MHAUS attends and exhibits at several medical and nursing conferences each year to share the latest MH information.

The Communicator Keeping MH Issues Current

The Communicator, MHAUS’ quarterly newsletter, provides current MH information. Articles cover topics ranging from the latest research finding and screening methods to suggestions to help patients deal with various MH concerns.

MHAUS Website

The MHAUS website provides direct access to many of our programs and education materials over the worldwide web. Recently revised with the "Faces of MH" look the site is now divided into subsites for the medical professional, MH-susceptible patient, information about MHAUS, and a media area to make it more easily maneuverable. The website has become a way to share the latest on new programs such as the In-service Kit and MH Slide Show, important upcoming MH meetings, a Message Board for patients and medical professionals to share experiences and insight, past issues of *The Communicator* to use as reference, brochures, testing information, and more. A very popular feature, the MHAUS website, has received 218,764 visitors this past year, with interest increasing steadily in newly offered podcasts (over 10,000 visits to this area specifically).

Patient Support Services

While educational programs address the primary MHAUS mission of reducing MH mortality and morbidity, the needs of MHS patients and their families go well beyond education. MH-susceptible patients require not only practical support in taking the necessary precautions to prevent negative MH outcomes, but also benefit from emotional support as they try to deal with the many fears associated with having MH. MHAUS tries to address these “secondary” needs of MHS patients and their families through a variety of programs including:

- MH alert sticker/wristband kit
- Distribution of safe/unsafe drug wallet cards
- MH testing center referral
- MH Mini-conference (this year in Madison, Wisconsin)
- Patient Liaison Committee
- Medical ID tag program - The *Sandi Ida Glickstein Fund* is available for those who need a bracelet but cannot afford it themselves

North American MH Registry of MHAUS

The North American MH Registry (NAMHR) of MHAUS was established in 1987 and merged with the Malignant Hyperthermia Association of the United States (MHAUS) in 1995 so data on MH could be stored in a site supported by one organization for greater support of research initiatives. Dr. Barbara W. Brandom at Children’s Hospital in Pittsburgh, PA currently directs the Registry.

The Registry’s goal is to acquire, analyze, and disseminate case-specific clinical and laboratory information related to malignant hyperthermia susceptibility. The Registry functions within HIPAA, OHRP, and IRB regulations. Registry data is available for research into MH. Each potential study must have IRB approval from its parent institution, and approval from our Scientific Advisory Committee.

Objectives of the Registry are to:

- Maintain a central database of individuals with MH susceptibility and similar syndromes.
- Provide information storage and analysis services to MH diagnostic referral centers for standardization and validation of MH diagnostic testing procedures, including genetic tests.
- Investigate the epidemiology of MH in order to improve diagnosis, treatment, and prevention of MH episodes
- Give a registered person the security of knowing that there is a central repository of information concerning their MH susceptibility status.

Molecular Genetic Testing Progress

MHAUS continues our progress this year through the simple, affordable diagnostic test. Molecular genetic testing for MH is now available at two CLIA-certified laboratories, in Marshfield, Wisconsin and Pittsburgh, Pennsylvania. The testing will be on a limited basis until 100% of all mutations are identified. At this time the testing is reserved for families with a positive muscle biopsy proving susceptibility to malignant hyperthermia. A brochure is available describing both types of testing. Molecular genetics, although in its infancy, offers accurate diagnosis of susceptibility to MH using a blood test and provides insight into the mechanisms of the disorder. MHAUS has developed a program to provide support to patients who can’t afford to have genetic testing done.

Third MH Molecular Genetics Workshop

In September 2007 the Third MH Molecular Genetic/Diagnostic Testing Workshop was held to review and update activities related to the caffeine halothane contracture test (CHCT) and alternative tests, review and discuss findings related to molecular genetic testing for MH, discuss perioperative and exertional rhabdomyolysis and potential links to MH, and develop strategies for increased enrollment of patients in CHCT and genetic studies.

