UNDERSEA AND HYPERBARIC MEDICAL SOCIETY

February 28, 2002

MEMORANDUM for the Blue Ribbon Panel, National Naval Program for Undersea Biomedical Research.

Dear Panel Member:

First, I want to thank you for your participation in this important panel. Your input was invaluable as the enclosed report was put together. The report has been reviewed by officials at the Office of Naval Research and has received favorable comments. It will be further briefed to other officials in the very near future and those who are tracking its progress are positively hopeful for the outcome.

You may recall, should a National Naval Program for Undersea Biomedical Research be approved, it will provide a measure of stability for undersea biomedical research that has been absent for a very long time. Moreover, we are told that, if approved, the funding will not be restricted to Navy laboratories.

The enclosed is our courtesy copy to you for your participation. Again, thank you very much for your involvement in this important task.

Sincerely,

Don Chandler
Executive Director

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DEPARTMENT OF THE NAVY
OFFICE OF NAVAL RESEARCH
800 NORTH QUINCY STREET
ARLINGTON, VA 22217-5660

IN REPLY REFER TO

5000
Ser 341/270
20 Feb 02

Dear Reader:

Subj: PROPOSED NATIONAL NAVY PROGRAM IN UNDERSEA MEDICINE

Encl: (1) "An Assessment of a National Naval Need for Undersea Biomedical Research"

As part of an initiative to establish Undersea Medicine as a National Naval Program, the Human Systems S&T Department, Office of Naval Research (ONR), commissioned the Undersea and Hyperbaric Medical Society (UHMS) to perform a comprehensive analysis of the Navy's research and development program in Undersea Medicine. The UHMS report, provided for your information at enclosure (1), includes the findings and recommendations of an expert, extramural review panel.

After careful review of this report, I have endorsed the overall aim to establish Undersea Medicine as a National Naval Program, and will use the UHMS analysis to gain the concurrence of ONR and Navy corporate leadership. It is my hope is that the establishment of Undersea Medicine a National Naval Program will stabilize resources for Undersea Medicine and thereby lead to the continued health and vitality of this important program area.

It should be noted that the opinions and conclusions of the expert panel contained in the accompanying report are solely those of the panel, and should not be construed as formal service requirements, referenced as official service requirements, or considered an ONR endorsement or policy statement.

HAROLD E. GUARD, Ph.D.
Head, Human Systems S&T Department

An Assessment Of A National Naval Need For Undersea Biomedical Research

Prepared
for the

Office of Naval Research

by the

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OFFICE OF ONR NAVAL RESEARCH

U. H. M. S.

TABLE OF CONTENTS

EXECUTIVE SUMMARY

In this report, *"undersea biomedical research"* encompasses research to support both the submarine and diving communities.

Since the early 1950s the Office of Naval Research (ONR) has been funding research in undersea biomedical research with 6.1 dollars, augmented by 6.2 funds from the Bureau of Medicine and Surgery and later by 6.3 funds from the office of the Assistant Chief of Naval Operations (Undersea Warfare). Some of the 6.1 funds and all of the 6.2 and 6.3 funds were administered by the Naval Medical Research and Development Command from 1974 until the dissolution of that command in 1998 when ONR took over administration of 6.1 through 6.3A funding. During the 1960s through the early 1980s this research program was a very successful, productive program. Unfortunately from the mid 1970s to the present date the total 6.1/6.2 funds have remained at the same level with no increases for inflation. In 1975 the 6.1/6.2 funds were about $4 million. Funding for this program in FY98, FY99 and FY00 was about $3.6 million. The equivalent funding today to continue research at the 1975 level would be $13.6 million. The 6.3 funding for undersea biomedical research has also been eroded due to lack of increases to keep up with inflation. A recent decrease in funding, due changes in emphasis by the Future Naval Capabilities program, reduces the funding available for transition of 6.1/6.2 products. Therefore, funds for basic research have gradually dwindled to the point where, unless funding is increased dramatically over the next few years, this program cannot continue. In the National Defense Authorization Act for FY1994 (Report 103-112), it was stated that "...erosion of the undersea medicine community (of the Navy) and the universities that support the program may be accelerating." This has happened and the current funding is no longer sufficient to ensure a viable research program to adequately support the Department of the Navy in maintaining superiority in undersea operations and enhancing the performance and safety of the personnel engaged in these operations. The current level of funding also prevents responding adequately to new requirements.

Because undersea biomedical research is specialized, the needs for this research are uniquely Navy needs, and there is no support from other governmental agencies or industry, the Navy must provide the necessary support if it wishes the submarine and diving communities to always have the benefit from superior undersea biomedical research and technology.

It is recommended that:

- Funding for basic undersea biomedical research be increased to a level which is appropriate to bring scientific productivity to a viable level.

This decreased funding and lack of sustained funding over the long term for basic research has resulted in significant deficiencies in basic biomedical knowledge needed to solve operational problems. A few examples of these deficiencies are the lack of knowledge of how inert gases are taken up or released from body tissues; knowledge of the effects of long term exposures to increased levels of carbon dioxide and trace contaminants in submarine atmospheres; how, why and where bubbles form in the body; and knowledge of the long term effects of submarine service. In addition, new disciplines in biological research have appeared along with many new technologies which show great promise in solving persistent problems. These have never been applied in undersea biomedical research. Without a strong basic research program solid solutions to operational problems will not be possible.

It is recommended that:

- ONR implement an expanded basic undersea biomedical research program which includes contemporary disciplines and technologies to address these issues. This program should receive adequate, stable and sustained funding on a long term basis where needed.

Decreased and unstable funding has resulted in a marked decrease in the number of investigators working on basic undersea biomedical research. During the past 15 years many young investigators (about 60%) have left the field after spending less than 5-10 years in research. Many of these were still in their twenties and thirties with many productive years ahead of them. The Navy has trained no investigators in the last 10 years. Many of the senior scientists who have remained in this area are approaching retirement which will result in a major loss of scientific expertise to the Navy.

It is recommended that:

- Adequate and stable funding be provided to induce investigators to remain in the field of basic undersea biomedical research and to recruit new investigators to enter the field. ONR should encourage the Bureau of Medicine and Surgery to recruit and train adequate numbers of military scientists to support this program in the Navy laboratories.

Again, because of decreased and unstable funding, the last 15 years have seen a marked decrease in the numbers of institutions engaged in this program. In 1973, in addition to the Navy laboratories that were performing research in this area, ONR supported research in 37 universities and private facilities in the United States, Canada and Europe. There are now less than a 10 U.S. universities involved. In addition, maintenance of large facilities, e.g., hyperbaric chambers and other exposure facilities, is expensive and diminishes the funds available for performance of research.

It is recommended that:

- Adequate and stable funding be made available to allow facilities in current use and others to be available for basic undersea biomedical research. ONR and other relevant organizations should pursue the use of Major Range and Test Facility Base (MRTFB) funds for the repair and maintenance of large hyperbaric chambers and other exposure facilities in order to free up funds for research.

In the last 10-15 years the integration of the 6.1/6.2/6.3/6.4 programs has been inadequate because of the lack of a workable system for doing this. During the past year efforts have been made to improve this situation, but further efforts are required to formalize a system for integration. Decreased 6.3/6.4 funding further threatens future integration efforts.

It is recommended that:

- Efforts continue with an integrated product team approach to the transition of basic research findings to 6.4. The program review of 6.1, 6.2 and 6.4 performers should continue on an annual basis.

The personnel managing the undersea biomedical programs at ONR have had less than optimal qualifications to perform this task. With the exception of one naval officer who was at ONR for a brief period, no ONR personnel in the past 20 years have had operational experience in submarine or diving medicine. The training of these personnel has been scientifically narrow, and they have been lacking knowledge of the capabilities and production history of investigators in the field. Since late 1995, four individuals have been in this position, three of whom have been active duty military officers subject to the vagaries of sudden changes of duty stations. This frequent turnover in management has hampered the coordination and implementation of research.

It is recommended that:

- ONR should hire a civilian scientist who will remain in the position for 8-10 years. Ideally, this individual would have operational experience in submarines or diving, have a strong scientific background, and have extensive experience in the field. ONR should resume sponsorship of the Underwater Physiology Symposia to enhance communication between scientists working in the field and draw new investigators into the field.

Finally, it is the strong recommendation of the working group that, in order to accomplish the above recommendations:

- A National Naval Need in Undersea Biomedical Research be established with adequate, sustained and stable funding[1]

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1 As stated by Fred E. Saalfeld in his memo Ser 01-8225 of 19 Nov 1998, Subject DDN Science and Technology National Naval Program Guidance, National Naval Programs (now called National Naval Needs) are those science and technology areas that are uniquely important to the naval forces and whose health depends on ONR investment.

1
INTRODUCTION

Late in 2000, the Office of Naval Research requested the Undersea and Hyperbaric Medical Society (UHMS) to prepare a report on the need for a National Naval Program in Undersea Biomedical Research. A working group was convened in December to gather information and ideas and comments on the past, present and future of this research. The names of the attendees at this meeting and others who have been consulted with or collaborated in the preparation of this report are provided in Appendix A. After this initial meeting, data and information including pertinent Navy requirements and needs were collected and analyzed for this report and are the basis for the recommendations of this report. Members of this working group and others have reviewed this report as it has been generated.

Undersea biomedical research is used in this report to define the study of problems which affect the performance and safety of personnel, or which need solutions to increase operational efficiency and operational capabilities in both the diving and submarine communities. Equal weight is given to both submarine and diving operations.

HISTORY OF UNDERSEA BIOMEDICAL RESEARCH

This section is very abbreviated because of space limits but should give the reader an overview of the undersea biomedical research done over the last century. All of the navy laboratories have published bibliographies of their research reports if more detailed information is required.

From the early part of the 20th century Navy medical department personnel, both in operational billets and laboratories, have worked closely with the operating forces to help solve the new operational problems that were arising because of the introduction of submarines and diving into the fleet. This included reports on submarine atmosphere and habitability problems and new operational needs in diving. There is no record of how these early researchers were funded for their work as there was no apparent research organization in existence. These early attempts were, in many cases, successful in solving the immediate operational problems such as ventilation in submarines and adaptation of the Haldane decompression schedules for U.S. Navy use. It was not until the establishment of the Experimental Diving Station in 1913 that any formal organization existed for investigating methods for making diving more operationally useful. On the staff of this organization was Passed Assistant Surgeon George R.W. French, who though not a trained diver or submariner, can be considered the first undersea medical officer. He and Gunner Stillson produced the first true diving manual in 1916, which contained the first standardized decompression schedules for the U.S. Navy. The Experimental Diving Unit (EDU) was established in 1927 at the Washington Navy Yard and began experimenting with the use of helium in diving. Although the first investigations were disappointing further work continued, and in 1938-39 a systematic study was conducted by Momsen, Wheland, Yarbourough and Behnke in a series of nearly 700 simulated dives to depths of 500 feet. Without this capability the salvage of the Squalus in 1939 could not have been accomplished. In 1927 the first case of cerebral gas embolism (CGE) was reported and subsequent independent experimentation by Navy Medical Officers demonstrated the mechanisms responsible for CGE and proved that CGE was not a manifestation of decompression sickness (DCS). In the 1930s EDU also undertook studies to try to understand inert gas uptake and elimination, effects of increased CO_2 and convulsions due to high oxygen pressures. In 1935 the limits for no-decompression diving were established and nitrogen narcosis was shown to be the cause of poor mental ability of divers at deep depths. The first diving course for Medical Officers was in 1939.

The Naval Medical Research Institute (NMRI) and the Naval Submarine Medical Research Laboratory (NSMRL) were established in 1942. At NMRI a small group of researchers worked to attempt to define the pathophysiology of oxygen toxicity, and perform basic studies on decompression and the factors affecting the risk of decompression sickness. Research at EDU was curtailed during World War II but the surface decompression tables were published in 1945. NSMRL began studying the visual and auditory systems in relation to submariners, particularly for sonarmen. They also studied the application of physical and mental standards for acceptance of personnel for submarine duty. These studies continued into the 1950s. NSMRL also continued some of the above research and began work on the effects of increased atmospheric carbon dioxide levels on submariners, submarine escape problems and the mechanisms involved with air embolism. With the advent of nuclear submarines and subsequent long term deployments underwater, investigations into submarine habitability, psychological effects of long term exposures to closed cabin environments (Operation Hideout, 1953) and atmospheric contaminants were begun. In 1957, at NSMRL, the Genesis experiments began which lead to the SEALAB experiments in the 1960s and operational saturation diving (ONR funded the biomedical studies for SEALABS I and II). Both EDU and NMRI continued low levels of research in diving after World War II and through the 1950s, reflecting the post-war cutbacks in funding and operational requirements. EDU pioneered the use of self-contained mixed gas underwater breathing equipment, which required extensive studies of oxygen requirements during exercise and the absorption of carbon dioxide needed with this apparatus. Studies of the physiologic considerations for the design of underwater breathing equipment were done then served as the basis for later research in this area with the establishment of breathing resistance standards. In 1959 helium-oxygen was adapted for mixed gas scuba. Undersea biomedical research in diving had a resurgence during the 1960s and 70s because of the new requirements for deeper diving, the loss of the USS Thresher and other operational requirements. This increased activity resulted in the studies, at NMRI, of DCS of the spinal cord which showed that bubbles interact with blood in a very complicated way resulting in further tissue damage even after the bubbles are dispersed (no-reflow phenomenon). NMRI also began studies of thermal balance in divers because of the problems of heat loss in deep helium-oxygen exposures and saturation diving with this gas mix. EDU established the engineering standards for more efficient breathing apparatus which allowed divers to use less energy to breathe and prevented problems with carbon dioxide build-up. Exercise tolerance studies assessed the work capabilities of divers in various situations. A new method for calculating decompression schedules for air and mixed-gas diving was validated. The current Treatment Tables 5 and 6 were published which have been used world-wide since 1965. In 1967 NSMRL proved that Tables 5A and 6A were efficacious in treating cerebral gas embolism. NSMRL also continued work in vision and audition concentrating on the man-machine interface, the effects of long term submarine missions, exposure to low-level atmospheric contaminants in submarines, vision and hearing underwater and psychological performance in saturation diving.

The 1970s saw a large increase in the undersea biomedical research particularly for diving with a large extramural component. Studies included work on thermal balance and thermal protection, the high pressure nervous syndrome (HPNS), oxygen toxicity, the pathophysiology of DCS and CGE, shallow nitrogen-oxygen saturation diving, metabolism during long-term submarine patrols, and aseptic bone necrosis. Audition and vision requirements for new submarine systems came under study. Notable results included the publication of unlimited upward and downward excursions for saturation diving and the development of the constant partial pressure decompression schedules for both nitrogen and helium mixed gas diving.

In the 1980s research slowed partially because the Navy reduced their requirement for saturation diving. NSMRL continued with research on submarine medical problems including work on a computer based diagnostic system for use by submarine hospital corpsmen. Work at NSMRL also included shallow water saturation diving with emphasis on submarine escape and rescue. In 1983 NEDU produced the first Navy diver held decompression computer. In 1985 the Mark 16 closed circuit, constant oxygen partial pressure, helium oxygen breathing equipment with associated decompression schedules was introduced after research at NEDU. During the 1980s, researchers at NMRI took a notable step forward when they devised the use of maximum likelihood and probabilistic models analysis for calculating decompression schedules, the first new look at calculating decompression schedules since the early part of the century. This method was validated for nitrogen-oxygen diving in 1999. There were few major advances in the 1990s and the number of reports from Navy laboratories dropped considerably. Most of the research at NMRI has dealt with decompression and oxygen toxicity. One important advance was the demonstration that decompression using hydrogen as the inert gas diluent can be significantly accelerated in small animals by the addition of hydrogen metabolizing bacteria in the animal's gastrointestinal tract. NMRI was ordered closed by BRAC IV in 1995 and portions were reconstituted as the Navy Medical Research Center jointly sited with the Walter Reed Army Institute of Research. Consequently many of the staff left or were transferred to EDU and all manned diving facilities at NMRI were closed. During this time, NSMRL began extensive studies on the effects of low frequency sonar on divers and began concentrating in submarine escape and rescue studies.

The first record of funding by the Office of Naval Research in the area of undersea biomedical research that we have located was research reported in 1953 from the University of Pennsylvania. Since then ONR has funded many studies of undersea biomedical research. Another important function of ONR has been the co-sponsorship of nine symposia in Underwater and Hyperbaric Physiology between 1955 and 1984. These symposia allowed researchers from all over the world to meet and interact. They allowed researchers who were working in areas not directly related to undersea to report their findings which were germane to undersea biomedical research. In this way ONR was able to take advantage of a great deal of research which was funded by other organizations. These symposia greatly expanded and generated other research ideas and, in some cases, resulted in cooperative projects.

PRODUCTS

In addition to the products and results referred to above, the following are considered of major importance to the Navy. The determination of the pathophysiologic effects of contaminants in submarine atmospheres and diving gases and the establishment of limits for these contaminants; Description of the basic pathophysiology of DCS and CGE and development of treatments for these conditions; Establishment of limits for noise exposure in submarines and for divers exposed to underwater sound; Studies of auditory and visual reception which have aided in the design of sonar equipment and increased the capability of operators to detect targets; Establishment of depth-time limits for prevention of oxygen toxicity; Development of specifications for the thermal protection of divers; and Determination of the physiologic and pathologic effects of chronic carbon dioxide exposure.

All of the uniformed services have benefited from Navy undersea biomedical research. The US Navy decompression schedules are used by the Marines, Army, Coast Guard, Air Force and NOAA divers, as well as the treatment schedules for DCS and CGE. NASA has used information developed for submarine atmosphere monitoring and control for space station and shuttle atmospheres. NASA also used data on oxygen use for denitrogenation prior to extra-vehicular activity. Decompression sickness and cerebral gas embolism also occur with exposure in increased atmospheric pressure. The treatment modalities for DCS and CGE developed by the Navy have been adopted by the aviation and aerospace communities for the treatment of these conditions. Without the pioneering work by the Navy in undersea biomedical research these organizations would not have developed their capabilities as readily or cost effectively.

Transition of Navy products to the civilian community have also proven beneficial. Hyperbaric Medicine, which is now a recognized medical specialty, is rooted in the Navy's research using oxygen to treat decompression sickness and cerebral gas embolism. Hyperbaric oxygen is now used as adjunctive therapy for a variety of medical conditions, some of which can result from combat trauma. Studies of oxygen also resulted in the improvement and safety of oxygen use clinically at one atmosphere. Results from research on the high pressure nervous syndrome (HPNS) have led to a better understanding of the mechanism of action of anesthetic gases. The treatment of cystic fibrosis uses a lung flooding technique to clear debris from the lungs which came from investigations by the Navy to determine if liquid breathing was feasible. Wilderness Medicine has used information from this program in that particular specialty. The development of saturation diving and diving equipment design has contributed greatly to the techniques used in development of deep off-shore oil and gas production fields. Studies of spinal cord decompression sickness and cerebral gas embolism have resulted in methods for the improved therapy of stroke and central nervous system trauma. Studies of breathing resistance in diving apparatus has resulted in the better design of breathing apparatus for firemen and miners and others who must wear respiratory protective apparatus.

NEED FOR CONTINUING BASIC UNDERSEA BIOMEDICAL RESEARCH

In view of the many advances cited above, a legitimate question that can be asked is why more undersea biomedical research is needed. Is the program proposed in Chapter 3 just another attempt at business as usual with increased funding? It is felt that this is not the case for a variety of reasons.

The research to date has not answered many of the basic questions which are needed to solve major operational problems. For instance, while we know a great deal about the pathophysiology of DCS and that the basic mechanism for initiating this condition is the formation of bubbles in blood and tissue, the mechanisms of bubble formation are still a mystery. In addition, the course of inert gas uptake and elimination is not known in enough detail to be used in developing efficient decompression tables. The pathophysiology of oxygen, in spite all the research done to date is still not understood. One of the major blocks is that the tools needed to study them have not been sophisticated enough. However, new tools from the fields of immunology, medical imaging, genetics, genomics, proteomics (the study of expressed cellular proteins) and pharmacoproteomics (protein-drug interactions) are now available which could aid research. New imaging techniques may provide the resolution to enable the visualization of developing bubbles; tissue mass-spectroscopy may aid in research into gas uptake and elimination; proteomics and pharmacoproteomics could be very useful in investigating oxygen toxicity. These and other areas need to be studied for application to undersea biomedical research.

There are new operational problems which require research. A few examples of these are the prevention of cold injury, the preservation of personnel capabilities in a disabled submarine in order that they may aid successful escape or rescue, better carbon dioxide scrubbing and more efficient means of providing an adequate oxygen supply. There has never been a definitive prospective longitudinal health study of submariners as there has been in aviators. This is a definite need, especially as there is little to no information on the problems of continuous long exposures to a mixture of trace contaminants on submarines. Diving at altitude is an increasing operational requirement and appropriate decompression schedules are needed.

Another block to performing conclusive research has been the lack of adequate and stable funding to continue research in an area once a "quick-fix" for a particular operational problem had been provided. Expertise in the Navy or at universities may be lost for a variety of reasons, particularly the lack of adequate funding for long range projects. Changes in Navy operational policy have resulted in certain areas of research being curtailed e.g., research in the high pressure nervous syndrome and other problems of deep saturation diving stopped in the early 1980s because the Navy made the decision to reduce operational saturation diving. This policy has recently been reversed. Finally, as in all research, approaches thought to be promising turned out to be unfeasible.

Navy requirements and operations change, but the basic physiologic mechanisms in undersea operations do not. Submarine and diving operations will continue in the Navy and will continue to require biomedical research to answer operational needs.

2

PROGRAM FUNDING

ONR FUNDING

Dr. Leonard Libber, former Program Director of the ONR Physiology Program, and Captain Robert C. Bornmann, MC, USN (RET), Program Manager for Undersea Medicine at the Naval Medical Research and Development Command (1973-1977) were interviewed regarding the Navy's undersea biomedical research program in the 1970's.

Captain Bornmann submitted the following statement:

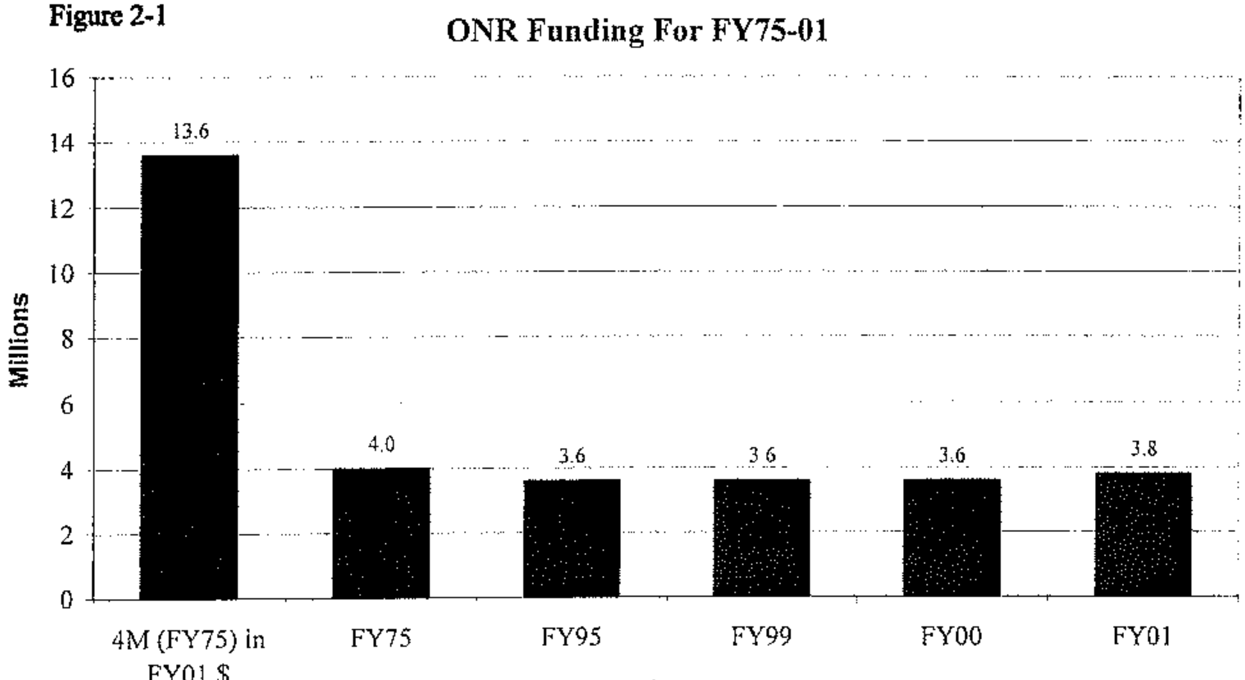
> "The quarter century between 1960 and 1985 was truly a remarkably productive time in the development and extension of man's capability to work under the sea. The United States, and particularly the United States Navy, were leaders in this global effort. The area of undersea biomedical sciences were pace-setting during this period, which also was marked by the tenure of Joseph P. Pollard, M.D. (ONR 440) from 1968-1980) and Leonard M. Libber, Ph.D. (ONR 441) from 1959-1980.
>
> In the late 1950's the funding of medical investigations at the Navy Experimental Diving Unit had been limited to about $10,000 per year, and that money came from the Bureau of Ships. In the office of the Navy Surgeon General only $200-250 K was budgeted annually for undersea medical research; funds were sent mainly to the Navy labs at Groton, CT [NSMRL], and Bethesda, MD [NMRI]. In the early 1960's Professor C.J. Lambertsen at the University of Pennsylvania received $30K each year for research support; $20K from BUMED and $10K from ONR. ONR was a leader even in those exiguous times, in the sponsorship of ground-breaking basic studies and reports. ONR [provided] funding for the triennial Underwater Physiology Symposia (1955, 1963, 1969, 1972, etc.). ONR was the executive agency for the Navy SEALAB undersea living experiments in 1964 and 1965.
>
> The tragic loss of the USS THRESHER in 1963 was followed by the official report of the Stephan Deep Submergence Systems Review Group. This laid out an underwater research and development program that included biomedicine as an essential component. Further loss of the SCORPION a few years later in 1968 heightened the national resolve to follow through on the broad and inclusive challenging recommendations of the DSSRG Report.
>
> Within a few years [mid-1970s] the Navy was spending close to $10 million each year in the area of undersea biomedical research. Of that total, Dr. Libber recalls

contracts during the 1970's to civilian and university laboratories with annual funding of about $4 million. Half of that total was ONR 6.1 funds, to which another $2 million of [Bureau of Medicine and Surgery] BUMED funds were added (mostly from 6.3 and 6.2 appropriations). With slight annual variations, those totals remained fairly constant until the late 1970's. However, the construction of multimillion dollar MILCON medical research facilities led to more of the BUMED funds being directed to BUMED laboratories. At the same time management changes in SECNAV and ONR led to decreases in the program funding through CODES 440 and 441. Staff position vacancies were left unfilled. Shortly after the retirements of Dr. Pollard and Dr. Libber, undersea programs supported by their offices were diminished and then terminated without essential replacements."

A considerable degree of effort was expended in attempting to ascertain what ONR's funding levels for undersea biomedical research were during the period from 1980 to 1997. Unfortunately, the NMRDC records for that period were destroyed. No copies of program guidance at NSMRL or NMRC (formerly NMRI) are available for this period. The Defense Technical Information Center is unable to supply this information. Captain Edward T. Flynn, MC, USN (Ret) recalls that ONR funding for this area of research circa 1990 was about $3-4 million.

ONR's funding for undersea biomedical research in FY98, FY99, and FY00 was $3.6 million, and in FY01 is $3.8 million. Thus, funding in this research area has been static for the past 30 years. Andrew Morrison, Ph.D., an economist with the International Development Bank in Washington, DC, has calculated that based on the Bureau of Labor Statistics, $4 million dollars in 1975 would be equivalent to $13.36 million dollars in 2001. Figure 2.1 depicts ONR's funding for 1975, and for FY98 - 01.