Promotion of MH Scientific Research

MHAUS supports scientific research into MH through direct research grants and financial support of the Registry and as a solicitor of third-party funds for important MH research initiatives.

Neuroleptic Malignant Syndrome Information Service (NMSIS)

NMSIS is a unit of MHAUS founded in 1997 by MHAUS along with a group of prominent psychiatrists with extensive experience in treating NMS. Neuroleptic Malignant Syndrome (NMS) is an uncommon but potentially life-threatening disorder associated with the use of antipsychotics and is characterized by disturbances in mental status, temperature regulation and autonomic and extrapyramidal functions. It is. The NMSIS component of MHAUS is governed by a voluntary Professional Advisory Council and includes several of the world's leading NMS investigators and authorities.

In 1997 an NMS Hotline was established with volunteer NMS experts from psychiatry and anesthesiology to help medical professionals during an NMS emergency.

In this fiscal year, NMSIS 1) again gave a *Promising New Investigators Award* grant, to encourage research on psychotropic drug safety and side effects; 2) initiated partnerships to develop medical educational webinars and webcasts; 3) fostered a liaison with the *American Psychiatric Nurse s Association* (APNA) resulting in two presentations on NMS at major APNA meetings; 4) formed international partnership members within the PAC; 5) coordinated a well-received workshop on NMS at the *American Psychiatric Association* (APA) annual meeting; and 6) offered a Case Challenge series on the website, www.nmsis.org.

NEW INITIATIVES

The New Faces of MH Look for MHAUS

A focused effort to create a "brand" look for the MHAUS organization to clearly define who we are and what we offer the "community at large" was completed this year. Incorporating brainstorming techniques and enlisting the help of creative leadership, the "Faces of MH" theme was developed and is being incorporated throughout the organization on exhibits, brochures, letterhead, and the website. Along with the picture of a man and his son is the theme to "be prepared for MH and save lives", the credo we have lived by for over 25 years.

Speakers Bureau

MHAUS has developed a program of expert speakers pulled from MH Hotline Consultants and Professional Advisory Council members who are available to speak at medical association meetings, hospital in-service presentations, and to other groups keenly interested in MH education. The expert speakers share information on MH crisis management, MH testing options, a mock drill of an MH episode and questions and answers from the audience. Any medical professional who has ever dealt with a case of MH understands the need for this kind of presentation as watching a patient's physiology deteriorate over minutes due to MH is one of the most frightening and potentially devastating events he or she may experience in her/his career. MHAUS offers limited grant funding for this program as we feel it is an important step in our mission to share MH education and to keep patients safe.

Scientific Officer

During this fiscal year the MHAUS Board of Directors decided there was a need for a Scientific Officer who would be asked to seek funding from grants, attend biomedical meetings, and work within MHAUS/NMSIS to assist with and develop programs to promote education on MH, NMS and other heat-related disorders in the organizations' focus areas. This person will be working closely with the MHAUS Executive Director and President and various members of the Board of Directors and Professional Advisory Council in the development of funding opportunities as well as new programs to help build the organization's self-reliance.

MHAUS Consensus Meeting

A number of MH experts were brought together in Philadelphia, Pennsylvania in September 2007 to discuss the present thinking with regard to whether ambulatory surgery centers and officebased surgicenters are prepared to recognize and treat MH and if consideration has been given and a clear plan in place for the transfer of the patient from the center to a hospital Emergency Room. It is planned that the findings from this meeting will be developed into a report to be used to develop an MH Treatment Protocol for medical professionals working in these types of institutions. Additionally, the present out-of-date MH Monograph will also be updated using the group's feedback and findings.

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John A. Yagiela, DDS, PhD—University of California, Los Angeles

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Gloria B. Artist, Hotline Coordinator
Doreen K. Bates, PR/Projects Coordinator
Sharon Hirshey Dirksen, PhD, Scientific Officer
Fay F. Kellogg, Fulfillment Administrator
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North American MH Registry of MHAUS

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Michael Young, Technical Manager
Jessica Fondy, Data & Technology Specialist
Sara Marrs, Research Assistant