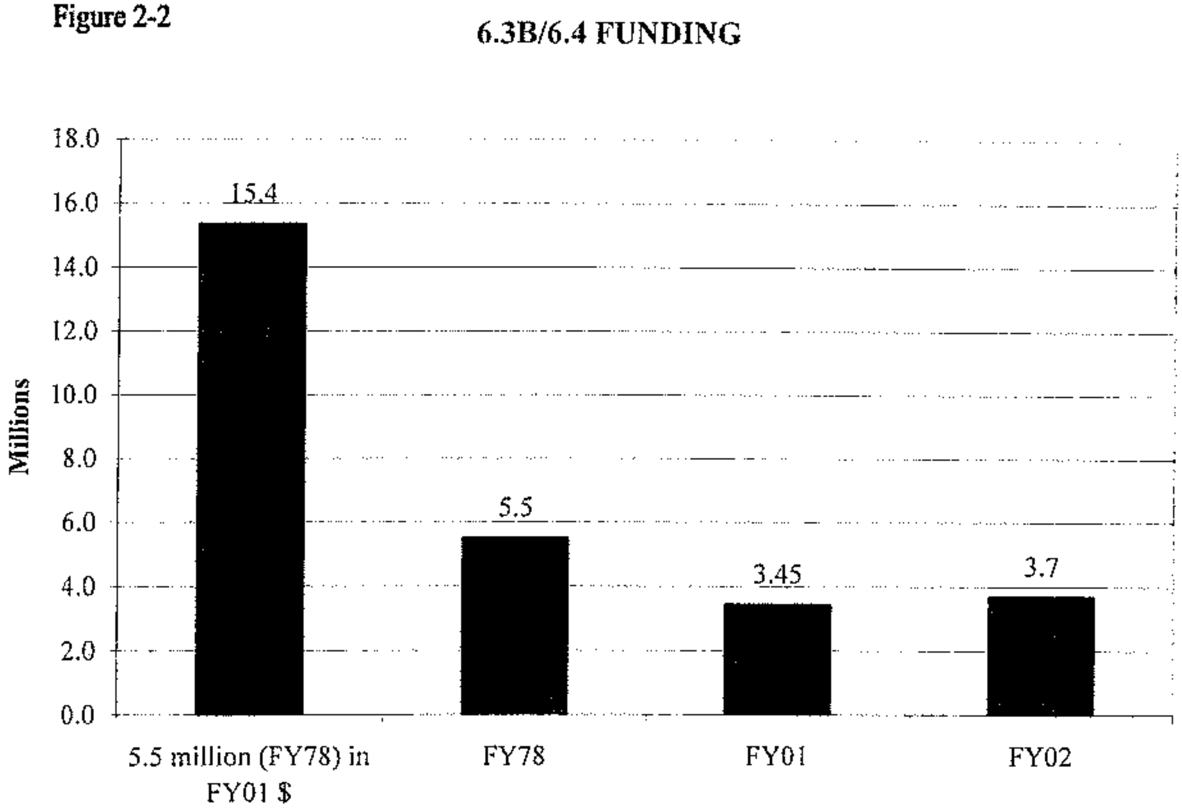
Figure 2-1



OTHER NAVY FUNDING

In the early 1970's, OPNAV 21 (Deep Submergence, now N773) began to provide 6.3 funding to the Naval Medical Research and Development Command which managed these funds for undersea biomedical research. By 1978, the level of funding from this source was 5.5 million dollars. In 1997 these funds were designated as 6.4 funds. During the same year the 6.3/6.4 funding level was decreased by 1 million dollars as OPNAV felt that these funds had been supporting 6.2 work. With the dissolution of the Navy Medical Research and Development Command in 1998, the responsibility for the management of 6.3 funds from OPNAV was assumed by NAVSEA. The FY01 funding level for undersea biomedical research was 3.45M, and that for FY02 is 3.7M. Thus, funding for undersea biomedical research from OPNAV has decreased by 2 million dollars from 1978. Dr. Morrison calculated that 5.5 million dollars in 1978 would be equivalent to 15.37 million dollars in April, 2001 (Fig. 2.2).

Figure 2-2



NON-NAVY FUNDING

Historically, neither the National Institutes of Health nor the National Science Foundation, have provided any funding for research into submarine and diving biomedical issues. The National Oceanic and Atmospheric Agency (NOAA) has two funding programs for marine sciences. There is the Sea Grant program which encompasses 26 Sea Grant Colleges. However, the only funding this program for undersea biomedical research that could be identified was 110K per year which has sporadically been provided to the University of Wisconsin. NOAA manages the National Undersea Research Program (NURP) which has never funded undersea biomedical research. In the past, the some commercial diving companies have funded projects to develop proprietary decompression tables for their own use, but none of the companies have been a sponsor of undersea biomedical research. Thus, the only source of funding for undersea biomedical research is, and has been, the U.S. Navy.

ESTIMATED CURRENT RESEARCH FUNDING NEEDED

In order to obtain an estimate of the amount of funding currently needed to support basic undersea biomedical research, a sample research program for this area was developed. This research program is comprised of elements of some of the needed areas of undersea biomedical research in the next section. These elements were felt to be 6.1/6.2 in nature, and were considered to represent important underpinnings for progress in these various research areas. Some of these suggested research programs would take only a year or two to complete. Others would clearly take longer, perhaps considerably longer, to complete. Appendix B describes a one year basic undersea biomedical research program, and the assumptions involved in its formulation. The total funding estimated to conduct this research program was 13.34 million dollars.

3

NAVY REQUIREMENTS AND NEEDS

REQUIREMENTS

The following requirements documents were reviewed: Chief of Naval Operations Non-Acquisition Program Definition Document for Deep Submergence Biomedical Development dated 11/23/99; Commander, Naval Special Warfare Command Medical Research and Development Tasks dated 1990-2000.

CHIEF OF NAVAL OPERATIONS NON-ACQUISITION PROGRAM DEFINITION DOCUMENT FOR DEEP SUBMERGENCE BIOMEDICAL DEVELOPMENT

This document outlines what biomedical development is required to support all Navy manned submarine and diving operations. Three areas of effort are described in this document and are quoted below.

Enhance DISSUB Survival

"Develop methods, procedures and equipment to enhance the probability of survival and minimize injury of submariners while: a) on board a DISSUB; b) performing escapes; c) being rescued. Develop senior survivor expert decision tools. Develop methods of assessing and providing a habitable closed environment when electrical power is lost. Identify and assess thermal, atmospheric, psychological and toxicological threats in DISSUB, and develop effective measures to neutralize these threats. Priority will be given to solve the problem of elevated carbon dioxide levels in the DISSUB. Devise and test models to calculate the risk of decompression sickness upon exit from a pressurized DISSUB. Develop adjunctive therapies for treating decompression sickness (DCS) in DISSUB survivors at 1 ATA."

Diver Health and Safety

"Develop strategies to accelerate decompression for various scenarios. Develop algorithms that enable real time calculation of decompression schedules for multiple-gas, multi-level dive profiles, for any specified risk of DCS. Develop procedures to increase flexibility and safety of oxygen diving by a) developing procedures that decrease the risk of oxygen, b) modifying susceptibility to oxygen toxicity. Establish underwater noise exposure guidance for the operational range of wet and dry diving missions. Develop guidance for exposure to underwater blast."

Biomedical Engineering for Diver Equipment Selection

"Provide biomedical/bioengineering criteria for designing improved underwater breathing apparatus (UBA) and UBA procedures to maximize safe operational performance in support of diving missions. Develop empirical data-based UBA acceptance criteria, based on human factors standards. Analyze respiratory, regional, and total heat loss of divers exposed to various environments and provide guidelines for passive and active thermal protection. Develop acceptance criteria for thermal protective garments. Develop non-chemical methods of CO_2 scrubbing."

Another important project, already underway, is to develop systems to support submarine escape and rescue missions and, conventional diver operations. Diver operations include ship husbandry, salvage/recovery, and submarine rescue operations to support national, as well as, Navy needs around the world. Modern certifiable diving systems to ensure diver safety and allow maximum work efficiency will replace currently antiquated systems. Efforts are currently focused on the Submarine Rescue Diving and Recompression System (SRDRS) to provide a new rapidly deployed emergency submarine rescue capability. SRDRS will fill the gap created by the decommissioning of USS Pigeon (ASR 21) and USS ORTOLAN (ASR 22) and provide a new capability of pressurized transportation of rescuees from a stricken submarine directly to the decompression system eliminating the requirement for Deep Submergence Rescue Vehicles, Mother Submarines, and Submarine Rescue Chambers. SRDRS is to include an air transportable rapid assessment/underwater work system, a decompression chamber system and a pressurized rescue module. The SRDRS will provide a global rapid response capability to support submarine rescue missions with an increase in capability at a fraction of the cost of the currently available systems.

COMMANDER, NAVAL SPECIAL WARFARE COMMAND MEDICAL R&D TASKS

These Medical R&D Tasks are not formal operational requirements but they contain background information regarding operational requirements to support the need for the Medical R&D Task. The requirements pertaining specifically to diving are: long exposures to heat or cold stress while diving, high altitude diving, going to high altitude after diving (parachuting from 35,000 feet or operating on land at high altitude), long duration exposures to high oxygen concentrations, operating away from any medical support (no treatment chamber facilities), and exposure to severe exertion and fatigue while diving.

The following Medical R&D Tasks have been approved which relate specifically to Special Warfare diving operations. The following titles include only tasks which are of major importance for assessing undersea biomedical research needs. These are: Development of Standard Thermal Protection Indices, Active Warming Methods for Extremities, Air/ 0.7 ATA O_2 Multi-Level Dive Decompression Table Verification, Prophylactic Measures for CNS Oxygen Toxicity, Emergency Oxygen Decompression Procedures, Flying After Diving (procedures to shorten the delay prior to altitude exposure to at least 15,000 ft. for an indefinite time), Altitude Diving (tables for use with air/0.7ATA O_2 up to 15,000 ft, maximum depth not less than 150 ft., maximum dive time of 12 hours), Surface Interval Oxygen Breathing, 1.2 ATA O_2 Decompression Algorithm, Oxygen-Enhanced Breath-hold Diving, Immune Function in Basic Underwater Demolitions/ SEAL Training, Adjuncts to Recompression Therapy for Severe Dysbaric Disease, Oxygen Arterial Gas Embolism Studies, High Altitude Parachute Operations After Diving (required interval after diving before ascent to altitude, decompression algorithm for operations up to 40,000 ft., use of denitrogenation techniques), and Antioxidant Prevention of Pulmonary and Lenticular Oxygen Toxicity.

OTHER REQUIREMENTS

The Explosive Ordnance Disposal diving community has a requirement to dive to 300 feet. The Underwater Construction Teams have requirements for diving at altitude, protection from cold, attenuation of underwater noise from stud guns and hydraulic tools, protection for diving in polluted water, increased bottom times which are more efficient for work in deeper diving, and improved treatment of decompression sickness/arterial gas embolism in isolated environments. All of these are included in the above documents.

NAVAL UNDERSEA NEEDS AND NECESSARY RESEARCH

In addition to reviewing the above documents and to obtain a clearer picture of these requirements and their translation into biomedical research needs, a meeting was held with the following representatives: the U.S. Navy ONR representative for submarine and diving medical research, two senior retired Undersea Medical Officers, the submarine and diving representative from the office of the Chief of Naval Operations (N773), Supervisor of Diving from the Naval Sea Systems Command (Code 00C), the Commanding Officer of the Navy Experimental Diving Unit, Head, Undersea and Radiation Medicine branch at the Bureau of Medicine and Surgery (Code 21), and the Executive Director of the Undersea and Hyperbaric Medical Society (See Appendix A). The following two questions were posed.

Question One. "*What are the current biomedical research needs in the Navy for diving and submarine operations?*" The responses from the Navy fleet representatives were unequivocal. Specifically, the Navy leaders identified the following areas as high priority Fleet needs. They are presented below with a short discussion outlining the problem and what is required for resolution.

Carbon dioxide detection and removal.

Problems. Currently, carbon dioxide removal in submarines is achieved by absorption into a monoethanolamine (MEA) packed tower absorber. This is effective in reducing ambient carbon dioxide levels to 0.3 % to 0.5%. It is known that hypercarbic stress results in metabolic and physiologic stress for the crew at atmospheric levels of 0.8% and above. No research has been identified which deals with long term exposures to carbon dioxide levels at or below 0.5%. Additionally, the MEA scrubbers are large and power intensive. The large amounts of MEA solution present can lead to carry-over of MEA, which is a respiratory irritant. Thus, improved methods of removing carbon dioxide from submarine atmospheres are needed.

Lithium hydroxide is currently carried aboard nuclear submarines to be used in DISSUB or other emergency situations for removing carbon dioxide from the atmosphere. Lithium hydroxide is caustic, and an eye and respiratory system irritant. It is not a particularly efficient means of removing carbon dioxide, and on the 688 class boats, only about a three day supply is carried, which may not be adequate in a disabled submarine situation. A non-caustic means of scrubbing carbon dioxide is needed, as well as a means of circulating airflow.

During dives with closed circuit rebreathers, there can be channeling of the carbon dioxide absorbent. During saturation and sub-saturation dives of several hours duration the CO_2 absorbent can be exhausted. A sensor which can detect high concentrations of carbon dioxide in the breathing gas, and alert the diver of this, is needed. Additionally, a means of non-invasively monitoring arterial carbon dioxide is needed. This would ensure that the levels of CO_2 in the body are not reaching pathological levels because of intrinsic retention, and/or deficiencies in the equipment such as channeling of the absorbent, excessive underwater breathing equipment resistence and/or dead space.

Research approaches. Novel methods of scrubbing carbon dioxide from the atmosphere of nuclear submarines should be explored. Examples of these methods include facilitated transport membranes, which consist of a reactive carrier species immobilized within a support membrane. Absorption and separation is achieved in a single stage with the regeneration of the carriers being accomplished by the application of a vacuum to the waste gas side of the membrane. Another type of system which should be examined is a method which utilizes sea water in contact with the air or in conjunction with a membrane system. Carbon dioxide, being 20 times more soluble in sea water than oxygen and nitrogen, would be differentially reduced. New detection methods for carbon dioxide on divers' breathing mix and a non-invasive method for determining arterial carbon dioxide levels need development. New developments in lasers or near infra-red technology should be reviewed for applicability to this area.

Improved thermal protection.

Problems. During diving operations, the diver's safety is jeopardized and performance degraded by exposure to cold water. Despite improvements in thermal protective garments in the last 30 years, divers still get cold, especially during long exposures such as during special warfare operations in a swimmer delivery vehicle. Inadequate hand thermal protection during operations in cold diving environments exposes personnel to an increased risk of cold injury and results in decrements of tactile sense, manual dexterity, and strength. Hypothermia results in poor judgment jeopardizing the diver's safety and impairing mission efficiency. Without a supplemental heat supply, current diving protective equipment provides inadequate whole body thermal protection during long underwater operations. In some situations, as in deep diving using helium-oxygen breathing mixtures, supplemental heat must be provided to the diver. Improved, more efficient thermal protective garments need to be developed, and compact, portable underwater energy sources for providing supplemental heat must be invented.

While most of the world's waters are cold, there are some, such as parts of the Persian Gulf, where the water is hot. In these circumstances the potential for heat stress is considerable and this, in turn, limits operational capabilities.

Research approaches. While the physiological and psychological effects of exposure to cold water have been somewhat defined, there is still considerable uncertainty about the amount of thermal protection that is needed, and when and how much supplemental heat is needed in various conditions in the diving environment. Additionally, better thermal protective suits which preserve diver dexterity need to be developed, This requires the investigation of new and novel materials and systems in providing passive insulation such as Dewar, e.g. vacuum systems, and insulative liquids. Also, novel systems that provide supplemental heat to the diver need investigation. For example, conductive polymers that can be molded into shapes that can be used as an active thermal protective garment need to be investigated. Methods which heat the diver's breathing gas, such as adding small amounts of hydrogen to the breathing mix and passing the gas over a platinum catalyst can be tested. Studies of the use of drugs such as tyrosine to prevent hypothermia and performance degradation need to be conducted.

Diving in hot water greatly increases the potential for heat stress which also limits operational capabilities, especially if protective garments against chemical, biological or other toxic agents must be worn. Physiological studies need to be conducted which establish standards for exposure (water temperature versus time) for divers working in these conditions. Additionally, methods to reduce diver heat gain during operations in hot water need to be developed.

Hyperbaric Oxygen Toxicity. In diving operations, inspired oxygen in high concentrations is used to limit inert gas uptake and to facilitate decompression (i.e. speed up or eliminate). In some operations, 100% oxygen breathing is a requirement. Unfortunately, oxygen in high concentration is toxic, especially to the central nervous system; and can cause convulsions and unconsciousness. Since the onset of CNS oxygen toxicity is totally unpredictable (i.e., no early warning signs) there is no way an episode can be avoided. Thus, lower concentrations of oxygen than are desirable must be used. This limits operational boundaries, and even with the use of these lower concentrations, central nervous system oxygen toxicity may occur, and this endangers the diver. Oxygen is also toxic to other organ systems, especially the lung. This is especially important in long duration exposures to higher than normal oxygen levels as in saturation diving or extended therapy. Despite our current understanding of the formation of reactive oxygen species this has not made a dent in operational limitations. A small increase in tolerance would have a dramatic effect on almost all diving. We need a much clearer idea of the basic mechanisms by which oxygen causes these effects.

Research approaches. Research in the toxic effects of oxygen is needed in a number of areas. Firstly, we need to better understand the mechanisms by which oxygen toxicity occurs in the central nervous system (CNS) and the lungs. With better understanding of the mechanisms of this problem rational methods to lessen the likelihood of oxygen toxicity can be developed. Potential methods that may be decrease oxygen toxicity are chemical scavengers of oxygen and the use of antioxidants. Lastly, a system by which impending oxygen toxicity can be detected in the operational diver is needed. This would permit the diver to lower the concentrations of oxygen that are breathed, thereby forestalling an episode.

This is one area in which the research techniques and ideas from other biomedical research fields might be very fruitful. The fields of proteomics and pharmacoproteomics need to be investigated as to applicability to the study of oxygen toxicity.

Enable a diver to safely dive in polluted water.

Problems. There are times when Navy divers need to dive in water that is polluted with toxic chemicals and/or hazardous microbiological agents. The selection of the type of protective equipment depends on the type(s) of contaminants present. In order to safely dive in such water, a sensor(s) that indicates which agent(s) is present in suspected polluted water is needed.

Research approaches. In order to select the appropriate protective clothing for divers entering polluted waters the type(s) of pollution present need to be known. This requires the development of sensors which can rapidly analyze both bacterial and chemical contaminants. Off-the-shelf sensors should be surveyed to ascertain which may be useful. Others may need to be developed for less common contaminants.

Escape and rescue from a disabled submarine.

Problems. Better methods are needed to provide the survivors of a disabled submarine with a respirable atmosphere, thermal protection, and nutrition until they can be rescued or can escape. Since a pressure greater than that of sea level will likely be present in the boat, methods of decompressing submarine personnel, and of treating injuries which they have sustained, are required.

Research approaches. There are multiple major difficulties associated with the escape or rescue of the survivors of a sunken submarine. First, there are the problems associated with maintaining a survivable environment in a disabled submarine, until the survivors can be rescued. A respirable atmosphere needs to be provided. Currently, this would be done by bleeding oxygen from an oxygen bank into the submarine, or by the use of chlorate candles. Carbon dioxide levels would be controlled by the use of lithium hydroxide scrubbing. There are considerable problems associated with the manner in which these devices can be used. Better systems need to be developed to supply oxygen and remove carbon dioxide. As it will be cold within the submarine, thermal protection of some sort will need to be provided to the crew. Issues of acclimatization, as well as, to what degree of thermal protection is necessary need to be studied to help assure survival. Additionally, the nature and degree of nutrition, which needs to be available to the crew under these conditions, needs to be assessed. A disabled submarine will almost assuredly have increased atmospheric pressure in the boat, as a result of flooding. This "overpressure" may be as much as several atmospheres. The result of this is the survivors' tissues will be saturated with the inert gas, and they will require decompression to avoid decompression sickness. Methods of accelerating the rate of decompression are required in order to evacuate the survivors in a timely fashion. Thus, new decompression schedules need to be studied for these conditions, as well as other methods to facilitate decompression. The personnel who are involved in the rescue of survivors will also require decompression, and novel methods for ensuring their well-being need to be developed.

Some of the survivors in a disabled submarine will likely have sustained injuries in the course of events that events that put the boat out of action. These include smoke/toxic gas inhalation, as well as mechanical trauma. Means of treating these casualties while awaiting rescue will be developed. Systems for extricating injured personnel from the submarine into the rescue vehicle must be provided.

The long-term effects of exposure to submarine atmosphere contaminants.

Problems. The atmosphere of submarine environments is a complex chemical mixture. Some of these contaminants result from the off-gassing of substances used during the construction or overhaul of the boat (e.g. adhesives, plastics, etc.). Others are generated by the crew (e.g. carbon dioxide, carbon monoxide, etc.), or operating equipment aboard the vessel (e.g. charging batteries, carbon dioxide scrubbing, etc.) At the present time, little is known about the presence of these contaminants or how they effect the crews over the long term. The BUMED Representative stated that "A longitudinal prospective health study has never been done well for submariners." [and such a study is needed].

Research approaches. Nuclear submarine atmospheres may have carbon dioxide levels in the range of 0.3% to 0.5%. It has been established that exposure to 0.8% - 1.0% CO_2 has a profound effect on respiration resulting in an increase in respiratory minute volume and physiological dead space. Acid-base balance studies showed cyclic alterations between metabolic and respiratory acidosis at 30 day intervals. With these cycles, there is a 50% decrease in excretion of calcium. As a result of this chronic hypercarbia, there are possible health hazards which include nephrocalcinosis, hypertension of renal origin, chronic lung disease, and hemopoietic abnormalities. There have been no studies of long term exposures to levels of carbon dioxide at 0.5% or lower. Research should be undertaken to determine if long term exposure to levels of up to 0.5% carbon dioxide causes any physiological effects.

Submarine atmospheric environments may have a complex mixture of low levels of chemical contaminants. Studies have shown that chronic exposure to low levels of volatile organic compounds can cause respiratory system disease, as well as immune system and nervous system disorders. A prospective longitudinal study of submariners is required to determine if any long term health effects of exposure to submarine atmospheres occur. Research continues to be needed to elucidate the physiological and metabolic alterations that occur in men exposed to chronic hypercarbia and during exposure to other atmospheric contaminants, and to develop methods to allay the untoward effects of these exposures. Additionally, long-term surveillance of nuclear submarine personnel needs to be done to determine if there is an increased incidence of disease.

Saturation diving.

Problems. Although it has been reduced in the past ten years, the U.S. Navy has a requirement to maintain a saturation diving capability to 1,000 feet of seawater (fsw). The High Pressure Nervous Syndrome (HPNS) is an impediment to the efficient use of a deep saturation diving system. Currently, in order to avoid the untoward effects of HPNS, a slow compression rate must be used, thereby keeping the diver(s) from reaching the bottom in the fastest possible time. Additionally, the decompression rate from saturation dives is extremely slow, and methods which could accelerate this are sorely needed. It has been discovered that saturation diving using normobaric oxygen partial pressures is not possible: increased levels of oxygen are needed to preserve the divers' cognitive abilities so that they can efficiently do their jobs. In addition, it was found that increased oxygen levels are also required to allow successful decompression without decompression sickness. We do not know why increased levels of oxygen are required to facilitate decompression and preserve cognitive abilities.

Research approaches. There are times when it is desirable, or necessary, to get a diver to considerable depth, e.g. 500 to 1,000 feet, in a short period of time. For example, an explosive device attached to the legs of an offshore oil platform may need to be disarmed. However, at these depths, increased pressures of helium-oxygen breathing mixtures induce a condition of increased excitability of the nervous system. This has been known as the High Pressure Nervous Syndrome (HPNS) in which tremor, disequilibrium, incoordination, disorientation, short-term memory loss, etc. are prominent. Clearly, these symptoms would preclude the diver from disarming the explosive device. Research is needed which can elucidate the mechanisms underlying the high pressure nervous syndrome. This knowledge would then facilitate the development of methods to ameliorate this condition, thereby preserving the divers ability to perform tasks under these conditions.

There is no information on why higher levels of oxygen are required during saturation diving. Basic studies are needed to determine whether this is a result of a defect in oxygen transport, changes in cell metabolism, other some other problem.

Decompression.

Problems. Decompression is a burden that all diving operations must face unless pure oxygen is breathed. Decompression is time consuming and exposes the diver to decompression sickness (DCS) and other deleterious factors such as hypothermia. Although many decompression tables have been developed over the years decompression is still not adequate. For example, 10-12 cases of DCS occur annually following shallow dives, which according to the Navy tables do not require decompression. DCS results in diver morbidity and decreased operational effectiveness. Development of improved decompression models that accurately predict decompression outcome are needed to improve fleet operations and enhance diver safety. New methods of decreasing the decompression time for all types of navy diving are needed. If decompression could be significantly reduced or even eliminated this would greatly enhance diving operations and prevent casualties due to DCS. Recent research suggests that the role of Patent Foramen Ovale (PFO) in diving needs to be investigated, as about 30% of adult populations have this condition. This represents a potential right to left shunt, thereby possibly allowing bubbles to enter the arterial circulation during decompression and producing cerebral decompression sickness. If this condition causes a significant increase in DCS, the available pool of personnel for diving duty could be significantly decreased.

There are still considerable gaps in our knowledge of the basic processes that are operative in decompression and in the development of decompression sickness. There is no clear evidence of how inert gases are taken up or released from body tissues. Although we know bubbles are the proximate cause of DCS we have no idea of how they form in the body or where they form. This basic information is essential to the development of rational decompression schedules, and to facilitating decompression.

Research approaches. Development of improved decompression models that accurately predict decompression outcome are needed to improve fleet operations and enhance diver safety. Ancillary methods of enhancing inert gas elimination are needed. Possible areas of exploration include the use of perfluorocarbons (small amounts can transport large amounts of inert gas), as well as negative pressure breathing which facilitates inert gas elimination. Drugs that increase cardiac output, thereby increasing tissue perfusion, having individuals perform gentle exercise during decompression or the use of negative pressure breathing need to be evaluated to determine if these will aid in inert gas elimination. The role of a Patent Foramen Ovale as a predisposing factor for DCS will be elucidated by prospective controlled studies. A non-invasive screening method such as improved thoracic and carotid artery Doppler detection may be required if this condition is of significant importance in the development of DCS.

One method of obviating decompression would be to use the technique of liquid flooding of the lungs so that no inert gas would be breathed. This technique was investigated over thirty years ago and was judged to be unfeasible. The literature on this topic should be reviewed to determine if any new advances in this field make this feasible.

A novel way of decreasing inert gas load during diving, and of accelerating the rate of decompression, while improving diver safety may be chemical decompression. Initial research in this area has examined decompression during dives where hydrogen was used as the diluent gas. This research implanted a colony of obligate anaerobic bacteria which are normally found in the human gut and which convert hydrogen to methane in the gastrointestinal tracts of small and large experimental animal models. In these experimental models, the incidence of decompression sickness was reduced by 50% when these bacteria were present. Thus the gastrointestinal tracts of these animals served as an inert gas scrubber to reduce gas loading and facilitate decompression. Note that the technical spin off of this research (which was funded by ONR) is likely to be improved treatment of gastrointestinal disorders such as irritable bowel syndrome. What is needed is to extend the basis of chemical decompression to situations where nitrogen is the diluent gas. Bacteria which can metabolize nitrogen will clearly be needed and this needs to be investigated. While we know that bubbles play a central role in the pathogenesis of DCS, there is still considerable uncertainty regarding the location and quantities of bubbles in various types of DCS. Ultrasonic bubble detectors have been employed to monitor bubbles that are present and moving in the circulation. However, these are relatively crude instruments and do not provide the information required to adequately study bubble formation and fate. What is needed is a device which will detect, size, and identify the location of stationary bubbles that are present in various parts of the body. New imaging techniques developing in clinical medicine need to be investigated as to their suitability for this purpose. Studies are needed to investigate the immunologic response to bubbles in blood and tissue.

Because of the wide variability in the susceptibility of individuals to decompression sickness, genomics should be looked into to determine if there is application to the study of decompression risk.

Lastly, there are considerable gaps in our knowledge of the basic processes that are operative in decompression and in the development of DCS. For example, research needs to be focused on quantifying the rates and amounts of inert gas uptake and elimination of various gases for various tissues, as well as for the body as a whole. New instrumentation such as tissue mass spectrometry may be useful for application to this research. Studies should be performed that determine the mechanism by which bubbles form and grow in the body. This information is essential to the development of rational decompression tables and to facilitating decompression.

Improved treatment of decompression sickness and cerebral gas embolism.

Problems. The most common, serious, conditions resulting from diving are decompression sickness and cerebral air embolism. Improved therapeutic modalities are needed, as the current treatments are frequently ***not*** curative. Also needed, since recompression is not always completely effective, are improved ancillary means of treating decompression sickness and cerebral air embolism. In addition, methods for treating these conditions without recompression are needed by special forces because they frequently operate at long distances from recompression facilities or cannot be evacuated to a facility in the time required. This also applies to the DISSUB situation where there would be mass DCS casualties. Technical spin-off of this work could be improved methods to treat stroke and central nervous system trauma.

Research approaches. Improved therapeutic modalities are needed. This includes better definition of the appropriate depth and duration of recompression therapy. Better understanding of the most efficacious breathing mixture to provide during treatment is needed. Since recompression is not always curative, improved ancillary means of treating these conditions are needed. This includes various drugs that will facilitate reperfusion of areas of the central nervous system that have been deprived of blood flow, as well as evaluation of various substances such as perfluorcarbons that should facilitate bubble dissolution. A technical spin off of this work should be improved methods to treat stroke and central nervous system trauma.

Improved watch schedule for submarines.

Problems. Currently, the watch schedule aboard nuclear submarines is 6 hours on duty, and 12 hours off. This disrupts circadian rhythms and causes desynchronization. This, in turn, has deleterious effects on health and performance. A watch schedule which does not cause desynchronization is needed.

Research approaches. For many years now, the watch schedule aboard nuclear submarines has been 6 hours on duty and 12 hours off duty. This schedule produces desynchronization of internal circadian cycles from environmental cycles. The desynchronization produces alternations in respiratory frequency, heart rate, body temperature, and hormone levels, which control metabolic functions. Desynchronization may increase susceptibility to disease. For example, it has been shown that the influence of circadian cycles on susceptibility to intraperitoneal injection of E.Coli endotoxin is that the same amount of endotoxin kills 80% of mice at one time, and 20% at yet another time. Studies of shift workers have shown that desynchronization has deleterious effects on health and performance. There are increased cardiovascular and gastrointestinal disease rates in shift workers. Decreases in vigilance, concentration, cognition, and motor performance have also been noted to be present in shift workers.

There is a need to examine the effects of the current rotating shifts aboard submarines, and to develop a better work-rest schedule which does not produce desynchronization and the untoward effects of desynchronization.

Adverse effects of long duration submarine operations.

Problems. The long duration of certain submarine operations may produce deleterious psychological effects on crewmembers and affect retention. If these effects are present they need to be defined and methods developed to ameliorate them.

Research approaches. Research should be done to investigate the effects of long duration submarine operations on the psychological health of personnel involved and determine if the psychological changes are due to the exposure or whether some other causes are involved. This may involve research in standardizing psychological testing for submariners and validating them with the psychological outcome of exposures.

Diuresis and dehydration during swimmer delivery vehicles operations.

Problems. During lengthy special warfare operations with swimmer delivery vehicles, particularly in cold water, there may be considerable diuresis, with resultant loss of fluid in the vascular space. This can result in a considerable degree of hypotension upon exiting the water. This can be so severe as to prevent these personnel from being able to perform their mission. Means of ameliorating the degree of dehydration and hypotension must be developed.

Research approaches. The shift in fluid centrally that occurs as a result of immersion and cold produces a brisk diuresis. This can, and does, result in considerable loss of fluid from the vascular space, potentially causing hypotension and syncope when leaving the water. Methods to prevent or decrease the degree of the diuresis and to restore vascular fluid volume will be devised.

Heads up display system for divers.

Problems. Sensors for equipment and physiological status are needed as noted in previous sections. Other equipment such as decompression meters and navigation devices are presently in use and their outputs are not presented to the diver in an integrated read-out requiring the diver to actively find and read these devices. This can be a problem to a diver who must keep track of all these outputs as well as do a mission which may be very hazardous and require extreme attention. A "heads-up" display which would integrate this information would be extremely useful. A read out of all diver data topside is desired.

Research approaches. An method of a heads-up needs development. This may require, in addition to the equipment development, research on the optimum method of presenting this data, such as color, intensity, size of output and contrast. The literature concerning this type of display for pilot use should be surveyed for information for adaptation for diver use. If this is not satisfactory more laboratory research will be required.

Electric motor driven propulsion systems and electromagnetic fields.

Problems. The U.S. Navy is examining the feasibility of placing electric motor driven propulsion systems aboard submarines to replace existing power distribution and propulsion systems. These new systems would be considerably lighter, smaller and more efficient than the current systems. However, there is concern that electromagnetic fields generated by these systems might have adverse biological effects on the crew.

Research approaches. A report on electromagnetic fields (EMF) by the U.S. Office of Technology Assessment indicated that in vitro experiments suggest that EMF exposure has the potential to effect cell function in the following ways:

- Modulation of ion and protein flow across the membrane
- Chromosome damage and interference with DNA synthesis and RNA transcription
- Interference with cell response to different hormones and enzymes, including those involving cell growth and stress responses
- Interaction with cell response to chemical neurotransmitters
- Interaction with the immune response to the cell
- Interaction with cancerous cells

Because the cell membrane is the primary site of action of magnetic fields, processes governed by the cell membrane, such as immune function and cell-cell communication are likely places to look for EMF effects. Thus, a thorough review of the scientific literature on the effects of EMF on biological systems is indicated. Studies utilizing the new technologies of genomics, proteomics, among others on reproduction, teratogenicity, immune function, oncogenesis, and neuro-modulation may need to be performed.

Question Two. *"Looking ten years into the future with unlimited funds and with all bureaucratic barriers removed, which biomedical research needs would get priority?"* The Navy fleet representatives were very specific in their responses and the priorities did not change significantly from the responses to Question One. The representatives listed the following as high priority needs:

1. Rescue survivors from a disabled submarine to depths of 2,000 feet.

2. Decrease decompression obligation. The fleet representatives expressed that solving the decompression problems would, more than anything else, make a difference in how they managed rescuing survivors from a disabled submarine and in conducting diving operations.

3. Completely solve the CO_2 scrubbing problem aboard submarines.

4. Develop a sensor array for diving which will inform the diver, and topside, of physiological and equipment status.

5. Determine if electromagnetic radiation generated in direct electric drive vessels has deleterious biological effects on the crew, and if so, develop means of providing protection.

6. Evaluate the usefulness of multiple diluent gas mixtures in diving (e.g. trimix) and develop procedures for its use by the Fleet.

7. Develop a system to warn the diver of an impending episode of oxygen toxicity.

8. Develop thermal protective garments that will maintain a diver in an euthermic state during long duration diving operations regardless of ambient conditions.

9. Develop non-invasive methods of screening divers who retain carbon dioxide or who have Patent Foramen Ovale.

10. Determine the physiological basis for the day-to-day variation in susceptibility to oxygen toxicity.

11. Develop the best basic environmental protection possible for divers who must work in contaminated water (e.g. ship husbandry).

ADDITIONAL AREAS REQUIRING RESEARCH

These research needs were not identified in response to Questions 1 and 2, but are considered to be of importance to Navy needs. The first, underwater blast, is listed in the requirements as an important area for biomedical research. The others were identified by experts in the working group as areas which are in need of further research.

Underwater Blast.

Problems. A special case of underwater sound is underwater blast. There are several models used to predict injury safe stand-off distance from underwater blast. However, these are based on different experimental parameters such as depth, type of bottom or surrounding structures (reflected waves), type of explosive, types of diving equipment, etc. These models may vary greatly in the safe distances predicted. They do not address the problem of the impulse wave which occurs after the initial blast wave has passed. Impulse waves may produce low frequency waves which travel over long distances and are akin to low frequency sonar waves. Repetitive exposure as occurs in the use of stud guns has not adequately been addressed. All of the studies are based on relatively few diver or animal exposures. These gaps need to be filled to provide adequate guidelines for underwater blast exposure.

Research approaches. Research needs to conducted which will lead to a common effect criteria at the diver, whether this be based on peak pressure, impulse or some other physical parameter that can be related to physiological injury or psychological impact. This requires studies aimed at filling the gaps in the current knowledge including further studies of different types of explosives, different depths (mainly deeper than those investigated to the present), studies on repetitive exposures, exposure to large charges at long range, and frequency components within various impulse waves.

Man-machine interface.

Problems. Basic research is required in this area because of the increasing complexity of detection and fire-control systems on submarines. A recent article by CAPT P. Barron, USN, put this very clearly: "Without operators who can *recognize* modern threat signature characteristics, the system is useless."[2] The introduction of multiple displays in sonar and fire-control systems greatly complicates the ability to efficiently analyze the data presented and come to correct conclusions.

Research approaches. In view of the increasing complexity of detection systems on submarines, research, which has proven to be extremely valuable in the past, should be continued into visual and acoustic cognitive function and in the integration of these signals. This requires research in cognition and neuroscience to determine how the human brain processes and integrates signals from various sources. Research is also needed in the optimum methods of presenting this information to the operators to enhance their capabilities.

Underwater sound exposure.

Problems. Both submariners and divers may be exposed to underwater sound (i.e. sonar at various frequencies, intensities, and patterns). Exposure can hazard these personnel by adversely affecting auditory and vestibular function and cause adverse effects to the central and peripheral nervous systems. Permanent damage to these organ systems can result as a result of excessive exposure to underwater sound. Standards for exposure and for the operation of sonar systems are needed. The European scientific literature has described a condition known as the "Vibroacoustic Disease" which results from exposure to sound frequencies below 500 Hz and at intensities of 90 to 110 dB. Studies have shown that these exposures can cause cardiac and respiratory dysfunction, seizure disorders, balance disturbances, and immunological disorders.

Research approaches. Studies are needed to define the mechanisms by which sound adversely affect the auditory, vestibular and nervous systems. Standards for exposure and for the operation of sonar systems are needed. Thus, studies need to be performed to examine the effects of various frequencies, intensities and patterns of underwater sound on submariners and divers. Better means of protecting submariners and divers from the adverse effects of underwater sounds need to be developed. It also needs to be determined whether underwater sound at certain intensities and frequencies causes bubble formation in personnel exposed to these sounds. A means of monitoring the extent of an individual's exposure to underwater sound, e.g. a dosimeter, needs to be developed and tested in various settings.

It needs to be established whether chronic exposure to underwater sound can produce changes akin to those seen in vibroacoustic disease.

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2 CAPT. Claude Barron, USN. "The Operator is Part of the System". The Submarine Review, January 2001.

Chronic absence of sunlight.

Problems. Calcium metabolism and bone mineralization in the body are controlled by vitamin D, which is synthesized in the human body by exposure to sunlight. It has been shown that during long patrols, vitamin D levels fall and a chronic state of hypovitaminosis D occurs. It has also been shown that a lack of sunlight can have a deleterious effect on the psychological well being of certain individuals. This condition, which tends to occur in winter when days are short, has been termed the "*Seasonal Affective Disorder.*" This disorder can successfully be treated with light therapy in which the individual affected with this is exposed to lights of a certain frequency. Whether this condition occurs in submarine personnel is unknown at this time.

Research approaches. There is a need to closely examine the effects of chronic absence of sunlight on metabolic and nutritional status, particularly hypovitaminosis D and calcium metabolism, and psychological status. It needs to be shown whether "light therapy" aboard submarines obviates untoward metabolic and psychologic effects of lack of sunlight.

4

INFRASTRUCTURE - RESEARCHERS

CURRENT STATUS

In the 20 year period from 1979-1980, to 1999-2000, the number of scientists working in the field of undersea biomedical research has sharply decreased (Figure 4.1). This has been true both in the United States, as well as in foreign countries elsewhere in the world. Not surprisingly, there has been a marked decrease in scientific publications resulting from ONR sponsored research in the journal, Undersea and Hyperbaric Medicine, and other elected publications (Figure 4.2). It can be seen in Figure 4.3, that many researchers with five or less years of experience in the field, stopped working in the field in their twenties and thirties. As a consequence of the loss of young investigators, most of the scientists who have continued to work in undersea biomedical field are in their late forties and fifties, with many approaching retirement (Figure 4.4).

Figure 4-1

Estimated number of Investigators Doing Undersea Biomedical Research

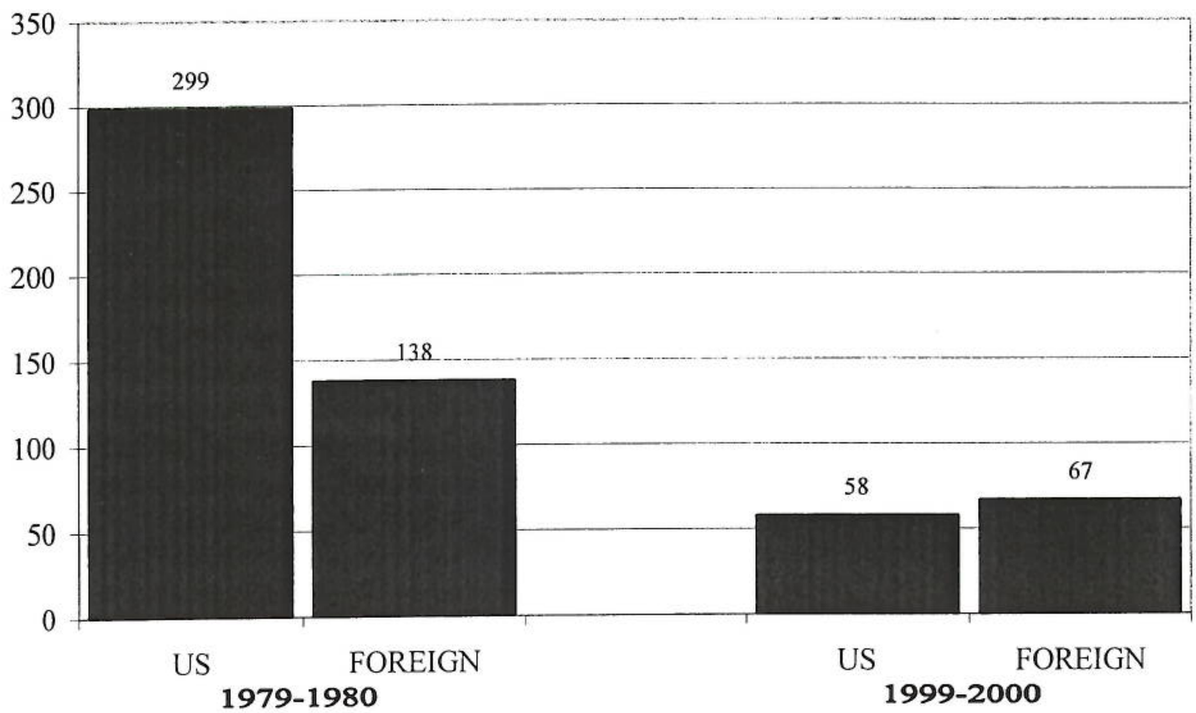


Figure 4-2

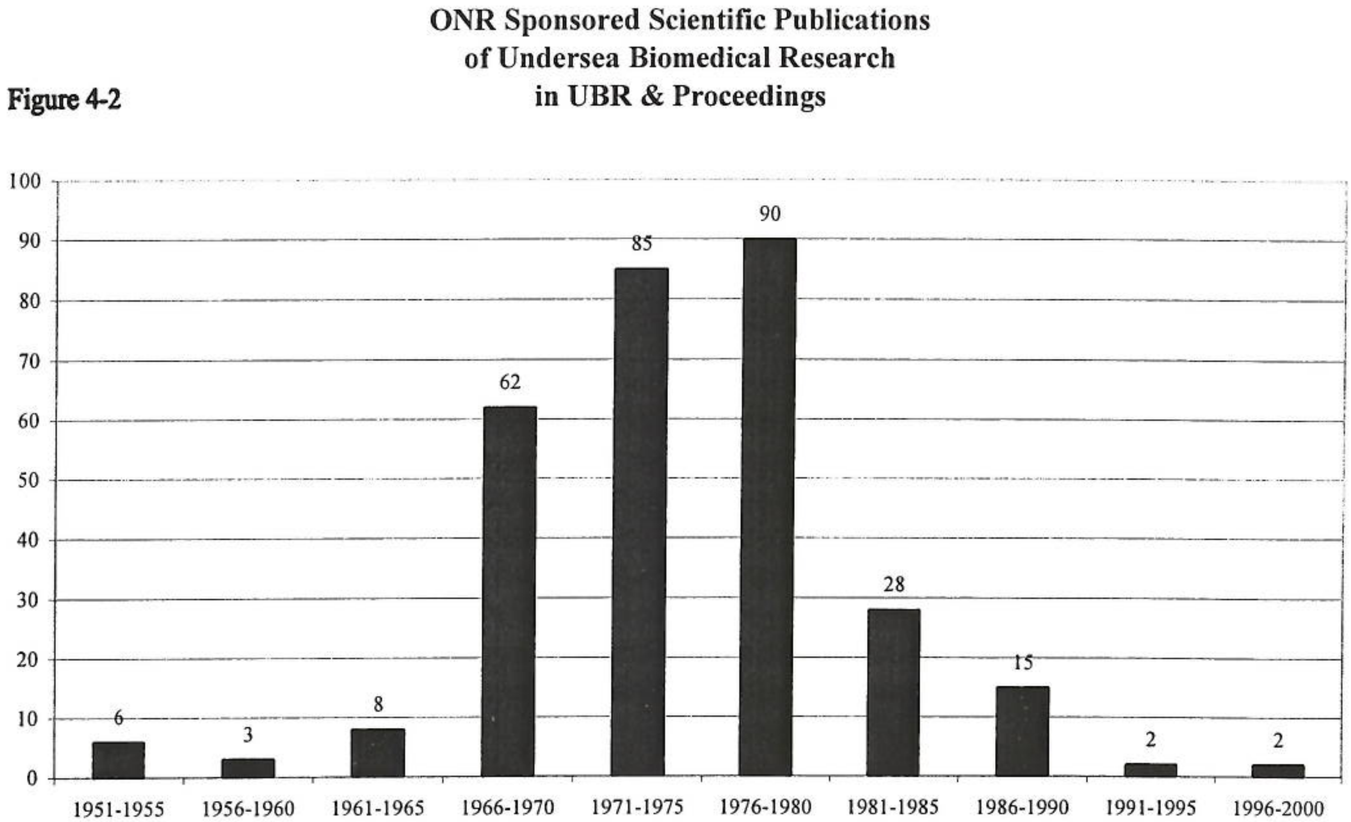


Figure 4-3

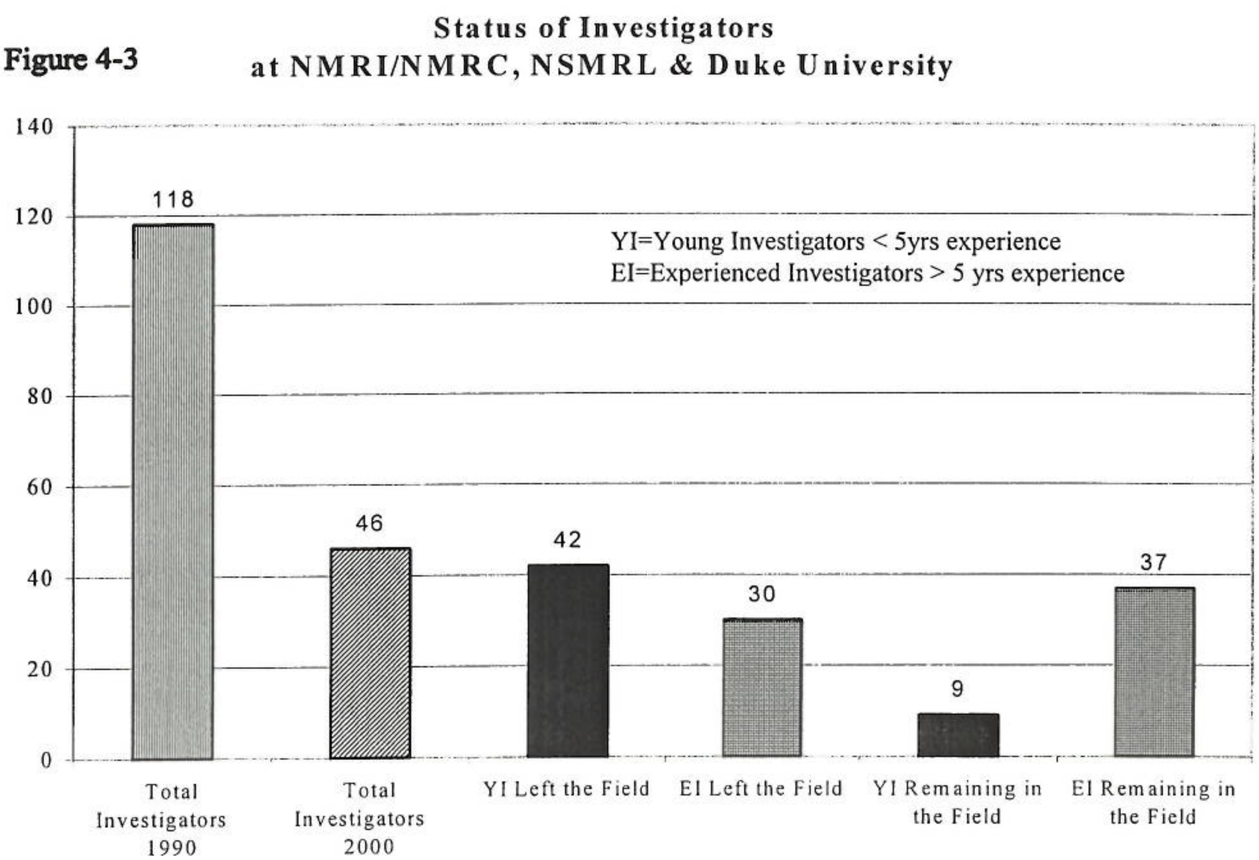
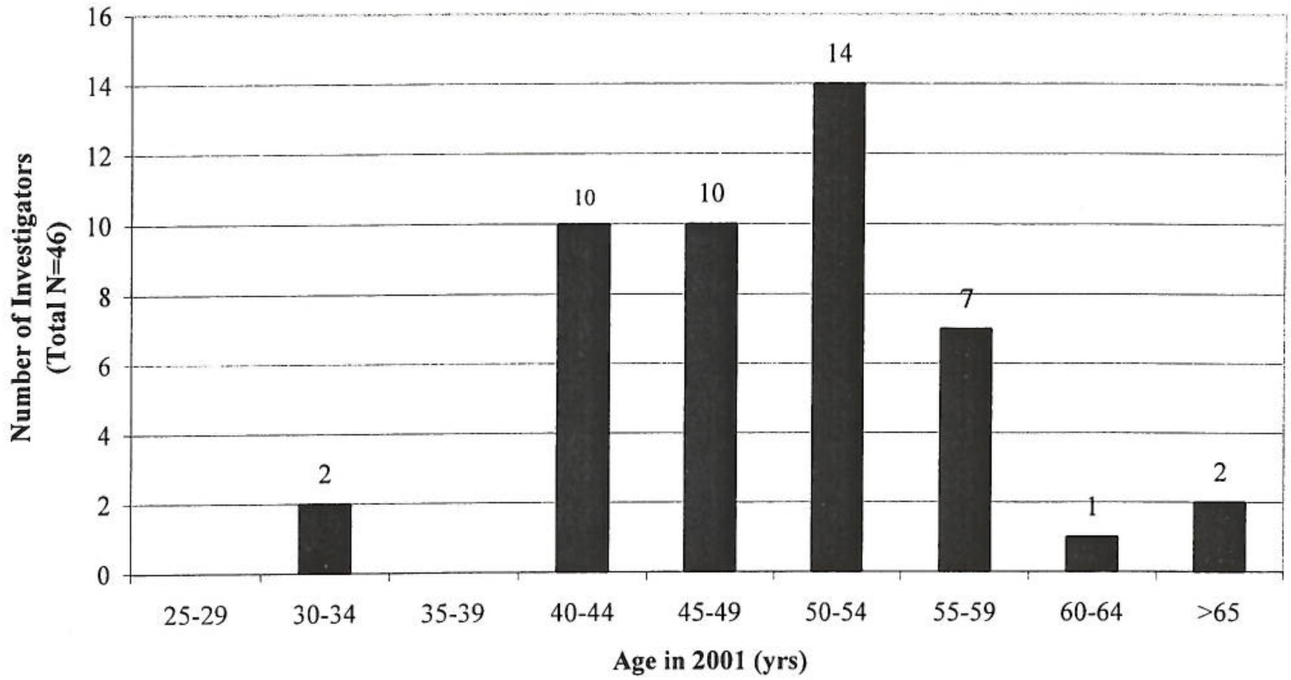


Figure 4-4

Age Distribution of Experienced Investigators Remaining Active in 2001



Those researchers who have remained active in this area, have done so because of the scientific challenges of undersea biomedical research. In some instances, there have been personal hardships that have resulted from decisions to remain in the field. For example, the head of the program at the University of Wisconsin, a Ph.D. with over twenty years in the field, draws an annual salary of $50,000. He states that this makes for a difficult situation. An M.D. in his laboratory is currently drawing a salary of $26,000.

There was unanimous agreement by the December working group, that the major reason for the loss of investigators from the field, was the inadequacy and instability of funding for undersea biomedical research. The group also concluded that many naval officers leave the field because of the lack of a career path and lack of promotion potential if they remain in undersea biomedical research, when compared to their peers in clinical specialties and operational and administrative positions.

RECRUITING

The working group concurred that when adequate and stable funding is available, recruiting scientists into the field of undersea biomedical research will be greatly enhanced. A diverse group of scientists will need to be recruited. These include physicians, physiologists, engineers, cell biologist, psychologists, scientists with expertise in genomics and proteomics, biophysicists, and mathematicians.

The field poses exciting and rewarding scientific challenges. The experience of the past has been that when adequate and stable funding is provided, scientists are drawn to work in it. While this is true of the civilian sector, military scientists may need to be recruited to work in this field. The working group agreed that **at least** four military officers should be recruited into the program each year.

TRAINING

It is useful for scientists who work in undersea biomedical research to have some understanding of Naval undersea operations, as well as the Navy's problems and needs in this area. Therefore, it is proposed that a one to two week orientation problem be developed, and provided to civilian scientists working in the field. This would include civilian scientists working in Navy laboratories, as well as those working in civilian laboratories. Such an orientation program could be presented at The Uniformed Services University of the Health Sciences, or possibly at the Navy Diving and Salvage Training Center.

It was the consensus of the working group, that prior to receiving training in research, undersea medical officers should have at least one tour in an operational billet in either diving or submarines. While there are no operational billets for Medical Service Corps officers, training should be provided to them at the Navy Undersea Medical Institute and at the Navy Diving and Salvage Training Center. Moreover, it may be possible to provide Medical Service Corps officers with Temporary Additional Duty orders to an operational diving or submarine activity to allow them to participate in biomedical research studies which are being conducted in the field. This would provide a degree of exposure to the operational setting, and to the problems attendant to these settings. Training in these areas and/or operational experience is invaluable in research-operational personnel interactions.

The working group discussed where training in research should take place. It was felt that training investigators in experimental design and the scientific method, as well as in specific scientific areas was of paramount importance. It was agreed that it was not necessary that a hyperbaric chamber or other environmental exposure facilities be available at the facility where the training takes place. Currently, the most appropriate venues are civilian universities. However, the working group was informed that a residency program and a graduate degree program which could award a Masters and Ph.D. degrees in the area of undersea medicine was in the developmental stage at the Uniformed Services University of Health Sciences. The residency program in undersea medicine would provide training in research methodology to Medical Officers. The Graduate program in undersea biomedical sciences would be open to both Medical Service Corps and Medical Corps officers. This, and other programmed in the university would provide scientists with advanced degrees to the Navy's undersea biomedical research activities.

Civilian scientists at the Ph.D. level also need to be trained so that they can work in Navy laboratories and in universities in the undersea biomedical sciences. Adequate funding, which is not currently available, must be provided to universities in order to train graduate students who are working on doctoral degrees, as well as to train scientists at the postdoctoral level.

The length of the training program was discussed by the working group. This group strongly felt that two years were needed at the postdoctoral level to teach an individual the scientific method and to make them knowledgeable in a specific scientific area. For individuals who are in Ph.D. programs, the length of time to complete their thesis and other requirements may take 3 to 4 years. Thus, training should be at the appropriate academic level for the individual program.

The costs associated with training an individual at the postdoctoral level at the University of Pennsylvania and at the State University of New York at Buffalo are given in Table 4.1.

Table 4.1 COST OF TRAINING AT THE POSTDOCTORAL LEVEL

	M.D.	NON-M.D.
Duke University	45-50K	40-45K
Univ. Pennsylvania	43.75K	38.5K
SUNY at Buffalo	34.5K	28.33K

The costs associated with training individuals in a doctoral (Ph.D.) program at the University of Pennsylvania, Duke University, and the SUNY at Buffalo are given in Table 4.2.

Table 4.2 TUITION FOR THE Ph.D. PROGRAM

Univ. Pennsylvania	22.2K	
Duke University	25.6K	
SUNY at Buffalo	9.4K	(Non-State Resident)
	6.1K	(State Resident)

RETENTION

A major problem in undersea biomedical research has been the retention of trained scientists who are interested in the field. The working group concluded that if adequate and stable funding were available, that this problem would be largely resolved. For both Medical Corps and Medical Service Corps officers, the lack of clear career paths to higher level positions in the Navy Medical Department, and slower promotion are impediments to retention. The working group felt that the Bureau of Medicine and Surgery should provide clearer career paths for its officer scientists who work in undersea biomedical research, and that it should work to eliminate inequities of promotion. One way that the Underwater Physiology Symposia that ONR sponsored in the past were useful was in interesting young scientists in entering this field. Re-initiation of these symposia could be a way to help recruiting and retention.

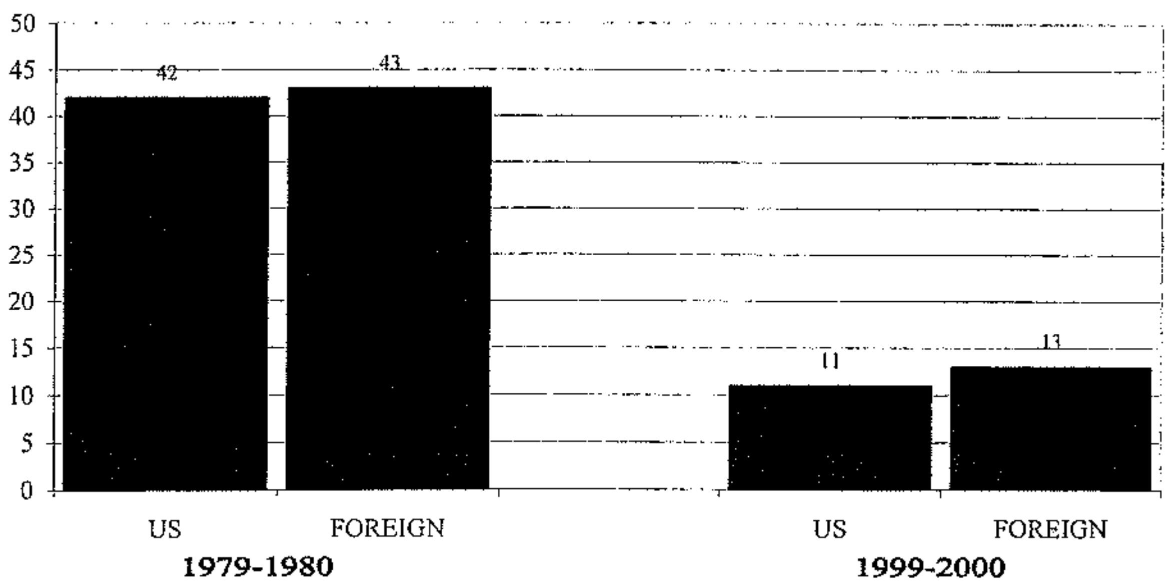
5

INFRASTRUCTURE - PERFORMER FACILITIES

Historically, the performers of undersea biomedical research have been universities, government, and private industry. In 1973, in addition to the Navy laboratories that were performing research in this area, ONR's contract program in undersea biomedical research included 37 universities and private facilities in the United States, Canada, and Europe.

In the years since 1979-80, the number of laboratories that are involved in undersea biomedical research has dwindled (Fig. 5.1). Currently, there are a number of institutions in the United States that have small research programs in this area using animal models. Examples of these are Wright State University and The State University of New York at Syracuse. There are only two Navy facilities and four universities in the United States that can be considered to be major centers of undersea biomedical research. A major center of undersea biomedical research is defined as an institution that has at least 6 investigators who spend a significant amount of time performing research in this area, that has a large hyperbaric chamber capability, and that has been working in this field for at least 20 years.

Figure 5-1 **Estimated Number of Institutions Doing Undersea Biomedical Reasearch**



UNITED STATES NAVY FACILITIES

NAVY MEDICAL RESEARCH CENTER The Environmental Physiology Department of the Naval Medical Research Center is tasked to perform diving biomedical research using animal models. Currently, its research program focuses on understanding the mechanisms of central nervous system and pulmonary oxygen toxicity and developing means to ameliorate these processes. There is also research on the elucidation of the pathophysiology and treatment of decompression sickness, and on enhancement of performance in the presence of thermal stress. There are 31 personnel in this Department, which is less than one third the number of personnel working in its predecessor department five years ago. There are seven hyperbaric chambers to perform research, including a large, formerly man-rated, chamber complex which is currently used for animal research.

NAVAL SUBMARINE MEDICAL RESEARCH LABORATORY The Naval Submarine Medical Research Laboratory is tasked to perform biomedical research to enhance the health, safety, and effectiveness of submariners. Some of the research activities include the elucidation of the physiological, biochemical, and performance effects of atmospheric contaminants in submarines, enhancement of auditory discrimination of sonarmen, and the development of standards for exposure of divers to underwater sound. There is also ongoing work in the improvement of submarine watch standing schedules, and development of improved methods to preserve the health of personnel in disabled submarines and to enable them to safely escape. This laboratory is staffed with 52 personnel. The laboratory has one man-rated hyperbaric chamber and several animal sized chambers.

NAVY EXPERIMENTAL DIVING UNIT This facility is the Navy's test and evaluation center for equipment and procedures pertaining to Navy diving. It has several hyperbaric chambers including a giant chamber capable of simulating depths equivalent to 2,250 feet. It has not conducted basic biomedical research since the mid-1970's. However, with the BRAC95 closure of the Naval Medical Research Institute, the Navy Experimental Diving Unit has a small cadre of scientists that give the command the capability of conducting basic biomedical research in diving. There is currently no capability for conducting animal research. However, there is an effort to establish collaboration with Florida State University where such research might be conducted.

UNIVERSITY UNDERSEA BIOMEDICAL RESEARCH FACILITIES

DUKE UNIVERSITY The focus of research at this facility has been the development of models of inert gas kinetics and decompression tables, and the elucidation of respiratory and cardiovascular function at depth. One scientific goal of the laboratory is the study of oxidative metabolism and oxygen toxicity in living tissues using reflectance fluorometry, differential spectrophotomy and multiwavelength NIR spectroscopy. The core facility has a very large, man-rated, multi-chamber hypo/hyperbaric chamber complex (including a wet pot for immersion at depth) for human exposures and clinical hyperbaric oxygen treatment. Adjacent laboratories support human and animal research.

UNIVERSITY OF WISCONSIN AT MADISON Research at this University has been directed at the study of factors associated with the development of decompression sickness and dysbaric osteonecrosis in large animal models. Recent work has been concerned with the development of accelerated decompression from a saturated state, and minimization of risk of decompression sickness for survivors of a disabled submarine. The laboratory has a large (40' length, 6' diameter) hyperbaric chamber which is not man-rated and is used for animal research. Several small chambers for animal work are available.

UNIVERSITY OF PENNSYLVANIA The University of Pennsylvania Institute for Environmental Medicine has a long history of research into the pathophysiological processes operative in pulmonary and central nervous system oxygen toxicity, and the development of methods to ameliorate these processes. Additionally, it has also performed much research into respiratory function at increased depths, and also into the phenomenon of isobaric counterdiffusion. The laboratory maintains data bases for decompression experiments and oxygen tolerance. It has a very large, man-rated hypo/hyperbaric complex (with wet pot for immersion at depth) which is used for human research and clinical hyperbaric oxygen therapy. There is a clinical treatment facility, and state of the art laboratories oriented towards biochemistry, cell biology, and molecular genetics.

STATE UNIVERSITY OF NEW YORK AT BUFFALO This University houses the Center for Research in Special Environments. Research interests at this laboratory include the study of the pathophysiological and physiological responses to high and low pressures and to immersion. There has also been considerable work into design criteria for equipment and the development of methodological approaches to counteract stresses resulting from the use of equipment and improve human performance. There is a 2 compartment, man-rated hypo/hyperbaric chamber with an immersion capability which is used exclusively for research. There is also a small, double lock aluminum chamber for human exposures, as well as small animal chambers. There are laboratories adjacent to these chambers to support research activities. There is additionally a temperature controlled, circular water filled pool for performing immersion studies. A human centrifuge inside this pool can be extended so that free-swimming research subjects can be instrumented and tracked.

COSTS OF MAINTAINING LARGE HYPERBARIC CHAMBER FACILITIES IN THE UNITED STATES

Large hyperbaric chambers are expensive to maintain, especially when they are man-rated for human exposures. For example, the man-rated, multi-chamber complex at the former Naval Medical Research Institute, required 1.1 million dollars to maintain in 1984. Currently, to maintain one chamber of this complex for use in large animal research costs 185K per year (2 hyperbaric technicians, 75K each/year, 30K for equipment). Large, man-rated hyperbaric chamber complexes at universities are also expensive to maintain. The annual maintenance costs for the hyperbaric chambers at Duke University, University of Pennsylvania, and SUNY Buffalo were obtained. The chamber facilities at Duke are used for clinical hyperbaric oxygen therapy as well as for hypobaric research for NASA, as for hyperbaric research. Since 1995, the chamber facility at the University of Pennsylvania has been largely used for clinical therapy, and to a small degree for hyperbaric research. It was not possible to separate the maintenance costs at these universities for each of these activities. The hyperbaric chamber complex at SUNY Buffalo is the smallest of these chamber facilities, but it is used exclusively for undersea biomedical research, as are also its pool and related facilities. It was therefore considered that this institution's maintenance costs were most representative of the cost of maintaining facilities for human undersea biomedical research exposures. These costs are presented in Table 5.1

Table 5.1 MAINTENANCE COSTS OF EXPOSURE FACILITIES AT SUNY BUFFALO PER ANNUM

Hyperbaric chamber maintenance...........	$93.7K
Shop equipment & repairs......................	3.2
Documentation updates..........................	12.1
Equipment upgrades...............................	4.3
Pool maintenance & upgrades................	4.3
Administrative.......................................	10.6
Technician salaries & benefits................	85.1
Subtotal................................	$213.3
University overhead @ 55%..................	132.0
Total....................................	$345.3K

There is no doubt that the maintenance costs of the Duke and Pennsylvania facilities, if they were used exclusively for undersea biomedical research would be considerably larger, perhaps double or more, that of the facility maintenance costs at Buffalo. Annual maintenance costs of the chamber complex at Wisconsin were estimated to be in the range of 30 - 40K. However, this chamber is not man-rated, and much of the maintenance is performed by personnel from the school of engineering at no cost.

A major problem that all of these facilities, both Navy and university have, is that in the past and currently, maintenance costs must be defrayed with funds which are allocated for undersea biomedical research. This seriously diminishes the funding available for research activities at these institutions.

THE COMMERCIAL DIVING SECTOR

The commercial diving community in the United States has not conducted any undersea biomedical research in the last 25 years. There is little likelihood that these companies will resume performing research, as the current level of technology appears to meet their needs.

FOREIGN FACILITIES

Over the period from 1960 to 1990, undersea biomedical research was conducted by many laboratories in countries other than the United States. Most of these facilities ceased research in this area due to a lack of funds or change in military mission requirements. Examples of institutions that no longer work in this area, but which previously had large research programs, include Oxford University in the United Kingdom, GKSS Geesthacht in Germany, the University of Lund in Sweden, and essentially all French facilities. Currently, only five foreign research institutions could be identified that could be considered major centers for undersea biomedical research. These include:

Defense and Civil Institute of Environmental Medicine (Canada)
Israeli Navy Medical Research Institute (Israel)
Japan Marine Science Technology Center (Japan)
Norwegian Underwater Technology Center (Norway)
Defense Evaluation and Research Agency (United Kingdom)

6
INTEGRATION WITH AND TRANSITION TO HIGHER BUDGET CATEGORY PROGRAMS

Historically the Undersea Biomedical Research Program in ONR was been a 6.1 program. This was the case from 1960s until 1972 when ONR also began managing 6.2 funds, a function it took over from the Bureau of Medicine and Surgery (BUMED). In the 1960s and early 1970s other funding for diving research was provided through the Bureau of Medicine and Surgery with 6.2 funds. In 1974 the Naval Medical Research and Development Command (NMRDC) took over the management of the 6.3 program with funds supplied by the Deep Submergence Branch in the office of the Assistant Chief of Naval Operations (Undersea Warfare). The NMRDC also managed some 6.1/6.2 funds provided by ONR. The current status is that ONR manages the program with 6.1 through 6.3A funds while 6.4 (previously 6.3B) funds are managed by the Ocean Engineering/Supervisor of Salvage and Diving Office of the Naval Sea Systems Command.

In the early 70s and 80s there was good coordination between the program managers at the Naval Medical Research and Development Command (NMRDC) and those at ONR with sharing of allocated resources and frequent communication concerning different proposals and contracts. 6.3 funding was provided the NMRDC for higher budget category research by the Deep Submergence Branch in the office of the Assistant Chief of Naval Operations (Undersea Warfare). The integration of the 6.1/6.2 programs and 6.3 program was basically between these two offices. Integration to the 6.4/6.5 programs, when required was generally through personal communications between researchers at the various laboratories doing 6.1/6.2 research and the facilities doing 6.4/6.5 technology such as the Naval Experimental Diving Unit (NEDU). Other communications and integration was through periodic meetings of all researchers and representatives of the various Navy diving commands, both operational and experimental. However, there was no formal program for integration. In more recent years coordination of these programs has been poor and there is still no formal system for the orderly integration of research and funding to higher budget levels. Recently there have been efforts made toward improved integration.

In the undersea biomedical research program, the products of the 6.1/6/2 program do not often translate into hardware which requires much closer higher integration. Results of this program are often changes in guidance for exposure to hazards or changes to procedures which can be accepted during or after confirmation of findings during research funded with 6.3/6.4 dollars. For instance, if a new method is found for safer exposure to oxygen during 6.1/6.2 research, these exposures can be tested on humans in a series of studies funded by 6.3/6.4 dollars and then, if found acceptable, can be accepted into the standard procedures used by the Navy submarine or diving community. In the case that equipment is developed in a 6.1/6.2/6.3 program this, of course, must progress through the higher budget categories for final development and

Navy acceptance. This final step has been poorly coordinated in the recent past and requires immediate attention.

One example to show how a smooth transition should occur is from the early 1970's when the Department of the Navy decided to develop a new surface supported diving system. 6.1 funding was first utilized to perform some basic studies on valve characteristics, air flows and ocean current drag forces, and to complete a survey of existing surface-supported diving systems used by North American Treaty Organization (NATO) countries. Using this information a design was completed using 6.2 funding followed by the development of a prototype system using 6.3 funds. The 6.3 funding was used through the first technical evaluation of the prototype and initial prototype system changes. After needed changes, 6.4 funding was available to fund the cost the second generation of the prototype and the cost of conducting the operational evaluation. Following the operational evaluation and Department of the Navy acceptance of the system, 6.5 funding was used to pay for the first production run of the system the establishment a centralized spare parts inventory. While this example did not involve biomedical research, it is this kind of smooth transition that should be aimed for in the undersea biomedical research program.

It is suggested that in order to provide close integration and transition of the products of the biomedical research program and ensure the timely provision of 6.4 funding that an Integrated Product Team be formally established. The basic members of this team should be Program Officers from ONR and NAVSEA. This basic team should be augmented as needed by representatives from various laboratories and from the headquarters of the following commands and organizations: Director, Deep Submergence Branch of the office of the Assistant Chief of Naval Operations (Undersea Warfare), the Deep Submergence Systems Program Office of the Naval Sea Systems Command (PMS 395), Explosive Ordnance Disposal Headquarters, Special Operations Warfare Command, Marine Corps Combat Diver Element (Expeditionary Warfare) and the office of the Assistant Commander for Ocean Facilities of the Naval Facilities Engineering Command (for Underwater Construction Teams).

In addition, although not a part of the formal acquisition process, it would also be extremely useful to have an annual program review with all of the above representatives along with representatives of the laboratories and universities actively engaged in the undersea biomedical research program, as was done in the past and recently restarted by ONR in conjunction with the Deep Submergence Systems Program Office of the Naval Sea Systems Command. This would allow the members of the academic and operational communities to meet for discussions of basic research and operational needs and provide a forum for early introduction of research progress and possible products to those involved in the acquisition process.

The combination of the Integrative Product Team and the annual program review should provide the means for the acquisition managers to be informed in a timely manner about products which require higher integration and allow them to schedule funding for further development without long undue delays in getting products to the fleet.

7

MANAGEMENT OF UNDERSEA BIOMEDICAL RESEARCH at the OFFICE OF NAVAL RESEARCH

From 1960 to 1982, what was called the Undersea Physiology program was under the direction of the same office at ONR. In 1982 this program was dissolved and the management of the dwindling 6.1 funds was assumed by the Naval Medical Research and Development Command (NMRDC). When the NMRDC was disestablished in 1998, responsibility for the management of the 6.1/6.2 funds returned to ONR. Since 1995 four different individuals at ONR have been managers of undersea biomedical research, three of whom have been active duty military. These managers were responsible for several programs in addition to undersea biomedical research, all of which were much larger than the undersea biomedical program. This frequent turnover of managers and divided attention has not allowed any single manager enough time to learn the program, or plan a long range research or funding strategy. In addition, some of the managers since 1998 have had only relatively narrow scientific training and experience. None have had operational experience and only one was trained in undersea medicine. Therefore, in recent years, the program has not had the sustained management required for a successful, diverse, and integrated program in basic undersea biomedical research. This situation requires a change for the undersea biomedical research program to be successful in responding to fleet needs.

It is strongly suggested that the management of this program be improved by the hiring of a civilian who is willing to spend at least 8-10 years in the position and who has a strong scientific background and experience. It is suggested that a civilian scientist be hired for several reasons, not the least of which is that active duty military officers are subject to orders and even if this were not the case, would be in the position for no more than three years. Ideally, the person for this position should come from a background in undersea research and have some operational experience. A military billet should be established to provide fleet liaison.

Again, it stressed that long term leadership is required in this program so that a coherent, continued program results which is responsive to fleet needs in the future.

8

FINDINGS AND RECOMMENDATIONS

1. Undersea medicine and the biomedical research associated with this field are unique to the Navy.

2. Funding for basic biomedical research has markedly decreased, as it has been level funded for the past 20 - 25 years. FY01 funding for 6.1/6.2 research in this field is 25% of the equivalent of 1975 dollars. This diminution of funding has resulted in a proportionate decrease in scientific productivity in this field. Other than ONR, there are no funding sources for basic undersea biomedical research.

Recommendation: Funding for basic undersea biomedical research needs to be increased to a level which is appropriate to bring scientific productivity to a viable degree.

3. The U.S. Navy has extensive requirements for undersea operations by submarines and divers.

4. The Navy has extensive needs to enhance personnel performance and safety, and operational capabilities in multiple areas of the undersea environment. These needs can only be resolved through the performance of basic research in these areas.

5. There are areas in undersea operations where significant biomedical problems are still present because of the lack of sustained scientific effort. This is largely the result of a lack of stable and adequate funding for research in these areas. New problems in undersea operations have arisen which have not been addressed because of the lack of adequate funding for this biomedical research. New scientific disciplines and technologies have become available in the last two decades which have application to solving major problems in undersea biomedical research.

Recommendation: An expanded, basic undersea biomedical research program needs to be implemented with contemporary disciplines and technologies to address these issues. This program should receive adequate, stable and sustained funding which should be on a long term basis where needed.

6. In the past 15 years, there has been a marked decrease in the number of investigators working in basic undersea biomedical research. During this period, the majority of young researchers have left the field. The U.S. Navy has not trained any investigators in this field in the last 10 years. Many of the senior scientists in this who have been working in this area are approaching retirement, with the result that there will be a major loss of scientific expertise to the Navy. This situation is the result of inadequate and unstable funding.

Recommendation: Adequate and stable funding is required to induce investigators to remain in the field of basic undersea biomedical research, and to induce new investigators to enter the field. ONR should encourage BUMED to recruit and train adequate numbers of military scientists to support this program in Navy laboratories. ONR should resume sponsorship of the Underwater Physiology Symposia to enhance communication between scientists working in the field and to draw new investigators into the field.

7. In the past fifteen years, there has been a marked decrease in the number of institutions engaged in basic undersea biomedical research, because of a lack of adequate and stable funding. Maintenance of large facilities, e.g. hyperbaric chambers and other exposure facilities, is expensive, and diminishes the funds available for performance of research.

Recommendation: Adequate and stable funding is required to allow these and other facilities to be available for basic undersea biomedical research. ONR and other relevant organizations should pursue providing Major Range and Test Facility Base (MRTFB) funds for the repair and maintenance of large hyperbaric chambers and other exposure facilities in order to free up monies for research.

8. Integration of the 6.1 and 6.2 programs to higher budget categories has been inadequate until this past year, when efforts were made to rectify this problem.

Recommendation: Efforts should continue with an integrated product team approach to transition 6.1 and 6.2 research findings to 6.4. The program review of 6.1, 6.2 and 6.4 performers should continue on an annual basis. Because of the inadequacy of 6.4 funds for integration of research products the Director, Deep Submergence Systems Branch of the Assistant Chief of Naval Operations (Undersea Warfare) should be informed of this.

9. The ONR personnel managing programs in undersea biomedical research have had less than optimal qualifications to perform this task. With the exception of one naval officer who was at ONR for a relatively brief period, no ONR personnel in the last twenty years have had formal training in undersea medicine. None of the ONR personnel have had operational experience in submarine and/or diving medicine. The research training and experience of these personnel has frequently been quite narrow, and they have been lacking knowledge of the capabilities and production history of investigators working in the field. Lastly, the frequent turnover of personnel managing these programs has hampered the coordination and implementation of research projects in the field.

Recommendation: ONR should hire a civilian scientist who will remain in the position for 8 - 10 years. Ideally, this individual would have operational experience in submarine and diving, have a strong scientific background, and have extensive experience in the field. A military billet should be established to aid in fleet liaison.

10. The above recommendations can be implemented only if a National Program in Undersea Biomedical Research is established with adequate, sustained, and stable funding.

APPENDIX A
Working Group Members

Military
CAPT M.E. Bradley, MC, USN, Retired Undersea Medical Officer
CAPT Michael Curley, MSC, USN, Commanding Officer, Naval Submarine Medical Research Lab
CAPT Henry Schwartz, MC, USN, Medical Representative to the Naval Sea Systems Command
CAPT Chris Murray, USN, Supervisor of Diving, Naval Sea Systems Command (Code 00C)
CAPT John Murray, MC, USN, National Naval Medical Center, Bethesda
CAPT Charles Auker, MC, USN, Head, Combat Casualty Care, Naval Medical Research Center
CAPT James Vorosmarti, MC, USN (Ret), Former C. O., Naval Medical Research Institute
CAPT Edward Flynn, MC, USN (Ret), Medical Consultant to NAVSEASYSCOM and NEDU
CAPT Edward Thalmann, MC, USN (Ret), Duke University
CAPT Paul Weathersby, MSC, USN (Ret), Former Commanding Officer, NavSubMedRschLab.
CAPT Leon Greenbaum, USPHS (Ret), Former U.S. Navy Aviator and Diver
CDR Stephen Ahlers, MSC, USN, ONR Program Manager for Undersea Biomedical Research
LCDR David Keyser, Head, Diving Research Program, Naval Medical Research Center

Civilian Federal Employees
Dr. John Thomas, Naval Medical Research Center
Dr. Edward Cudahy, Naval Submarine Medical Research Laboratory
Dr. John Clarke, Navy Experimental Diving Unit
Mr. Bob Whaley, Naval Sea Systems Command (Code 00C)

Academia
Dr. Christian Lambertsen, University of Pennsylvania Medical Center
Dr. Richard Moon, Duke University
Dr. Claes Lundgren, State University of New York at Buffalo
Dr. Charles Lehner, University of Wisconsin at Madison

Moderator
Don Chandler, Executive Director, Undersea and Hyperbaric Medical Society

Navy Representatives Interviewed for Navy Needs
CAPT Chris Murray, Supervisor of Diving, Naval Sea Systems Command (Code OOC)
CAPT Dale Mole', Bureau of Medicine and Surgery (Code 21)
CDR Bill Orr, Chief of Naval Operations (N773)
CDR Erik Christensen, Commanding Officer, Navy Experimental Diving Unit

APPENDIX B

SAMPLE ONE YEAR BASIC PROGRAM IN UNDERSEA BIOMEDICAL RESEARCH

General area	Specific Focus	Needed Resources	
Sub CO_2 Removal	Sea water absorption	Inv - 1	100K
	Facilitated Transport	Tec - 1	50
		E&S	150
		Ovh	150
		Total	450
Thermal Protect	Insulative liquids	Inv - 1	100K
	Conductive polymers	Tec - 1	50
	Other	E&S	150
		Ovh	150
		Total	450
O_2 Toxicity	Basic mechanisms	Inv - 4	400K
	Ameliorative measures	Tec - 8	400
	Predictive measures	E&S	800
		Ovh	800
		Total	2400
DISSUB Rescue	Maintain Survivable Envir.:	Inv - 2	200K
	Thermal, CO_2, O_2	Tec - 3	150
	Measures to prevent DCS	E&S	300
		Ovh	325
		Total	975
Sub Atmos. Contam.	0.5% CO_2 Exposures:	Inv - 2	200K
	Physiologic, Biochem.,	Tec - 6	300
	Pathologic, & Performance	E&S	450
		Ovh	425
		Total	1375

Sat Diving A.	HPNS mechanisms HPNS Amelioration	Inv - 2 Tec - 2 E&S Ovh Total	200K 100 300 300 900
Sat Diving B.	O_2 Level Effects O_2 transport O_2 cell metabolism	Inv - 1 Tec - 1 E&S Ovh Total	100K 50 100 125 375
Decompression	Bubble Formation Factors Inert Gas Uptake & Elimin. Studies Enhance Inert Gas Elimin.: Perfluorocarbons, Neg. Pressure Breathing, etc.	Inv - 4 Tec - 7 E&S Ovh Total	400K 350 800 775 2325
Therapy of DCS &	Eval. of optimum Rx depth, time, & breathing mix Develop Adjunctive Rx	Inv - 2 Tec - 3 E&S Ovh Total	200K 150 800 575 1725
Man-Machine Inter-face	Study visual & acoustic recognition & integration	Inv - 1 Tec - 1 E&S Ovh Total	100K 50 150 150 450
Underwater Sound	Mechanisms of effects on auditory, vestibular & nervous systems Vibroacoustic Dz. Studies	Inv - 1.5 Tec - 2 E&S Ovh Total	150K 100 300 275 825
Underwater Blast	Effects of: range, size of charge, depth, reflecting surfaces, repetitive exposures	Inv - 1 Tec - 2 E&S Ovh Total	100K 100 350 275 825

Electromagnetic Fields	Define nature of EMF Generated by electric drive	Inv - 1	100K
		Tec - .5	25
		E&S	50
	Review Scientific literature on EMF	Ovh	88
		Total	263
		GRAND TOTAL....	**13.4M**

Inv = Investigator Tec = Technician

E&S = Equipment & Supplies Ovh = Overhead

Assumptions: 1 Investigator costs 100K; 1 Technician costs 50K; Overhead is estimated at 50%. Training is included in E&S; Maintenance costs are discussed elsewhere.